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Assessment of Liver Function among Patients with Rheumatoid Arthritis Versus Patients with Psoriatic Arthritis Treated by Methotrexate

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Abstract

Background: Hepatotoxicity is a well-known adverse effect of methotrexate therapy.

Objective: To assess liver functions such as ALT and AST in patients with rheumatoid arthritis and psoriatic arthritis receiving methotrexate and compare the liver functions in those patients cured by using methotrexate.

Patients and Methods: This observational, cross-sectional analysis involved 50 patients with RA who satisfied EULAR-ACR-2010 standards for RA and 50 PSA cases who fulfilled CASPAR classification criteria for PSA, receiving constant weekly MTX therapy (oral or parenteral) up to 25mg, together with folic acid, liver function parameters such as ALT and AST in patients with rheumatoid and psoriatic arthritis were estimated and compared.

Results: 78% of the 100 participants who were enrolled in this study were females. 10% of the participants were smokers, but there was no significant difference between the two groups ($p = 0.410$). None of the patients were alcoholics. There was a significant difference between the groups regarding the type of medications. 42% of the RA group were on other medications compared with 2% of the PSA cases ($p < 0.001$). The mean ALT of the PSA group (26.0 IU/L) was considerably ($p = 0.005$) greater than the mean of the RA group (19.6 IU/L) which shows an insignificant ($p = 0.055$) change between the two groups regarding the means of AST (26.3 IU/L in the PSA participants matched with 20.6 IU/L in the RA participants).

Conclusion: Our research data shows that patients with PSA treated by methotrexate had a higher mean ALT level when compared with RA patients.

Keywords: Methotrexate, Rheumatoid arthritis, psoriatic arthritis, liver transaminases, Hepatotoxicity

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Introduction

Rheumatoid arthritis (RA) is a chronic, autoimmune, inflammatory illness that first affects the small joints, then the large joints, and finally the skin, eyes, heart, kidneys, and lungs. Frequently, the bone and cartilage of joints are destroyed, and tendons and

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ligaments deteriorate [1]. All of these joint injuries result in disfigurements and bone degradation, which are often quite painful for the patient. The morning stiffness of the affected joints lasting more than 30 minutes, fatigue, fever, weight loss, painful, swollen, and heated joints, and rheumatoid nodules under the skin are common symptoms of RA [1, 2].This ailment often begins after the age of 35 to 60 and might go into remission or worsen. It is estimated that 1-2 % of people in the West and 1 percent of people globally have RA [1]. Skin and the musculoskeletal system are both involved in the chronic inflammation illness known as psoriatic arthritis (PsA). Premature cardiovascular disease (CVD), metabolic syndrome, inflammatory bowel disease (IBD), liver disease, osteoporosis, cancer, and ophthalmic illnesses are among the comorbidities that frequently affect PsA patients. According to reports, biochemical liver abnormalities are present in 24-36% of psoriasis patients [3]. Methotrexate (MTX), a folic acid antagonist with anti-proliferative, immunosuppressive, and anti-inflammatory properties, has been used to treat arthritis since 1951 [4]. As a disease-modifying antirheumatic drug (DMARD), methotrexate is widely used to treat rheumatoid arthritis and other autoimmune illnesses. Methotrexate inhibits dihydrofolic acid reductase, which reduces DNA and RNA production as well as purine and pyrimidine synthesis. According to recent studies, methotrexate increases and releases adenosine, which may be how it suppresses the immune system [5]. One of the most common uses of MTX is to treat rheumatoid arthritis (RA) and psoriatic arthritis (PsA) [4]. The standard maintenance dose for the treatment of psoriasis and rheumatoid arthritis is 7.5 to 25 mg once a week, either orally or by injection. Side effects that are frequently dose-related include stomatitis, mouth ulcers, baldness, exhaustion, headaches, gastrointestinal disturbances, nausea, diarrhea, and bone marrow suppression. Bone marrow suppression, serious illnesses, liver and lung disease, lymphomas, severe skin reactions, fetal mortality, congenital abnormalities, and tumor lysis syndrome are examples of severe adverse effects [5]. The gastrointestinal side effects of MTX are the most common, followed by liver damage[4]. Long-term methotrexate treatment has been linked to the development of fatty liver disease, fibrosis, and even cirrhosis. Methotrexate has been shown to elevate blood aminotransferase levels. Methotrexate-induced hepatotoxicity appeared to be nonalcoholic steatohepatitis, a type of nonalcoholic fatty liver disease (NAFLD) that can progress to cirrhosis. Within 12 to 48 hours of receiving a high dose of intravenous methotrexate, serum ALT levels can rise to 10 to 20 times the upper limit of normal (ULN), but they quickly return to normal, with only infrequent episodes of jaundice or liver injury symptoms. Long-term, low-to-moderate-dose methotrexate therapy causes elevated blood ALT or AST levels in 15% to 50% of patients; however, these elevations are frequently minor and self-limiting. Nearly 5% of people have risen at twice the normal rate; these anomalies disappear quickly with dosage reduction or cessation, but they may also disappear if the same dose is maintained. Because of variations in determination frequency, the recommended amount of ALT

