EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

IN THIS ISSUE

Prepared by:

Reem Tarek
Amira Ayman
Shaimaa Raslan
Medhat Abd Elhakam
Lobna Samy
Mariam Morkos
Maysa Hussien
Asmaa Shalaby

Designed by:

Reem Tarek

Chief Editor

Maha Mohamed

Under Supervision of

Dr. Sherin Abdel Gawad

Head of the C.A for Pharmaceutical Care

EPVC
The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

EPVC Mission

Pharmaceutical Vigilance administration is the way through which the processes for authorizing, regulating, monitoring and evaluating the safety of any pharmaceutical product or medical device take place, in addition to disseminating any safety information for public health programs, healthcare professionals, and the Egyptian citizen.

The Pharmaceutical vigilance administration is an integral part of the Central Administration of Pharmaceutical Care that works on the enhancement of the pharmaceutical services to guarantee safe and effective use of medications in Egypt, under the patronage of the Egyptian Drug Authority.

Newsletter

December 2024

Volume 15 Issue 12

Safety Notification ! : Drug-induced tendinopathy

The Regulatory Authority in New Zealand has published the following safety notification:

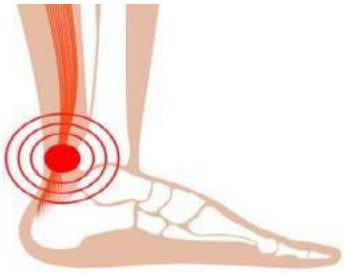
Fluoroquinolones, long-term glucocorticoids, statins and aromatase inhibitors are the most common medicine classes associated with tendinopathy.

Progressive tendon degeneration without inflammation is a typical sign of drug-induced tendinopathy.

Although the Achilles tendon is most commonly affected, drug-induced tendinopathy can occur in any tendon.

Tendonitis and tendon rupture have recently been associated with aromatase inhibitors, along with tenosynovitis. This article reviews tendon disorders with the most common classes of medicines.

Terminology of tendon disorders



Tendon disorders include tendonitis (tendon inflammation), tendon rupture (tendon tears) and tenosynovitis (inflammation of the tendon sheath) The term tendonitis is often used to describe a broad range of tendon conditions. However, where inflammation is minimal or absent, tendinopathy may be more accurate.

Inside a tendon: Tenoblasts and tenocytes make up 90% of cells in the tendon. Together, they generate collagen and elastin fibers, as well as extracellular matrix components. Chondrocytes make up the remaining 10% of tendon cells and these are found at entheses (tendon-bone junctions). Classic drug-induced tendinopathy shows signs of progressive tendon degeneration without inflammation.

Medicines associated with tendinopathy

Drug-induced tendinopathy is most commonly associated with fluoroquinolones, long-term treatment with glucocorticoids, statins and aromatase inhibitors

Fluoroquinolones

Tendinopathy can occur with any fluoroquinolone (eg, ciprofloxacin, moxifloxacin, norfloxacin) and at any dose and route of administration. It is usually an acute event occurring as early as within 48 hours but has been reported to occur up to several months after discontinuation of treatment.4–6 Tendinopathy with fluoroquinolones may be prolonged, disabling and irreversible. Discontinue fluoroquinolone treatment at the first sign of tendonitis (eg, pain, swelling, inflammation) and use alternative treatment. Advise patients to rest the affected limb and avoid inappropriate physical exercise.

Long-term glucocorticoids

Tendinopathy usually occurs after at least three months of treatment with an oral or inhaled glucocorticoid.3 Patients with autoimmune connective tissue disorders (eg, rheumatoid arthritis, systemic lupus erythematosus) treated with long-term oral glucocorticoids are particularly at risk.

Statins

Statin-induced tendinopathy can occur at any dose and about 8 to 10 months after exposure. Discontinue statin treatment if tendinopathy is suspected. Tendinopathy may recur if statin treatment is restarted.

