EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

IN THIS ISSUE

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EPVC
The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

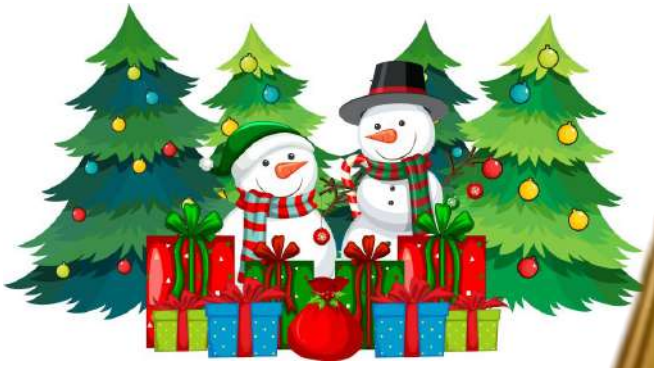
EPVC Mission

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

January 2025



Volume 16 **Issue 1**

Potential signal : Impaired gastric emptying associated with the administration of Tirzepatide

A safety signal of impaired gastric emptying associated with the administration of tirzepatide

PVGA has investigated a serious case of gastroparesis, the case was for a male patient that has been hospitalized due to gastroparesis after the administration of tirzepatide.

Background

A safety signal is reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously (1).

Tirzepatide is a novel dual glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptor agonist. Dual GIP/GLP-1 agonists have gained increasing attention as new therapeutic agents for glycemic and weight control, as they demonstrated better glucose control and weight loss compared to selective GLP-1 receptor agonists in preclinical and clinical trials. Tirzepatide is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (2).

Impaired gastric emptying is a condition in which the stomach muscles don't move food as they should for it to be digested. It is also called gastroparesis or delayed gastric emptying. Gastroparesis affects digestion. It can cause nausea, vomiting, and belly pain. It can also cause problems with blood sugar levels and nutrition (3).

Methods: A qualitative signal between tirzepatide and impaired gastric emptying has been detected through a case-by-case review by the Individual Case Safety Reports (ICSRs) Management Unit, triggered by a domestic serious case received in Dec/2024 that was hospitalized due to gastroparesis following the administration of tirzepatide. A case series analysis using the Bradford-Hill criteria method was made for cases retrieved from VigiBase/VigiLyze (the WHO global database of reported adverse events of medicinal products). In addition, the literature was screened for related information on tirzepatide-associated impaired gastric emptying.

Results: By reviewing the received domestic case, the case describes a male patient who received tirzepatide, and suffered from gastroparesis, he was hospitalized with serious adverse effects due to gastroparesis. When he stopped the medication as per the recommendation of his physician the reaction recovered. Then, by reviewing the cases retrieved from VigiBase/VigiLyze, the final dataset of 389 cases. In 279 cases (71.7%) out of the total (n= 389), Tirzepatide was the single suspect drug. Twenty-six cases (6.7%) are considered medically confirmed since they have been reported by physicians. In 25.7% of the cases, delayed gastric emptying or gastroparesis has been labelled to be associated with the co-reported drugs (semaglutide and dulaglutide). A plausibility mechanism of action with the known effect of delaying gastric emptying by the GLP1 RA Drug group (4).

Conclusion: The weighted available evidence identified from the case series analysis besides the literature screening suggests a potential signal of impaired gastric emptying associated with tirzepatide administration. The mechanism plausibility with the known effect of delaying gastric emptying, and the fact that cases have still been observed in post-marketing settings. PVGA agreed to consider it as a potential risk.

References:

1.Signal Info

2. Tirzepatide: *(Click Here)*

3. Delayed gastric emptying: *(Click Here)*

4. .Delayed gastric emptying: *(Click Here)*

Local Case Report

Glyceryl Trinitrate in hypertensive emergencies: A case of rapid decline in blood pressure after an inappropriate initial dose

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

Y.S. is a 75 years old male patient with a history of Peptic ulcer, Coronary artery bypass graft surgery (CABG) 10 years ago, ischemic heart disease (IHD), hypertension (HTN), melena for 3 days, Analgesic medication abuse, Chronic kidney disease (CKD).

On the 25th of November 2024, he was admitted to the intensive care unit due to hypertensive emergency and pulmonary edema. On the same day he started glyceryl trinitrate by an inappropriate initial dose (20 microgram/minute). As a result, the patient became shocked and needed vasopressors (his blood pressure fell to 90/60 which is considered a rapid decline and unfavourable in case of hypertensive emergency) and developed bradycardia.