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rises during therapy has varied significantly (every month vs. every three) [5]. Body mass index (BMI), alcohol use, medications associated with it such as vitamin A and NSAIDs, and a lack of folic acid supplements are all factors that can cause transaminase increases [6]. Last but not least, co-administration of folic acid reduces the symmetry and severity of hepatotoxicity without compromising the positive anti-inflammatory effect [4]. The reference ranges for LFTs vary depending on the test center; in this study, the ALT and AST reference ranges were 35 IU/l for females and 45 IU/l for males. The study's aim, as far as we know, is to evaluate the liver enzymes ALT and AST in patients with psoriatic and rheumatoid arthritis taking methotrexate in Erbil. Methotrexate-treated people with rheumatoid arthritis and psoriatic arthritis had their liver functions compared in this study.

Patients and Methods

This observational (non-interventional), cross-sectional study was carried out in the Rheumatology Department of Rizgary Teaching Hospital in Erbil city from December 2021 to May 2022,which included fifty cases who fulfilled EULAR-ACR-2010 measures for RA [7] and fifty cases who fulfilled CASPAR classification criteria for PSA [8] getting constant weekly MTX therapy (oral or parenteral) up to 25mg joined with folic acid 5mg 24 hour after receiving MTX, the treatment for the patients also included combination regimen of leflunomide (20mg/day), hydroxychloroquine (400mg/day),sulfasalazine (1-2g/day) in addition to oral corticosteroids(≤10mg of prednisone or related equivalents) , NSAIDs and biological drugs combined with folic acid were chosen by a convenience sampling method, their mean age and standard deviation (SD) was 49.0±10.9 for RA and 45.0±10.7 for PSA patients and female patients who were pregnant or breast feeding, History of an allergic reaction or significant sensitivity to ingredients of the study drug (methotrexate),active infection, knowing HIV or active hepatitis B/C infection, active TB, congestive heart failure, chronic liver failure and current or history of hepatic disease, including non-alcoholic fatty liver disease (NAFLD), non-alcoholic steatohepatitis (NASH) and alcoholic cirrhosis, were excluded. With the patients' verbal assent, data were gathered and recorded on a specially created questionnaire. Full history was taken from all participants including age, sex, weight, history of smoking, alcohol drinking, current medications, chronic diseases (hypertension, diabetes mellitus, ischemic heart disease), history of exercise and sport, history of supplement and herbal use, family history of the same disease and duration of disease in years, two ml of venous blood was collected in gelatin(yellow) tube from all RA and PSA patients in one occasion by hygienic venipuncture using plastic throwaway syringes. Blood was permitted to clot in room temperature for 45 minutes before centrifugation and serum were taken. ALT and AST level was measured for both RA and PSA patients and comparison of mean ALT and AST done for both RA and PSA patients. Also CRP, ESR, RF and Anticcp were performed. Aminotransferase includes AST and ALT.

