IN THIS ISSUE

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EPVC Mission

Pharmaceutical Vigilance administration is the way through which the processes for authorizing, Reguing, 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

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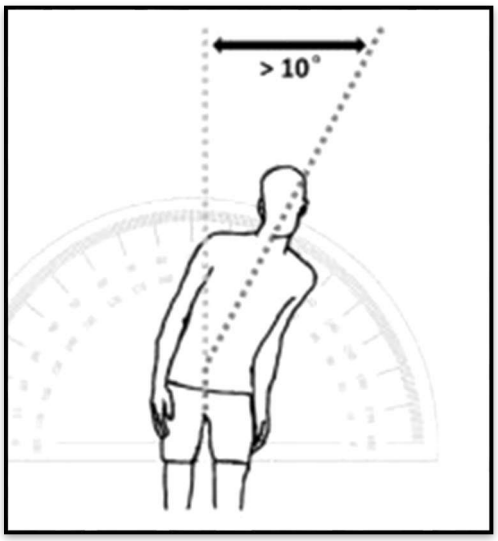
Label Update : Medicine-induced Pisa syndrome

The regulatory authority in New Zealand recently reviewed the risk of Pisa syndrome with donepezil (an anticholinesterase inhibitor) and concluded that there is sufficient evidence to support an association. We have requested sponsors to update their donepezil data sheets with this adverse effect.



Pisa syndrome (also known as pleurosthotonus) is a rare neurological condition characterised by more than 10 degrees of constant lateral flexion of the spine when the patient is upright. This abnormal posture resembles the Leaning Tower of Pisa, which gives the syndrome its name. Patients may have difficulty with walking or standing up straight. Some patients may be unaware they are leaning. There are a variety of causes for Pisa syndrome, and many other conditions can have similar presentations. However, Pisa syndrome is most strongly associated with older age, females, neurodegenerative diseases and polypharmacy with antipsychotics and anticholinesterase inhibitors (especially with prolonged use or high doses).

Medicine-induced Pisa syndrome

A recent review of medicine-induced Pisa syndrome cases reported in the literature found that anticholinesterase inhibitors and antipsychotics were the most frequently reported medicines associated with Pisa syndrome. The mechanism behind Pisa syndrome is unknown but may be due to an imbalance between dopaminergic and cholinergic neurotransmitters leading to postural control dysfunction. Medicines associated with Pisa syndrome affect these neurotransmitters.

Medicine class	Medicines
Anticholinesterase inhibitors	Donepezil Rivastigmine Galantamine
Typical antipsychotics	Haloperidol Chlorpromazine Droperidol
Atypical antipsychotics	Quetiapine Risperidone Olanzapine Aripiprazole Clozapine Paliperidone Ziprasidone
Antidepressants	Amitriptyline Clomipramine Nortriptyline Mirtazapine Sertraline
Antiparkinsonian medicines	Levodopa Pramipexole Ropinirole
Mood stabilisers	Lithium
Anti-seizure medicines	Valproate

Management

Though rare, Pisa syndrome is a recognisable and often reversible condition. However, the time between starting the medicine and the onset of symptoms is unpredictable, and it may occur weeks to

References

1. Medsafe: (click here)

Local Case Safety Report: Urinary incontinence Following Administration of a Drug Containing Isotretinoin

Reason for publishing

Two Individual Case Safety Reports (ICSRs) describing suspected adverse drug reactions associated with medicinal product containing isotretinoin capsule were received by the Cairo Regional Pharmacovigilance Center, as presented below:

Two adult female patients (19 and 24 years old) developed suspected adverse reactions associated with oral isotretinoin used for acne treatment. The reported reactions included urinary incontinence, while the first patient also experienced postictal state, disturbance of consciousness, sialorrhea, and viral encephalitis. Diagnostic investigations in both cases were largely unremarkable, although cerebrospinal fluid analysis in the first case supported the diagnosis of viral encephalitis. The reactions were considered serious, due to prolonged hospitalization in the first case and significant disability affecting quality of life in the second case. Isotretinoin was discontinued in both patients, resulting in improvement or recovery of most reactions (positive de-challenge). In the second case, rechallenge was performed and urinary incontinence recurred, supporting a possible association with isotretinoin. Concomitant topical medications were reported in the first case, while none were reported in the second case.