Background

Hypertensive emergency is defined as significantly elevated blood pressure with signs or symptoms of acute, ongoing target-organ damage (systolic pressure ≥180 mmHg and/or diastolic pressure ≥120 mmHg)

Glyceryl trinitrate is an organic nitrate (vasodilators) used in cardiac diseases by reducing the tone of vascular smooth muscle. Systemic vascular resistance, pulmonary vascular pressure and arterial pressure are also reduced by glyceryl trinitrate and there is a net reduction in the afterload. By reducing the preload and afterload, glyceryl trinitrate reduces the workload on the heart. Glyceryl trinitrate affects oxygen supply by redistributing blood flow along collateral channels from the epicardial to endocardial regions.

Labeled information: "Summary of product Characteristics (SmPC)"

According to Nitroglycerin (glyceryl trinitrate) Summary of product Characteristics (SmPC) [1] it was stated under section (Posology and method of administration) that: "Not to be given by bolus injection.

Glyceryl Trinitrate Sterile Concentrate is a concentrated, potent drug which must be diluted in Dextrose (5%) Injection BP or Sodium Chloride (0.9%) Injection BP prior to its infusion.

During Glyceryl Trinitrate administration there should be close haemodynamic monitoring of the patient.

Hypertensive emergency (alternative agent) (off-label use):Limitations of use include variable efficacy compared to other agents (eg, inconsistent and transient BP response), possible reflex tachycardia, and possible reduced cardiac output. May be used as adjunctive therapy for patients with acute coronary syndrome or acute pulmonary edema. In general, goal of therapy is to reduce mean arterial pressure by ~10% to 20% over the first hour, then by an additional 5% to 15% over the next 23 hours (Ref).

Continuous IV infusion: Initial: 5 mcg/minute; increase based on BP response and tolerability in increments of 5 mcg/minute every 3 to 5 minutes up to 20 mcg/minute; if no response at a dose of 20 mcg/minute, may increase by 10 to 20 mcg/minute every 3 to 5 minutes to a maximum dose of 200 mcg/minute. Lower doses produce venous dilation; however, arterial vasodilation may occur at high doses (Ref). Tachyphylaxis develops within 24 to 48 hours of continuous nitrate administration; if vasodilator requirements continue longer than 24 to 48 hours, transition to an alternative IV or oral vasodilator.

Hypotension/bradycardia: Severe hypotension and shock may occur (even with small doses); paradoxical bradycardia and increased angina pectoris may accompany hypotension. Orthostatic hypotension may also occur. Use with caution in volume depletion, preexisting hypotension, constrictive pericarditis, aortic or mitral stenosis, and extreme caution with inferior wall myocardial infarction (MI) and suspected right ventricular involvement.

Recommendations for Healthcare Professionals:

The Healthcare professional should stick to the initial recommended dose which is stated in the SmPC of the product "Continuous IV infusion: Initial: 5 mcg/minute; increase based on BP response and tolerability in increments of 5 mcg/minute every 3 to 5 minutes up to 20 mcg/minute (Maximum dose: 200 mcg/minute)".

In hypertensive Emergency the goal of therapy is to reduce mean arterial pressure by ~10% to 20% over the first hour, then by an additional 5% to 15% over the next 24 hours.

References

1. ***Glyceryl Trinitrate SmPC :*** (Click Here)
2. ***Hypertensive emergency (Adult Dosing*** (Click Here)
3. ***"Evaluation and treatment of hypertensive emergencies in adults*** (Click Here)

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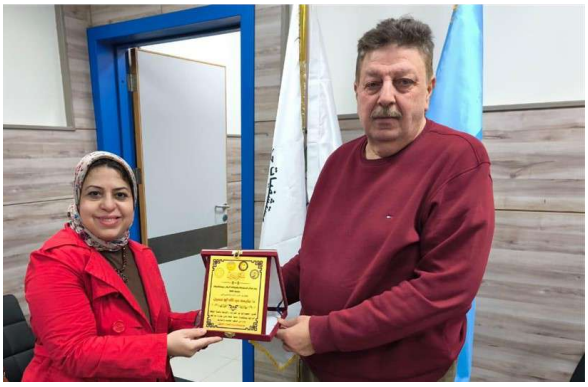
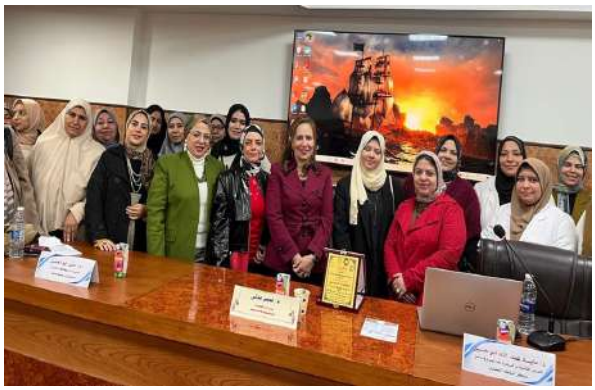
“Together for Safe Medicine“ Initiative News:





The Egyptian Drug Authority (EDA) took part in a drug safety event organized by the Drug Information and Pharmacovigilance Center of Tanta University, under the patronage of prominent figures, including Prof. Dr. Ahmed Ghoneim, Dean of the Faculty of Medicine at Tanta University, Prof. Dr. Hassan El-Tatawy, Executive Director of University Hospitals, Tanta University, and Prof. Dr. Mohamed Hantira, Vice Dean for Postgraduate Studies and Research at the Faculty of Medicine, Tanta Universityfocused on the theme “Introduction to Pharmacovigilance and the Importance of Monitoring and Reporting Adverse Drug Reactions (ADRs).” Held at Tanta University’s New Surgical Hospital, the event saw the participation of 60 healthcare professionals, including physicians, pharmacists, and nurses from various Tanta University hospitals. The EDA contributed by presenting two lectures and a workshop on pharmacovigilance, emphasizing the importance of ADR reporting and providing guidance on various reporting methods, such as E-reporting links, Arabic links, EDA hotlines, and Vigiflow accounts.

The event also addressed the risks associated with substandard and falsified products, aiming to raise awareness among healthcare professionals about these dangers. The participation of the EDA in this event aligns with its broader goals of strengthening collaboration between state institutions, promoting a culture of ADR reporting, and ensuring the safe use of medications. It also sought to equip healthcare professionals with the knowledge to monitor ADRs effectively, ensuring patient safety and high-quality pharmaceutical care.

The "Together for Safe Medicine" initiative, part of the event’s activities, aims to spread awareness of pharmacovigilance principles and ADR reporting across Egypt, particularly among healthcare workers in community pharmacies and governmental hospital pharmacies. By educating professionals across the country, the initiative helps ensure the safety of pharmaceutical, biological, and medical products, ultimately protecting the health of Egyptian citizens and improving the quality of healthcare across the nation.

The excitement is building: VigiTest Competition

Healthcare heroes, it's time to put your pharmacovigilance knowledge to the challenge. The VigiTest competition will sharpen your understanding of pharmacovigilance science and principles, that will be held every other month in our monthly newsletter. Starting from this month January 2025.

How to Join: It’s simple .Scan the QR code provided in the newsletter or tap the link below to access the competition questions. Answer correctly with your knowledge and skill, and you could be one of our monthly winners. Monthly Winners: Every month, the top participants will be celebrated for their expertise.

Annual Winners: At the end of the year, the top consistent winners will be recognized for their brilliance throughout the year and win certificate of appreciation for their participation and outstanding performance. Follow the next release, and stay tuned for the results and winners

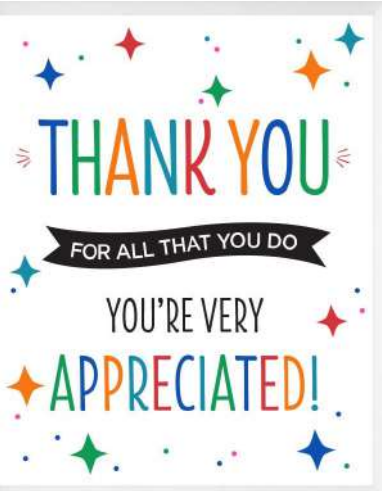
The competition starts now, this is your chance to showcase your knowledge and be part of healthcare professionals driving pharmacovigilance excellence. Don’t miss out on this opportunity to learn, win, and grow.

Scan the QR code or tap the link below, follow the instruction and answer the questions.