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Statistical Analysis

Data were evaluated using the Statistical Package for Social Sciences (SPSS, version 25). variables were offered in form of frequencies and percentages. Chi square test of association was used to associate proportions. Student's t test for two independent samples was used to match means. A p value of ≤ 0.05 was considered as statistically significant.

Results

Fifty patients with rheumatoid arthritis (RA), and 50 patients with psoriatic arthritis (PSA) were included in the study. Their mean age and standard deviation (SD) was 49.0±10.9 years for RA and 45.0±10.7 years for PSA patients. Only 7% of the whole sample were aged less than 30 years, and 13% were aged ≥ 60 years. Insignificant differences were detected when associating the age distribution of the two study groups (p = 0.449) as presented in Table (1). The table demonstrates that 88% of the RA group were females, in contrast to 68% of the PSA group (p = 0.016). The majority (91%) of the patients were married, but there was insignificant change between the participants (p = 1.000). The majority (70%) of the RA group were unemployed compared with 30% of the PSA group (p < 0.001). The percentage of smoking was 10 in the whole sample, but no significant difference was detected between the two groups (p = 0.410) Table (1).

Table (1): Basic characteristics of the study groups

	Rheumatoid arthritis	**Psoriatic arthritis**	**Total**	
	No. (%)	**No. (%)**	**No. (%)**	**p**
Age (years)				
20-29	3 (6.0)	4 (8.0)	7 (7.0)	
30-39	6 (12.0)	11 (22.0)	17 (17.0)	
40-49	15 (30.0)	16 (32.0)	31 (31.0)	
50-59	17 (34.0)	15 (30.0)	32 (32.0)	
≥ 60	9 (18.0)	4 (8.0)	13 (13.0)	0.449**
Mean (SD)	49.0 (10.9)	45.0 (10.7)		0.062†
Gender				
Male	6 (12.0)	16 (32.0)	22 (22.0)	
Female	44 (88.0)	34 (68.0)	78 (78.0)	0.016**
Marital status				
Single	4 (8.0)	5 (10.0)	9 (9.0)	
Married	46 (92.0)	45 (90.0)	91 (91.0)	1.000*
Occupation				
Employee	14 (28.0)	31 (62.0)	45 (45.0)	
Unemployed	35 (70.0)	15 (30.0)	50 (50.0)	
Retired	1 (2.0)	4 (8.0)	5 (5.0)	< 0.001*
Smoking				
Smoker	4 (8.0)	6 (12.0)	10 (10.0)	
Non-smoker	42 (84.0)	43 (86.0)	85 (85.0)	
Ex-smoker	4 (8.0)	1 (2.0)	5 (5.0)	0.410*
Total	50 (100.0)	50 (100.0)	100 (100.0)	

**By Fisher's exact test. **By Chi square test. †By unpaired t test.Note that none of the patients was alcoholic.

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It is evident in Table (2) that there was a significant difference between the groups regarding the type of medications. Around one third (30%) of the PSA group were on methotrexate as a monotherapy while 42% of the RA group were on other medications (combination therapy) compared with 2% of the PSA group ($p < 0.001$). No significant differences were detected between the two groups regarding the following: history of chronic diseases ($p = 0.068$), the type of the chronic diseases ($p = 0.163$), exercise and sport ($p = 1.000$), supplement and herbal use ($p = 1.000$), family history ($p = 0.072$), and weight-to-size ratio ($p = 0.132$). The period of the illness was ≥ 10 years in 44% of the RA group, compared with 22% of the PSA group ($p = 0.016$) Table (2).