Aromatase inhibitors

Tenosynovitis, particularly of the hands and wrists, has been linked with aromatase inhibitors (eg, anastrozole, letrozole, exemestane). The onset time is reported to range from 2 weeks to 19 months. More recently, cases of tendonitis and tendon rupture have also been reported in association with aromatase inhibitors.1 Closely monitor patients with tendon disorders and initiate appropriate measures such as immobilization of the affected limb. Medsafe has requested the data sheets for aromatase inhibitors be updated to include more information on tendon disorders

Other Drug-induced tendinopathy

It has also been reported after exposure to several other medicines, but the evidence is less consistent. These include anabolic steroids, isotretinoin and antiretroviral agents (especially protease inhibitors).

Risk factors

Risk factors for drug-induced tendinopathy include: advanced age (because of deterioration in tenocytes) obesity and physical exertion (because of high loads and sudden shifts in axial stress) pre-existing disease such as autoimmune connective tissue disorders and renal failure treatment with two or more medicines known to induce tendinopathy.

References:

MedSafe : *(Click Here)*

Local Case Report

" Interferon alfa and Neuropsychiatric adverse reactions

The Egyptian Pharmaceutical Vigilance Centre has received a case report, its details as following:

A 55-year-old male was treated for Hepatitis C with intramuscular interferon therapy from 2013 to 2014, receiving a total of 48 vials during treatment. Concurrently, he was prescribed Paracetamol 500 mg as an analgesic, taken at a dosage of 2 tablets every 4 hours. On days when he received interferon injections. Since 2013, he has suffered from depression, which has persisted for the past 10 years.

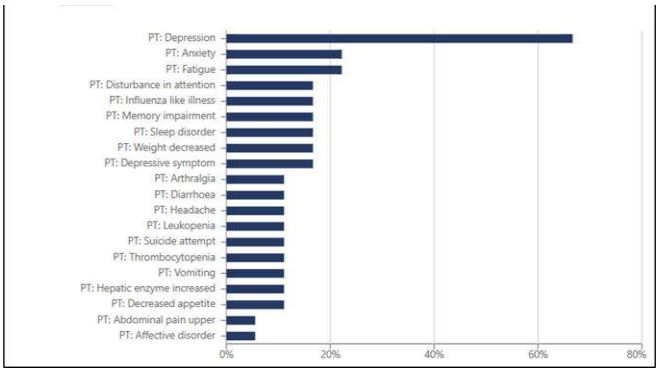
Depression is a prevalent mental health condition characterized by a persistent low mood, diminished interest, or lack of pleasure in activities. Unlike typical mood swings, depression profoundly affects daily life, influencing relationships, work, and overall well-being.

How Interferon Alfa Affects the CNS:

Interferon alfa is an immune-modulating agent that enhances the body's ability to combat infections and malignancies. However, its mechanism of action involves altering cytokine levels in the brain, which disrupts neurotransmitter systems, particularly serotonin and dopamine. These disruptions contribute to the development of depressive symptoms and other mood disorders.

Interferon alfa and Neuropsychiatric adverse reactions, VigiBase global view:

Between January 1, 2000, and December 1, 2024, the VigiBase received **28** cases locally for depression and **84** ICSRs from 9 countries related to Interferon alfa and Neuropsychiatric adverse reactions, the reported reactions were depression and suicidal ideation, among those ICSRs the most common co-reported reactions are shown in the following figure :



Interferon alfa induced Neuropsychiatric adverse reactions as mentioned in SPCs

According to interferon alfa Summary of product Characteristics (SmPC) [1] it was stated under section (4.4 Special warnings and precautions for use) that: "Psychiatric and Central Nervous System (CNS): Severe CNS effects, particularly depression, suicidal ideation and attempted suicide have been observed in some patients during interferon therapy, and even after treatment discontinuation mainly during the 6-month follow-up period.".

Recommendations for Healthcare Professionals:

Preventive Measures: Screen for depression history and consider prophylactic antidepressants for high-risk patients.