SCAN ME

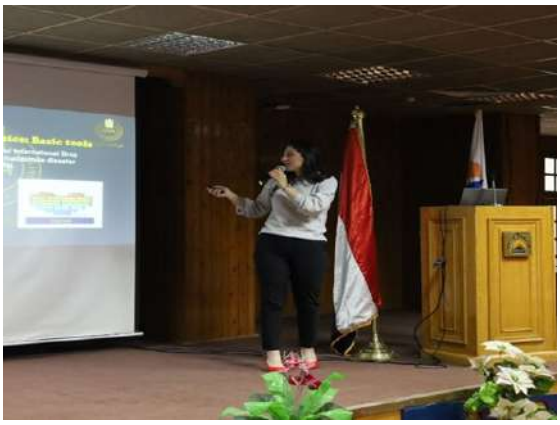
Egyptian Pharmaceutical Vigilance Center (EPVC) Vigiflow expansion project

The Egyptian Pharmaceutical Vigilance Center (EPVC) would like to appreciate the following entities for their recognizable and efforts in the field of pharmacovigilance: "Giza Health Directorate, Cairo Health Directorate, Menofia Health Directorate, Qena Oncology Center, Minya Oncology , Damanhour Oncology and Egyptian Health care authority different branches ."
We really value your participation in the national database reporting system, and we would like to express our gratitude to all of the organizations that collaborated with us to expand the Vigiflow system. We wish them continued success in their work and applaud their commitment to improving the monthly reported cases and the increasingly higher case's quality.



Egyptian Drug Authority celebration of Fighting the fakes for 2024

Fight the Fakes Week from 4 to 10 DEC is about uniting against substandard and fake medicines through collective action and raising awareness globally. It requires collaborative efforts from governments, healthcare professionals, pharmaceutical industries, and individuals to create a safer and more reliable healthcare landscape.
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 Fighting the fakes Week celebration 2024.
Egyptian Pharmacovigilance Center EPVC at EDA is participating in Member State Mechanism (MSM) working group E for Substandard and Falsified (SF) risk communications.
Aligning with the scope of SF risk communication approach, all PV activities include awareness about SF products.
December 2024, EPVC conducted visit for 6th October university to approach pharmacy students as they are the future generation of healthcare providers, in addition to approaching other students in different faculties as members of society.
Furthermore, another awareness activity was conducted at Xceed Contact Center to approach civil society members.
All activities with the aim of spreading awareness about the National role of Egyptian Pharmacovigilance Center EPVC at EDA in promoting drug and patient safety, raising awareness about SF products and how to report. In addition to providing training for pharmacy students on the principles of pharmacovigilance.



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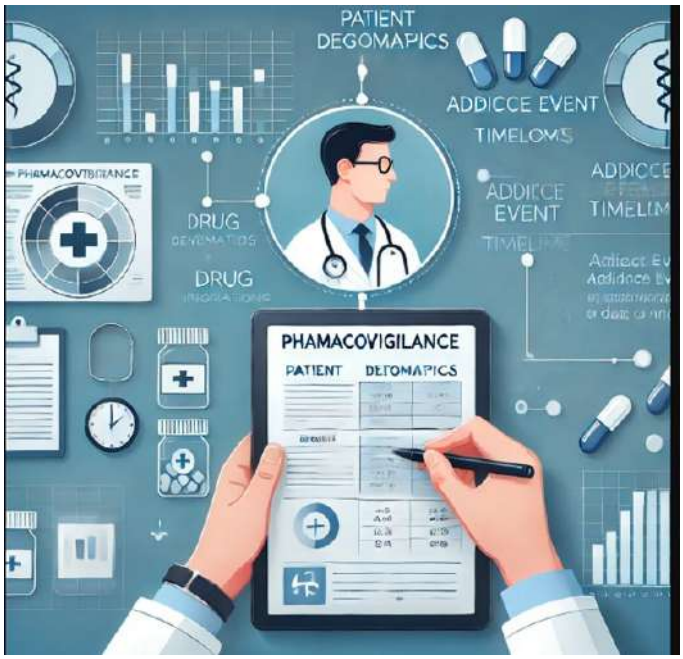
EPVC Tips

On Pharmacovigilance

Always ensure accurate and timely documentation.

Whether it's an adverse event report, medication error, or product quality issue, capturing all relevant details (e.g., patient demographics, drug information, event timeline, and outcomes) is crucial. Clear, concise, and standardized records improve signal detection, facilitate regulatory compliance, and support patient safety initiatives



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*

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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

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Pharmaceutical Care Administration
The Egyptian Pharmaceutical Vigilance Center (EPVC)

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https://sites.google.com/view/epvc-reporting/healthcare-professional-public-adverse-drug-event-reporting/reporting-other-adverse-drug-event-cases

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