Table (2): Medical history of the study groups

	Rheumatoid arthritis	**Psoriatic arthritis**	**Total**	
	No. (%)	**No. (%)**	**No. (%)**	**p**
Type of medication				
Methotrexate	0 (0.0)	15 (30.0)	15 (15.0)	
Methotrexate+Leflunomide	1 (2.0)	2 (4.0)	3 (3.0)	
Methotrexate+Nonsteroidal anti-inflammatory drug(NSAIDs)	4 (8.0)	6 (12.0)	10 (10.0)	
Methotrexate+Nonsteroidal anti-inflammatory drug(NSAIDs)+Biological agents	3 (6.0)	7 (14.0)	10 (10.0)	
Methotrexate+Biological agents	21 (42.0)	19 (38.0)	40 (40.0)	
Others	21 (42.0)	1 (2.0)	22 (22.0)	<0.001**
Chronic diseases				
Yes	17 (34.0)	9 (18.0)	26 (26.0)	
No	33 (66.0)	41 (82.0)	74 (74.0)	0.068
Type of chronic diseases				
Hypertension	11 (64.7)	7 (77.8)	18 (69.2)	
Diabetes mellitus	6 (35.3)	1 (11.1)	7 (26.9)	
Ischemic heart disease	0 (0.0)	1 (11.1)	1 (3.8)	
Sub-total	17 (100.0)	9 (100.0)	26 (100.0)	0.163*
Exercise and sport				
Yes	4 (8.0)	5 (10.0)	9 (9.0)	
No	46 (92.0)	45 (90.0)	91 (91.0)	1.000*

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Supplement and herbal use				
Yes	4 (8.0)	4 (8.0)	8 (8.0)	
No	46 (92.0)	46 (92.0)	92 (92.0)	1.000*
Family history				
Yes	21 (42.0)	30 (60.0)	51 (51.0)	
No	29 (58.0)	20 (40.0)	49 (49.0)	0.072**
Body mass index				
Normal	12 (24.0)	6 (12.0)	18 (18.0)	
Over-weight	18 (36.0)	27 (54.0)	45 (45.0)	
Obese	20 (40.0)	17 (34.0)	37 (37.0)	0.132**
Duration of disease (years)				
< 5	17 (34.0)	31 (62.0)	48 (48.0)	
5-9	11 (22.0)	8 (16.0)	19 (19.0)	
≥ 10	22 (44.0)	11 (22.0)	33 (33.0)	0.016**
Total	50 (100.0)	50 (100.0)	100 (100.0)	

*By Fisher's exact test. **By Chi square test

The mean ALT of the PSA group (26.0 IU/L) was considerably (p = 0.005) greater than the mean of the RA group (19.6 IU/L) as presented in Figure (1) which shows insignificant (p = 0.055) change among the two groups regarding the means of AST (26.3 IU/L in the PSA group matched with 20.6 IU/L in the RA group).

