EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

The Egyptian Pharmaceutical Vigilance center

مركز اليقظة الصيدلية المصري

IN THIS ISSUE

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

February 2021

Volume 12 Issue 2

SSRI/SNRI antidepressant medicines: small increased risk of postpartum haemorrhage when used in the month before delivery

Selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs) are two classes of commonly used antidepressant medicines. SSRIs and SNRIs are known to increase bleeding risks due to their effect on platelet function. Data from observational studies suggest that the use of SSRI/SNRI antidepressants during the month before delivery may result in a small increased risk of postpartum hemorrhage.

Prescribers should consider this risk in the context of an individual patient's bleeding and thrombotic risk assessment during the peripartum period and the benefits of antidepressants for the patient's mental health during this time.

Review of bleeding risks

Selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs) are two classes of commonly used antidepressant medicines. These medicines have been known for some time to increase the general risk of bleeding. This is thought to be due to serotonergic effect impairing platelet aggregation. Bleeding abnormalities associated with use of these medicines have been reported rarely and the absolute risk is thought to be low.

A recent review considered spontaneous data in the context of a wider literature review for SSRI and SNRI medicines. The review identified observational studies reporting an increased risk of postpartum hemorrhage in association with antidepressant use in late pregnancy, particularly for SSRIs and SNRIs.

Despite heterogeneous data and differences in definitions of postpartum hemorrhage, the review concluded that the data suggested a slightly increased risk of postpartum bleeding with use of SSRIs and SNRIs during the month before delivery. The review concluded that this risk might also apply to the newest antidepressant vortioxetine.

Medicines affected

- SSRIs: citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline
- SNRIs: desvenlafaxine, milnacipran, venlafaxine
- Vortioxetine

In reference to MHRA; Advice for healthcare professionals:

* SSRIs and SNRIs are known to increase the bleeding risk; observational data suggest that the use of some antidepressants in the last month before delivery may increase the risk of postpartum hemorrhage
* Continue to consider the benefits and risks for use of antidepressants during pregnancy, and the risks of untreated depression in pregnancy
* Healthcare professionals should continue to enquire about the use of antidepressant medicines, particularly in women in the later stages of pregnancy
* Consider the findings of the review in the context of individual patient risk factors for bleeding or thrombotic events
* Do not stop anticoagulant medication in women at high risk of thrombotic events in reaction to these data but be aware of the risk identified

References:

MHRA (Click here)

.

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

Local Case Report

Case Report from Alexandria: Sildenafil Co-administration with Nitroglycerin – Risk of death

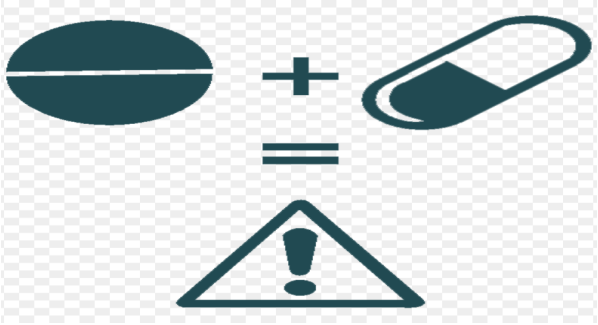
The regional center in Alexandria has received a case regarding male patient in his sixth decade who administered Sildenafil 100 mg only once for the treatment of erectile dysfunction. Few hours after its administration, the patient developed severe hypotension. He was hospitalized, where he was diagnosed as non-ST segment elevation myocardial infarction (Non- STEMI). A medical treatment was given, but the patient died five days later. It was found that the patient was using Nitroglycerin from long time ago.

A major drug-drug interaction was found between Sildenafil and Nitroglycerin, leading to severe hypotension and death in some cases.

Background :

Sildenafil is an oral phosphodiesterase type 5 inhibitor (PDE5 inhibitor). The four major PDE5 inhibitors are sildenafil, tadalafil, vardenafil, and avanafil. Sildenafil is indicated for the treatment of erectile dysfunction in adult men, by releasing nitric oxide (NO) in the corpus cavernosum of the penis during sexual stimulation. Nitric oxide then activates the enzyme guanylate cyclase, which results in increased levels of cyclic guanosine monophosphate (cGMP), producing smooth muscle relaxation in the corpus cavernosum and allowing inflow of blood. Sildenafil may also have other indication as in the treatment of pulmonary arterial hypertension (PAH) [1], [2]

Nitroglycerin or Glyceryl Trinitrate (GTN) belongs to the group of medicines called nitrates. It works by relaxing the blood vessels and increasing blood supply and oxygen to the heart while reducing its work load.



