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Assessment of Weight Gain Post Treatment with Biological Compounds among A Sample of Patients Attending Baghdad Teaching Hospital تقييم زيادة الوزن بعد الم علجة بللمركبات الاحيائية لدى عينة من المرضى الوافدين الى مستشفى بغداد التعليمي Atta Ah mousa Al sarray M.B.Ch.B.MSc.Ph.D\*

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#### المستخلص:

الهدف: تقيم زيادة الوزن بعد العلاج بالمركبات الاحيائية

المنهجية: عبر دراسة مستقبلية اجريت في مستشفى بغداد التعليمي في وحدة العلاج بالمركبات الاحيائية والعيادة الاستشارية للمفاصل ولمدة سنة م ن الاول من نيسان 2015الى نهاية اذار 2016وكان العدد الكلي للمرضى 120 مريضا 40 مريضا مصابا بالتهاب المفاصل الصدفي الفعال و40مريضا مصابا بالتهاب المفاصل المفاصل الرثوى

النتائج اشارت نتائج الدراسة الى وجود فروق معنوية في زيادة الوزن بعد العلاج بالمركبات الاحيائية انفليكسيماب وايتانرسبت واداليمامب بعد عام من العلاج لمرضى التهاب المفاصل الصدفي الفعال وتشمع المفاصل والتهاب المفاصل الرثوي على التوالي وان اعلى نسبة في زيادة الوزن وجدت عند انفليكسيماب والتهاب المفاصل الصدفي مع فرق المعدل لمؤشر كتلة الجسم والوزن (7.34-12.85) على التوالي بينما كانت اقل نسبة في زيادة الوزن وجدت عند اتانرسبت والتهاب المفاصل الرثوي مع فرق المعدل لمؤشر كتلة الجسم والوزن (5.95-8.61) على التوالي

التوصيات: تقترح الدراسة اجراء المزيد من الدراسات حول العلاقة بين زيادة الوزن والعلاج بالمركبات الاحيائية وكيف ولماذا هذه الادوية تسبب تغيير في الوزن وماالذي يمكن فعله لاكتشاف السبب الحقيقي وراء هذه الزيادة في وزن المرضى مفاتيح الكلمات الوركبات الاحيائية ، مستشفى بغداد التعليمي

### **Abstract:**

**Objective:** to evaluate the increase in weight after biological agents and the association of weight gain with the body mass index among a sample of patients attending Baghdad Teaching Hospital

**Methods:** A prospective study is carried out in Baghdad teaching hospital biological units and outpatient clinic of rheumatology for a period of one year starting On April 2015 and ending on March 2016. 120 patients were included in the study 40 psoriatic arthritis .40 ankylosing spondylitis and 40 rheumatoid arthritis

**Results**: The study findings indicate that significance differences are seen regarding weight gain and biological agents (Infliximab, Etanercept and\_Adalimumab after one year of follow up of patients with psoriatic arthritis rheumatoid arthritis, ankylosing spondylitis respectively ,highest percentage of weight gain was reported with inflximab and psoriatic arthritis with a mean differences of BMI and weight (7.34&12.85) respectively while lowest percentage of weight gain was reporter with *Etanercept* and Rheumatoid arthritis with a mean differences of BMI ant weight(5.94 &8.61) respectively

**Recommendations:** The study recommends further studies on the relation between weight gain and biological therapies and how and why this medication causes this weight change and what can be done to explore the real reason for these increments in weight of patients

Key words: Weight, Biological Compounds, 'Baghdad Teaching Hospital'

### **Introduction:**

ike other medications 'Infliximab' can cause some adverse effects, and weight gain appears to be one of them. Although clinical studies conducted on "infiximab" before it was approved by the "FDA" do not show weight gain as a possible side effect, Decrease in body weight can occur in patients with chronic diseases and has been appeared in chronic inflammatory diseases such as 'Rheumatoid Arthritis', where it may result in profound weight loss (1). These changes may be due to the effects of 'cytokines' such as "TNF- $\alpha$ ' and "interleukins" and also the level of disease activity. Currently, large numbers of biological agents have been introduced for the treatment of various diseases one of them is anti-TNF therapy which is approved for the treatment of many patients with inflammatory arthritis who fail to gain satisfactory disease control with conventional disease-modifying antirheumatic drugs. In 'randomized clinical trials' all of these biological agents have been shown to be effective in reducing clinical signs of inflammation in 'Rhematoid arthritis', "spondyloarthropathy". effects of anti-TNF therapy include activation of infections and reactivation of latent 'Tuberculosis'. Other adverse effects are weight gain which is rarely reported in small observational studies in 'Rhematoid spondyloarthropathy arthritis' and .These effects may be of great concern to some patients, especially females, and despite the benefits of these drugs, the adverse effects may lead to discontinuation of anti-TNF therapy. On other hands, inflammatory cytokines such as tumor necrosis factor (TNF) are considered the main mediators of cachexia (1.2). TNF. formerly named cachectin, can induce muscle loss directly by both stimulating muscle protein breakdown (3) and reducing

the sensitivity of skeletal muscle cells to anabolic stimuli (4). Some studies reveal that people taking 'infliximab' may experience an increase in weight. In one of the studies conducted on patients with Crohn's disease who are on infliximab therapy, it showed that patients gained about 60 to 75 pounds of body weight. Furthermore, the study revealed that in patients taking 'infliximab' for 'rheumatoid arthritis', an increase in weight was also apparent but not that dramatic. In patients with rheumatoid arthritis, weight is an important prognostic factor. Preliminary evidence has indicated that treatment with 'anti-tumor necrosis factor therapy' can affect the weight of patients with 'rheumatoid arthritis', but the relationship between improved prognosis and weight changes remains to be clarified.