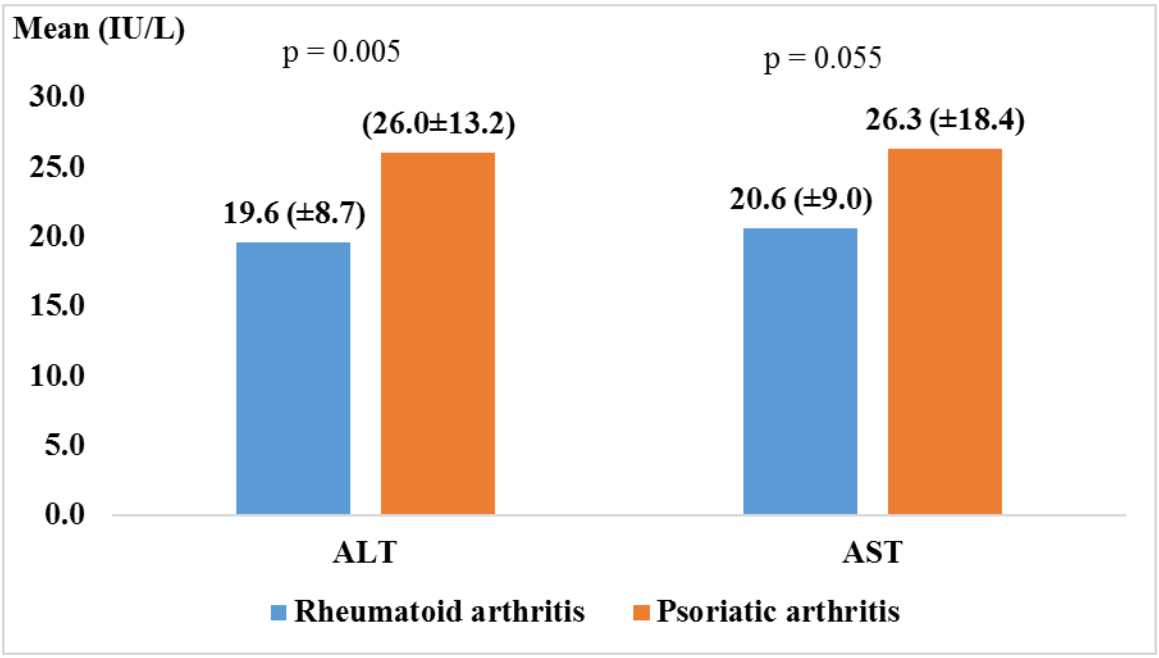

Figure (1): Means of AST and ALT of the study participants

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It is evident in Table (3) that 37% of the whole sample had high CRP, but there was no significant difference between the groups (p = 0.147). Half of the patients of each group had high ESR (p = 1.000). The percentage of patients with high ALT was 16% in the PSA group and 10% in the RA group (p = 0.372). Nearly the same result was for the high AST (16% in the PSA group vs 8% in the RA group) but the change was not significant (p = 0.218). The majority (94%) of patients of the RA group had positive rheumatoid factor compared with 0.0% of patients of the PSA group (p < 0.001). More than half (60%) of patients of the RA group had positive cyclic citrullinated peptide, compared with 0% of the PSA group (p < 0.001) as presented in Table (3).

Table (3): Laboratory findings of the study groups

	Rheumatoid arthritis	**Psoriatic arthritis**	**Total**	
	No. (%)	**No. (%)**	**No. (%)**	**p**
CRP				
Normal	28 (56.0)	35 (70.0)	63 (63.0)	
High	22 (44.0)	15 (30.0)	37 (37.0)	0.147
ESR				
Normal	25 (50.0)	25 (50.0)	50 (50.0)	
High	25 (50.0)	25 (50.0)	50 (50.0)	1.000
ALT				
Normal	45 (90.0)	42 (84.0)	87 (87.0)	
High	5 (10.0)	8 (16.0)	13 (13.0)	0.372
AST				
Normal	46 (92.0)	42 (84.0)	88 (88.0)	
High	4 (8.0)	8 (16.0)	12 (12.0)	0.218
Rheumatoid factor				
Positive	47 (94.0)	0 (0.0)	47 (47.0)	
Negative	3 (6.0)	50 (50.0)	53 (53.0)	< 0.001
Cyclic citrullinated peptide				
Positive	30 (60.0)	0 (0.0)	30 (30.0)	
Negative	20 (40.0)	50 (100.0)	70 (70.0)	< 0.001
Total	50 (100.0)	50 (100.0)	100 (100.0)	

Discussion

Methotrexate frequently prescribed in dermatology and rheumatology and has been shown effective in treating PSA and psoriasis. It is the most widely used DMARD for treating RA, both alone and in combination with other medications. Even though the dose considerably lower than that used in oncology and has been shown to be a main problem and requires patient monitoring, the toxicity profile of MTX assumed weekly at a low dose (7.5-25 mg) is obviously unlike from that of the drug given at a high dose (100-1000 mg/m^2 of body surface area per cycle), as in malignancy chemotherapy. Even in slight doses, adverse effects can occur [9]. Hepatotoxicity is a well-known adverse effect of methotrexate remedy [5]. This study focuses on the methotrexate side effect profile when given