Psychiatric Monitoring: Regularly assess for mood changes, aggression, and confusion during treatment and for 6 months afterward. Discontinue interferon alfa and provide psychiatric care if symptoms persist.

Severe Psychiatric Conditions: Ensure proper management before starting interferon alfa in patients with a psychiatric history. Contraindicated in children and adolescents with severe psychiatric conditions.

Substance Use Disorders: Assess and manage comorbidities or substance use before treatment. Involve mental health professionals and monitor closely during and after therapy.

Growth and Development in Children: Monitor weight loss and growth inhibition in children aged 3-17 years. Consider starting treatment after the pubertal growth spurt.Post-Treatment Care: Continue mental health follow-ups and encourage a healthy lifestyle for recovery.

General Considerations: Watch for early signs of psychiatric issues or substance use and intervene promptly.

References

1. ***Interferon alfa SmPC:*** (Click Here)
2. ***Patient drug information:*** (Click Here)
3. ***"Interferon alfa and its impact on mental health.":*** (Click Here)
4. ***Picture: VigiLyze, qualitative view***

Egyptian Pharmaceutical Vigilance Center (EPVC) Vigiflow expansion project Trainings for Raising Reporting Awareness

The Egyptian Pharmaceutical Vigilance Center (EPVC) is happy to announce that it provided around 282 focal points from different Health Affairs Directorates with high-level vigiflow expansion training in cooperation with the "General Administration for Pharmaceutical Affairs - MoHP". Also glad for high-level vigiflow expansion training given to around 17 focal points from various University Hospitals in collaboration with the SCU “Supreme Council of University Hospitals” In addition to promoting the information on the national database that announces the framework, the trainings aim to raise awareness of the significance of completeness scores and demonstrate support for the main goals of those organizations. Apart from conducting training sessions, EPVC oversees case intake procedures, conducts audits, gives planning organizations input, and determines if more preparation is required to ensure the highest calibre of cases are added to the national database. Meanwhile, EPVC is effectively locating examples from the national database, adjusting as needed, and contributing to the planning organizations. It is anticipated that this all-encompassing strategy will result in a more robust and dependable method of monitoring threats to pharmaceutical safety. Due to their high ICSRs entry rate on Vigiflow, the Egyptian Pharmaceutical Vigilance Center (EPVC) would like to thank the following MoHP organizations: "Cairo Health Directorate, Giza Health Directorate, Menofia Health Directorate, Gharbiya Health Directorate"; additionally, the following SMC organizations: "Minya Oncology, Qena Oncology Center". The Egyptian Pharmaceutical Vigilance Center (EPVC) would like to thank EHA “Egyptian Health Care Authority” organisations for their high entering quality of ICSRs on vigiflow. Your involvement in the national database reporting system is much appreciated. Furthermore, EPVC would like to thank every organization that worked with us to make the Vigiflow system larger. We applaud their commitment to enhancing the monthly section cases and the progressively higher case quality stages in the national database and wish them continued success.

“Together for Safe Medicine“ Initiative News:

EPVC is extremely proud to start inivative together for safe medicine wave 5&6 activities as EPVC team had organized two online lectures for more than 100 participants of pharmacists from Community and governmental pharmacies. Where EPVC team member had explained for the participants the basic of Pharmacovigilance science ,the concept of ADRs reporting , different method for reporting as E-reporting , EDA hot line , Arabic link on EDA website and vigiflow accounts in governmental organizations. Finally , participants had recognized the assignments required from them where assignments main aim is to spread the science of Pharmacovigilance all over Egypt governments either between public or HCPs.

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

Egyptian Pharmaceutical Vigilance Center (EPVC) participation in MedSafety Week for 2024

Based on the vision of the Egyptian Drug Authority and its role in developing pharmaceutical care services provided throughout the Arab Republic of Egypt for ensuring drug safety, The Egyptian Drug Authority participated in the activities of the MedSafety Week celebration 2024 in through conduction visits for Tanta university hospital, for faculty of pharmacy of Egyptian Russian University, Galala university and Al Nahda University to approach pharmacists, pharmacovigilance focal points, other health care providers and pharmacy Students with the aim of spreading awareness about the National role of Egyptian Pharmacovigilance Center EPVC at EDA in promoting drug and patient safety, in addition to providing continuing training for healthcare providers on the principles of pharmacovigilance.