**Objective:** to determine the increase in weight (WT) after biological agents and the association of weight gain with the body mass index among a sample of patients attending 'Baghdad teaching hospital'

### **Methodology:**

A prospective study was carried out in Baghdad teaching hospital, biological units and outpatient clinic of rheumatology for a period of one year starting on April 1<sup>st</sup> 2015 and ending on March 30 2016. A total 120 patients were included in the study (40 'psoriatic arthritis' .40 'ankylosing and 40 'rheumatoid arthritis') spondylitis' according to certain inclusion criteria consist groups of patients 1st group of three psoriatic arthritis biological on agent('Infliximab') group and second rheumatoid biological arthritis on agent('Etanercept' ) and third group 'ankylosing spondylitis' on biological

# Iraqi National Journal of Nursing Specialties, Vol. 29 (1), 2016

agent('Adalimumb') each groups had two measurement of weight and body mass index ('BMI') calculated as weight in kilograms divided by height in meters squared. At base line and second reading after one year after treatment.

## **Statistical analysis:**

Analysis of data is carried out using the available statistical package of SPSS-20

(Statistical Packages for Social Sciencesversion 20). Data are presented in simple measures of mean, standard deviation, using independent student-t-test for difference between two means. Statistical significance is considered whenever the P value equal or is less than 0.05

**Ethical considerations:** Informed consent was obtained from all participants.

#### **Results:**

Table (1): Distribution of the Study Sample According to Weight Gain and Infliximab

List	'Infliximab'								
	Baseline	After one year			95% Confidence Interval of the Difference				
	Mean ±SD	Mean ±SD	T test	P.V	Mean Difference	Lower	upper		
BMI	21.47±1.71	28.81±2.78	13.105	0.0001*	-7.34	-8.46	-6.22		
WT	74.18±8.09	87.03±10.14	-5.779	0.0001*	12.85	-17.29	-8.41		

BMI: body mass index ,WT: weight ,SD: standard deviation , P.V: probability value

Significance differences are seen regarding body mass index and weight gain after one year of follow up of patients with 'psoriatic arthritis' and 'Infliximab'therapy , with a mean difference (7.34&12.85) respectively.

## Iraqi National Journal of Nursing Specialties, Vol. 29 (1), 2016

Table (2): Distribution of the Study Sample According to Weight Gain and 'Etanercept'

List	'Etanercept'						
	Baseline	After one year				Interva	onfidence al of the erence
	Mean±SD	Mean±SD	T test	P.V	Mean Difference	Lower	upper
BMI	22.27±1.18	28.21±3.88	-8.410	0.0001*	-5.94	-7.35	-4.53
WT	80.73±6.15	89.33±9.73	-4.296	0.0001*	-8.61	-12.61	-4.60

BMI: body mass index ,WT: weight ,SD: standard deviation , P.V: probability value

The present study shows a significance differences are seen regarding body mass index and weight gain after Eanercept treatment of patient presented with "rheumatoid arthritis"

Table (3): Distribution of the Study Sample According to Weight Gain and Adalimumab.

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	'Adalimumab'						
List	Baseline	After one year				95% Confidence Interval of the Difference	
	Mean±SD	Mean±SD	T. test	P.V	Mean Difference	Lower	upper
BMI	22.74±1.71	27.99±6.80	-10.92	0.0001*	-5.25	-6.22	-4.29
WT	70.31±2.18	81.87±9.29	-5.77	0.0001*	-11.58	-15.58	-7.57

BMI: body mass index ,WT: weight ,SD: standard deviation , P.V: probability value

This table depicts significance differences which are seen regarding body mass index and weight gain after one year of follow up of patients of Adalimumab therapy and ankylosing spondylitis, with a mean difference (7.34&12.85) respectively.

#### **Discussion:**

Weight gain has been reported as side effects of anti-TNF in several studies. In patients with 'rheumatoid arthritis(RA)', weight is an important prognostic factor. Preliminary evidence has indicated that treatment with anti-tumour necrosis factor (TNF) therapy can affect the weight of patients with "RA", but the relationship between improved prognosis and weight changes remains to be clarified (5). The current study shows that a significance differences are seen regarding body mass index and weight after biological agent (Etanercept) of patient presented with rheumatoid arthritis this result is similar to other reported study (6) . Weight gain has also been observed in a number of chronic inflammatory conditions other than RA, which have been treated with anti-TNF therapy. In a study of 106 patients with ankylosing spondylitis (AS), a significant weight increment was observed after year of treatment with anti-TNF therapy, (2) This was approved in the present study , while highest percentage of weight gain is observed with psoriatic arthritis patients treated with Infliximab this result agree with other reported study <sup>(7)</sup>. TNF -alpha is involved in body weight homeostasis and it is known to induce production and release of

,a satiety hormone there for it is possible that anti-TNF -alpha could led to decreased leptin level resulting in increased hunger and weight gain .this has been reported in multiple disease states treated with anti "TNF -alpha therapy", including, 'psoriasis', 'sopndyloarthropathy, 'Crohn diseases' (7,8) It is also suggested that 'Infliximab' can affect tumor necrosis factor (TNF) in the body. The interaction between "infliximab" and "TNF" may be the cause of weight gain in patients taking the drug either for "rheumatoid arthritis" or "Crohn's disease" (9,10,11,12). Furthermore, some health care provider believes that the other active ingredients of "Infliximab" may be causing the weight gain. Currently, health experts are still inconclusive about the reason of weight gain more studies are required to determine how and why this medication causes this weight change and what can be done.

**Recommendations:** The study recommends further studies on the relation between weight gain and biological therapy and how and why this medication causes this weight change and what can be done to explore the real reason for these increments in weight of patients

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