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to RA and PSA patients in a general hospital setting. It also compares the effects of methotrexate on ALT and AST, two liver aminotransferases, through both RA and PSA groups. The study showed that there was a significant difference between the groups regarding the type of medications. Around one third (30%) of the PSA group were on methotrexate as a monotherapy while 42% of the RA group were on other medications compared with 2% of the PSA group ($p < 0.001$). The mean ALT of the PSA group (26.0 IU/L) was considerably ($p = 0.005$) greater than the mean of the RA group (19.6 IU/L) as presented in Figure (1) which shows insignificant ($p = 0.055$) change between the two groups regarding the means of AST (26.3 IU/L in the PSA group matched with 20.6 IU/L in the RA group) this is because psoriasis and psoriatic arthritis by itself will affect liver and cause elevation of liver enzymes; this was near to the study done in Denmark (2021) [6] where they found independent of other major risk factors like age, sex, smoking, alcohol use, diabetes, and hyperlipidemia, general comorbidities, and average weekly methotrexate dose, patients with psoriasis and psoriatic arthritis who received methotrexate were more likely to develop liver disease than patients with rheumatoid arthritis. Another research done in North America [10] (2010) also in agreement with our research result in which 14–35% of RA and PsA patients starting DMARD treatment developed abnormal ALT/AST levels. Risks were incrementally more in those with PsA and in those receiving MTX (≥ 10mg/day) + LEF. In Lindsey *et el* (2006) [11] studies they found that methotrexate-treated PsA patients have a greater incidence of hepatotoxicity matched with methotrexate-treated patients with RA. It is recommended that psoriatic patients may be usually more susceptible to methotrexate hepatotoxicity than are rheumatoid patients. A research which has been made in Israel (2009) [12] disagree with our results because they found no discernible differences in the MTX toxicity profiles between patients with psoriasis and RA.Daniel *et el* [4] (2019) differ with our result when using causality criteria for DILI, no biochemical or severe histological liver injury for MTX was established.

In this study none of the patients was alcoholic, in contrast to study done in UK (2006) were they matched alcohol drinking among the two patient's groups and genders, shown that there is no obvious association between drinking of alcohol and liver injury in these patients and they suggested that patients with RA are naturally less susceptible to MTX hepatotoxicity than psoriatic patients [11].

The good update for MTX users is that liver function abnormalities are frequently self-limiting particularly in case of termination of the drug or decrease of the dosage the liver function parameters restored gradually to normal limits within 4-6weeks [9].

Limitations

1. The major limitation of our study was we have short duration of time for study to find out newly diagnosed cases to start from base point (pretreatment) that's why we collect cases that was already on treatment.
2. A higher sample size might help to explain a more statistically precise conclusion

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because the study's very small sample size can be a constraint.

3. Additionally, in our study, the contributory effects of other drugs in the grouping course of therapy given to our patients (i.e. leflunomide (20mg/day), hydroxychloroquine (400mg/day), sulfasalazine (1-2g/day) in addition to oral corticosteroids (≤10mg of prednisone or related equivalents), NSAIDs and biological drugs) could not be well-ordered. Liver damages due to hydroxychlorquine and prednisolone are very uncommon and only stated in isolated cases. Even though sulfasalazine has been accepted for causing liver injury, the incidence rate of sulfasalazine induced liver injury is quite low (1 per 1000 users) [9].

Conclusions

Our research data shows that patients with PSA treated by methotrexate had high mean ALT level when compared with RA patients.