Nitroglycerin is used to prevent angina (chest pain) caused by coronary artery disease. It is also used to relieve an angina attack that is already occurring. [3]

Labeled information:

- According to Sildenafil SmPC, it is stated that undesirable effects include:

  Cardiac disorder in the form of tachycardia, palpitations, sudden cardiac death, myocardial infarction, ventricular arrhythmia, atrial fibrillation and unstable angina. While vascular disorders include hypertension and hypotension. [1]

- According to Nitroglycerin SmPC, it is stated that undesirable effects include:

  Cardiac disorder in the form of enhanced angina pectoris symptoms, bradycardia, cyanosis, hypoxaemia and palpitations. [4]

- According to the interaction checker between Sildenafil and Nitroglycerin, there is a major interaction, as Phosphodiesterase-5 inhibitors (including Sildenafil) may potentiate the hypotensive effect of organic nitrates. Severe hypotension, syncope, or myocardial ischemia may result from use of the combination. [5]

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

Case Report from Alexandria: Sildenafil Co-administration with Nitroglycerin – Risk of death continued

Recommendations for Healthcare professionals :

* The co-administration of Sildenafil and Nitroglycerin is contraindicated, as sildenafil was shown to potentiate the hypotensive effects of nitrates.
* Safety concern regarding the co-administration of nitrates with other PDE5 inhibitors is shown as following:
  - ⇒ Avanafil: at least 12 hours after the last dose of avanafil are recommended before nitrate administration.
  - ⇒ Tadalafil: at least 48 hours after the last dose of tadalafil are recommended before nitrate administration.
  - ⇒ Vardenafil: A suitable time interval following vardenafil use for the safe administration of nitrates has NOT been determined. [5]
* The recommended dose of Sildenafil is 50 mg taken as needed approximately one hour before sexual activity. Based on efficacy and tolerability, the dose may be increased to 100 mg or decreased to 25mg. [1]
* Patients should be advised to seek immediate medical attention if they experience anginal chest pain after taking a PDE5 inhibitor. [5]

References:

1. *EMC* *(Click here)*
2. *NCBI* (Click here)
3. *Drugs.com* (Click here)
4. *EMC* *(Click here)*
5. *Drugs.com* *(Click here)*

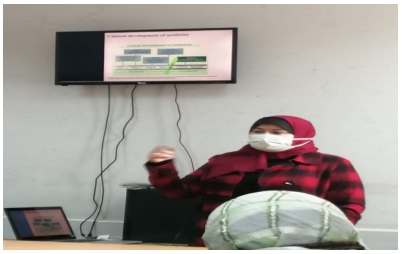
The Egyptian Pharmaceutical Vigilance center
مركـــز اليـــقظة الصـــيدلية المـــصري

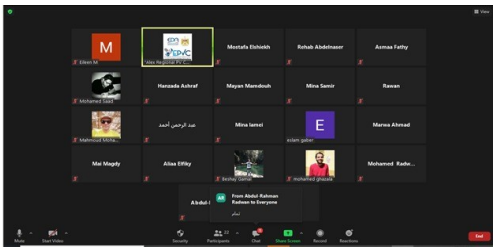
Healthcare Awareness Sessions All Over Egypt

In line with the vision of the Egyptian Pharmaceutical Vigilance Center (EPVC) to increase the awareness of healthcare professionals about Pharmacovigilance and strengthening its practice in different healthcare facilities all over Egypt; Regional centers at Alexandria & Sohag continued to hold sessions for health care professionals in different Egyptian governorates.

To date, 8 Sessions "online & Physical" have already taken place for total 153 Healthcare professionals in the following facilities "Assuit University children Hospital, Assuit Health Directorate Hospitals, Alexandaria University hospitals, Matrouh Directorate of Health affairs & Shark Medical District in Alexandria".

Sessions included basics of Pharmacovigilance scope, methods of reporting and an interactive workshop on how to detect the Adverse Drug Events (ADEs) and other drug-related problems





Supporting Menofia Collaborating Center & Opening new channels for Pharmacovigilance in Delta region

In the context of the cooperation plans with the Directorate of Health Affairs in Menoufia and the support of its collaborative pharmacy vigilance team, the Head of the Egyptian Pharmaceutical Vigilance Center & Head of Regional Centers visited the Directorate of Health Affairs in Menoufia and met with both the Undersecretary of the Ministry of Health in Menoufia and the General Manager of the General Administration of Pharmacy to discuss collaboration & new means of implementing Pharmaceutical Vigilance in Menofia & Delta region

And within the framework of opening new communication channels with different parties, EPVC Team have conducted a visit to Al-Arabi Hospital in Menofia governorate, and agreed on further collaboration to enhance Pharmacovigilance activity and Practices to guarantee safe medicine for Egyptian Citizens .

One report counts

A call for reporting

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

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

Communication information

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

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

Address: 21 Abd El Aziz AlSoud Street. El-Manial, Cairo, Egypt, PO Box: 11451
Telephone: (+2)02 25354100/ (+2)02 23684288/ (+2)02 23648046/ (+2)02 23640368/ (+2)02 23648769
Extension: 1303
Fax: +202 – 23610497
Email: pv@edaegypt.gov.eg, pv.report@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)