In addition to providing support, follow-up and participation with pharmacies, hospitals and primary centers affiliated with various health sectors in Egypt with the following aims:

Spreading community awareness about the importance of pharmacovigilance.

Enhancing commitment among healthcare providers about the importance of reporting

Participation was represented by the Secretariat of Specialized Centers, as well as the Egyptian Healthcare Authority sector and the supreme Council of University Hospitals sector. In addition to the participation of the community pharmacies sector from the graduates of the Together Towards Safe Medicine initiative by EPVC.

In light of participation of 88 hospitals, the total participation resulted in:

2 scientific days and 75 lectures targeting approximately 3600 health service providers including doctors, pharmacists, nurses and medical students.

Holding 76 physical or social media awareness campaigns where the number of targeted patients and society reached approximately 10,000 through the use of various tools such as flyers, publications, posters and awareness magazines in addition to awareness videos.

Holding 117 activities by 34 graduates of the fifth and sixth batches under the Together Towards Safe Medicine initiative.

In addition EPVC has participated in a very fruitful way by holding a number of activities presented in the following link : (Click Here)

EPVC Tips

On Pharmacovigilance

Food drug interactions

A large number of drugs are introduced every year. Food-drug interactions can produce negative effects in safety and efficacy of drug therapy, as well in the nutritional status of the patient.

Generally speaking, drug interactions are to be avoided, due to the possibility of poor or unexpected outcomes. Like food, drugs taken by mouth must be absorbed through the lining of the stomach or the small intestine. Consequently, the presence of food in the digestive tract may reduce absorption of a drug. Often, such interactions can be avoided by taking the drug 1 hour before or 2 hours after eating. Like drugs, foods are not tested as comprehensively so they may interact with prescription or over-the-counter drugs.

So the doctors and pharmacists should ask patients about their food intake and dietary supplements so that interactions can be avoided.

References:

Pubmed : *(Click Here)*

Picture: *(Click Here)*

Visit EDA website to find all medicine- related news, updates and alerts *Click here*

You will find all EPVC Newsletters and DHPCs here

You will also find all alerts regarding counterfeited and falsified products released by Central Administration of Operations *here*

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

One report counts

A call for reporting

Please remember that you can report safety information of medicines to EPVC using the following communication information:

What is Pharmacovigilance

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug- related problem.

What is the Egyptian Pharmaceutical Vigilance Center?

With the increasing demand for patient's safety which is becoming more stringent, . The Egyptian Pharmaceutical Vigilance Center was established to be responsible for the safety monitoring of the pharmaceutical products throughout its lifecycle and it is the regulatory authority regarding Pharmacovigilance and its applications .

EPVC monitors the safety of all types of pharmaceutical products, including human medicines, biological products, supplements, cosmetics, veterinary medicines, medical devices, Biocides and pesticides

Participate with us

We invite you to take a quick survey on how much our communication with you is effective
We value your feedback! Help us enhance our communication by taking a quick survey. Your insights are crucial in ensuring we meet your expectations.
Survey Link: (Click Here)

Thank you for your valuable input

Communication information

The Egyptian Drug Authority (EDA)
Pharmaceutical Care Administration
The Egyptian Pharmaceutical Vigilance Center (EPVC)

Address: 21 Abd El Aziz AlSoud Street. El-Manial, Cairo, Egypt, PO Box: 11451
Hotline: 15301
Fax: +202 – 23610497
Email: pv.followup@edaegypt.gov.eg
Reporting link: www.edaegypt.gov.eg
https://sites.google.com/view/epvc-reporting/healthcare-professional-public-adverse-drug-event-reporting/reporting-other-adverse-drug-event-cases

هيئة الدواء المصرية (الرعاية الصيدلية)