Recommendations

We recommend to the most of the rheumatologists and dermatologists to carefully monitor liver function test of PSA patients for preservation of healthy liver and adjustment of dose of MTX according to patient's situation. Controlling of patient's health (liver) during exposure to the methotrexate therapy will increase quality of life and less coast on health system.

Future research was required to identify the reasons underlying variations in liver function tests between PSA and RA patients. For that reason, liver transaminase profile should be checked every 2-4 weeks for the first 3 months after commencement (or increasing the dose) of MTX, and for the next 3 months should be observed every 8-12 weeks and after the first 6 months of therapy should be watched every 12 weeks [9].

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Ethical clearance: An ethical agreement was obtained from the Ethics Team of the College of Medicine at Hawler Medical University. A verbal consent was attained from all contributors in this research. The patients were shown examples of the study's objectives.

Conflict of interest: Nil

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تقييم وظائف الكبد بين مرضى التهاب المفاصل الروماتويدي مقابل مرضى التهاب المفاصل الصدفي المعالجين بالميثوتريكسات

بيريڤان نوزاد أدهم [١] ، د. شوان قادر ميديا [٢]

الملخص

خلفية الدراسة: السمية الكبدية هي أحد الآثار الضارة المعروفة لعلاج الميثوتريكسات.
اهداف الدراسة: لتقييم وظائف الكبد مثل ALT و AST في المرضى الذين يعانون من التهاب المفاصل الروماتويدي والتهاب المفاصل الصدفي الذين يتلقون الميثوتريكسات ومقارنة وظائف الكبد لدى المرضى الذين تم علاجهم باستخدام الميثوتريكسات.
المرضى والطرائق: تضمن هذا التحليل المقطعي القائم على الملاحظة ٥٠ مريضًا مصابًا بالتهاب المفاصل الروماتويدي ممن استوفوا معايير EULAR-ACR-2010 الخاصة بـ RA و ٥٠ حالة من PSA الذين استوفوا معايير تصنيف CASPAR لـ PSA ، وتلقوا علاج MTX أسبوعيًا مستمرًا (عن طريق الفم أو بالحقن) حتى ٢٥ مجم ، مع حمض الفوليك ، معلمات وظائف الكبد مثل ALT و AST في المرضى الذين يعانون من التهاب المفاصل الروماتويدي والصدفي تقدير ومقارنة.
النتائج: من إجمالي ١٠٠ مشارك شاركوا في هذه الدراسة ٧٨٪ منهم من الإناث ، وكانت نسبة التدخين ١٠٪ في العينة بأكملها ، ولكن لم يتم الكشف عن فرق معنوي بين المجموعتين ($p = 0.410$). لم يكن أي من المرضى مدمن على الكحول. كان هناك اختلاف كبير بين المجموعات فيما يتعلق بنوع الأدوية. كان ٤٢٪ من مجموعة RA على أدوية أخرى مقارنة بـ ٢٪ من حالات PSA ($p <0.001$). كان متوسط ALT لمجموعة PSA (26.0 وحدة دولية / لتر) أكبر إلى حد كبير (ع = ٠,٠٠٥) من متوسط مجموعة RA (19.6 وحدة دولية / لتر) مما يدل على تغيير ضئيل (ع = ٠,٠٥٥) بين المجموعتين فيما يتعلق بالوسائل. من AST (26.3 وحدة دولية / لتر في المشاركين في PSA مطابقة مع ٢٠,٦ وحدة دولية / لتر في المشاركين في RA
الاستنتاجات: تُظهر بياناتنا البحثية أن المرضى الذين يعانون من PSA الذين عولجوا بالميثوتريكسات كان لديهم مستوى مرتفع من ALT عند مقارنتهم بمرضى التهاب المفاصل الروماتويدي.
الكلمات المفتاحية: ميثوتريكسات، التهاب المفصل الروماتويدي؛ التهاب المفاصل الصدفية؛ ناقلة أمين الكبد السمية الكبدية
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