Background:

Urinary incontinence

- Urinary incontinence is the involuntary leakage of urine. This condition is prevalent in older adults but can also affect younger adults and significantly impacts both health and quality of life.
- There are 5 main types which include stress, urge, mixed, overflow, and functional incontinence.
- Possible treatments include lifestyle adjustments, physical therapy, pelvic floor exercises, fluid management strategies, prompted voiding, biofeedback, catheters (intermittent or permanent), pads, pharmaceuticals, botulinum toxin injections, sacral neuromodulation, bedside suction devices, and numerous procedures, including male and female slings, artificial sphincters, and prostate surgery.

Isotretinoin

An oral retinoid medication that affects sebaceous glands and is used to treat severe forms of acne (such as nodular or conglobate acne or acne at risk of permanent scarring) resistant to adequate courses of standard therapy with systemic antibacterials and topical therapy.

Posology:

Isotretinoin should only be prescribed by or under the supervision of physicians with expertise in the use of systemic retinoids for the treatment of severe acne and a full understanding of the risks of isotretinoin therapy and monitoring requirements.

Mechanism of action:

According to summary of product characteristic (SmPC) of products, Isotretinoin is a stereoisomer of all-trans retinoic acid (tretinoin). The exact mechanism of action of isotretinoin has not yet been elucidated in detail, but it has been established that the improvement observed in the clinical picture of severe acne is associated with suppression of sebaceous gland activity and a histologically demonstrated reduction in the size of the sebaceous glands. Furthermore, a dermal anti-inflammatory effect of isotretinoin has been established.

Clinical efficacy and safety:

Hypercornification of the epithelial lining of the pilosebaceous unit leads to shedding of corneocytes into the duct and blockage by keratin and excess sebum. This is followed by formation of a comedone and, eventually, inflammatory lesions.

Local Case Safety Report: Urinary incontinence Following Administration of a Drug Containing Isotretinoin

Isotretinoin inhibits proliferation of sebocytes and appears to act in acne by re-setting the orderly program of differentiation. Sebum is a major substrate for the growth of Propionibacterium acne so that reduced sebum production inhibits bacterial colonization of the duct.

Labeled information:

According to Summary of product Characteristics (SmPC), it was stated under section 4.8 Undesirable effects in Renal and urinary disorders stated that: "it may cause Glomerulonephritis as it is very rare adverse drug reaction, but urinary incontinence not listed in SmPC of the drug"

Isotretinoin induced Urinary incontinence

A case report published in Elsevier journal which conclude that 29 years old male patient who developed overactive bladder shortly after commencing oral isotretinoin for acne. No alternative cause was identified, and urodynamics revealed no detrusor overactivity. It remains unclear exactly why the patient's symptoms did not resolve entirely following cessation of isotretinoin and is apparent that the exact effects of retinoid medications on the urinary tract remain poorly understood and are potentially under recognized.

This is supported by the various reports highlighting a range of urological issues secondary to isotretinoin use, as well as animal studies demonstrating the direct impact of isotretinoin on cystometric parameters.

According to Global database Vigilyze for of individual case safety reports, there are 38 reports reported urinary incontinence as adverse drug reaction from isotretinoin which includes 2 reports from Egypt.

Although urinary incontinence is not currently listed in the product labeling, the receipt of two serious local reports, including one case where the event reappeared after the drug was readministered, together with supportive global database reports, suggests that a potential association cannot be excluded so need to be vigilant if there are any similar **reports.**

Recommendations for Healthcare Professionals:

1. Isotretinoin should be prescribed strictly in accordance with approved indications for severe acne unresponsive to standard therapy.
2. Treatment must be initiated and supervised by physicians experienced in systemic retinoid therapy and familiar with its risk profile and monitoring requirements.
3. Conduct thorough baseline assessment, including medical history with particular attention to neurological disorders and urinary tract conditions.
4. Educate patients about the importance of reporting if there are new-onset urinary symptoms (e.g., urgency, leakage, incontinence), neurological symptoms such as confusion, altered level of consciousness, or seizures and other adverse drug reactions.
5. Reinforce the importance of pharmacovigilance reporting by ensuring that any suspected drug-related adverse events are promptly documented and submitted to the Pharmaceutical Vigilance General Administration (PVGA (formerly known as EPVC)) for continuous safety monitoring.

References

1. ***Urinary Incontinence NIH:*** *Click here*
2. ***Isotretinoin SmPC*** *:Click here*
3. ***Isotretinoin NIH :*** *Click here*
4. ***Case Report :*** *Click here*

Agile Mindset for Growth Initiative 2026–2027

The **Egyptian Drug Authority** is pleased to announce the official launch of the **"Agile Mindset for Growth Initiative 2026–2027,"** which aims to integrate students of medical faculties into the field of **pharmacovigilance** by developing their capabilities and equipping them with the necessary skills to contribute to enhancing drug safety and achieving the primary goal of pharmacovigilance: **ensuring patient safety**.

This national initiative aims to:

1. **Prepare a generation of graduates from medical faculties** who possess adequate awareness of the importance of pharmacovigilance and its role within the healthcare system.
2. **Provide opportunities for the new generation** to participate in raising awareness about the importance of pharmacovigilance and how to monitor and report adverse drug reactions.
3. **Promote community integration** and strengthen a culture of positive and active participation in serving society.

- The initiative was launched through **3 field visits** to faculties of pharmacy at the following universities: **Port Said University**, **Damanhour University**, and **Pharos University in Alexandria**.
- **3 introductory awareness lectures** were delivered, covering the 6 topics about **pharmacovigilance landscape in Egypt and globally (PV Landscape)**. Including, a lecture titled **"Pharmacovigilance: A Core Professional Skill for Pharmacists and Its Role in Protecting Society"** was presented. Further lectures addressed **pharmacovigilance principles, reporting channels, and methods for detecting adverse drug reactions**.

The events were attended by 186 participants from **faculty deans, academic staff, teaching assistants, and students**, reflecting the academic interest in supporting and strengthening pharmacovigilance concepts among students.

EPVC Tips On Pharmacovigilance

Safe Fasting Starts with Smart Medication Use

* During fasting periods such as Ramadan, patients should take extra care when using medications. Do not stop or change your medicines without consulting a healthcare professional, as this may lead to reduced effectiveness or unwanted adverse reactions.
* When appropriate, medication schedules may be adjusted to coincide with Ramadan schedule. Some medicines should be taken with food to avoid stomach irritation, while others may increase the risk of dehydration or low blood sugar during prolonged fasting.
* Patients using treatments such blood sugar lowering agents should monitor their blood sugar levels closely and seek medical advice before fasting.
* If you experience unusual symptoms such as dizziness, severe weakness, or fainting while fasting, consult your healthcare provider and report any suspected adverse effects through any of our portals
* Maintaining safe medication use during fasting helps ensure both effective treatment and patient safety.

You can report any Adverse drug Reactions to the Egyptian Drug Authority (EDA)
Email: pv.followup@edaegypt.gov.eg
Hotline: 15301
Website: (click Here)
Or report through your pharmacy / product distributor / company hotline — they are required to forward it to EDA.

Why Your Report Matters

Every report submitted to us counts when it comes to the safety of medicines and patients worldwide

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*

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.

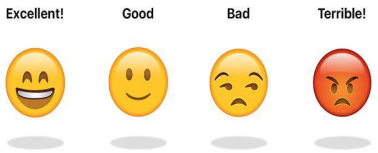
What is the Egyptian Pharmaceutical Vigilance Center?

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

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