

Adulterated over the Counter Energy Supplements-A Case Report to Reiterate the Need for Regulation of Herbal Supplements

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ABSTRACT

Numerous herbal and dietary supplements available in the market are gaining popularity as they claim to be natural without synthetic analogs. These pills can be hazardous, as their clinical efficacy and safety have not been proven and they can interact with prescription medication, potentially causing life-threatening side effects in patients with preexisting heart conditions or at risk of stroke. We present the case of a 70-year-old male with a history of hypertension and diabetes who was brought to the emergency after a motor vehicle crash and had altered sensorium and severe bradycardia upon arrival which required external pacing. Paramedics recovered a large amount of over-the-counter "Rhino" pills from his car, which was sent for toxicology analysis. Each pill contained 709 mg of powder from which 100 mg was extracted with methanol and subjected to liquid chromatography-mass spectrometry (Thermo-scientific analyzer) which identified 149.5 mg of sildenafil citrate in the pill contents. The patient recovered well with external pacing and pressor therapy and was discharged after 8 days of hospitalization. Unregulated herbal supplements containing synthetic analogs can result in adverse health effects including emergency department visits and fatalities. The lack of regulation and standardization in the production and distribution of these supplements poses a great risk to consumers and healthcare professionals who may not be aware that their patients are taking such supplements. Reporting such incidents can create awareness and can lead to the strengthening of regulatory procedures. **Keywords:** Herbal supplements; Unregulated OTC supplements; Hazardous; Sildenafil

INTRODUCTION

There are numerous herbal and dietary supplements available Over the Counter (OTC) without a prescription in the USA with many being marketed for weight loss, improved well-being and enhanced sexual performance. Many of these are marketed as "all-natural" with no synthetic drugs or compounds. Some however, can be dangerous because their clinical efficacy and safety have not been tested, whereas others, have the potential to interact with prescription medications. Therefore, it is important to consult a healthcare professional before consuming OTC supplements.

Globally, consumption of dietary supplements for enhanced sexual performance is common. In this context we present a case of an elderly male who consumed a sexual performance enhancing herbal medication obtained from a convenience store that lead to a potentially fatal complication.

CASE PRESENTATION

A 70-year-old male with history of hypertension and diabetes was transported to the emergency department by Electrical Muscle Stimulation (EMS) after a motor vehicle crash. When paramedics arrived at the scene he had altered mental status and severe bradycardia with a heart rate between 30 and 40. He was found to have Type II heart block and required external pacing. Upon arrival the patient was intubated for airway protection and an epinephrine infusion was started for severe hypotension and bradycardia. EMS personnel reported that there were over ten packaged male enhancement pills scattered across the front seat and floor of his vehicle, which were recovered for analysis. As

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Received: 17-Jun-2024, Manuscript No. JCT-24-31403; **Editor assigned**: 20-Jun-2024, PreQC No. JCT-24-31403 (PQ);**Reviewed**: 04-Jul-2024, QC No. JCT-24-31403; **Revised**: 11-Jul-2024, Manuscript No. JCT-24-31403 (R); **Published**: 18-Jul-2024, DOI: 10.35248/2161-0495.24.14.573.

Citation: Chaudhary R, Aravind A, Kyle PB (2024) Adulterated over the Counter Energy Supplements-A Case Report to Reiterate the Need for Regulation of Herbal Supplements. J Clin Toxicol. 14:573.

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per the sales receipt, the supplements had recently been purchased at a local convenience store.

Imaging studies revealed non-displaced sternal fractures and bilateral pulmonary contusions. The patient's cardiac troponin value was 16 ng/L (<22 ng/L) upon arrival and his echocardiogram was unremarkable with an ejection fraction of 65-70%. Transcutaneous cardiac pacing was intermittently required when his heart rate dipped lower than 30, and the patient was transferred to the intensive care unit for monitoring. Intravenous epinephrine was required over the next 3 days for continued bradycardia but, no pacing was required after the first 24 hours. The patient was discharged from the hospital after 8 days of hospitalization.

For toxicology analysis, one of the recovered capsules was opened and found to contain 709 mg of powder. A 100 mg portion of the powder was removed and extracted with 5.0 ml of methanol. The mixture was centrifuged at 3,000 × g for 10 minutes and the supernatant was removed for analysis. The extract was diluted 1:1000 prior to injection onto an LC-tandem mass spectrometer (Q-ExactiveTM Focus, Thermo ScientificTM). Sildenafil was identified at 4.86 minutes and exhibited ion transitions 475.2122 \rightarrow 311.1510 and 475.2122 \rightarrow 283.1194 m/z using positive ionization. D3-Cocaine was used as an internal standard to establish a calibration curve, which exhibited excellent linearity across the range of 10 to 5000 ng/ml (R2=0.9991) as illustrated in Figure 1.



Quantification revealed a concentration of 149.95 mg of sildenafil in the capsule contents. The total ion chromatogram and extracted ion chromatograms of the extracted capsule are illustrated in Figure 2.



RESULTS AND DISCUSSION

In the last few decades, dietary supplements have gained widespread popularity all over the world due to the ease of accessibility and marketing as a natural, herbal and nonsynthetic supplements. Many have an unconscious bias when it comes to products labelled as herbal and natural and they often turn a blind eye to a product's potential for harm. We have encountered many such cases where consumption of such products over concerns of weight loss, sexual performance and erectile dysfunction has led to both fatal and non-fatal complications.

These products are readily available as over the counter food supplements at smoke shops, gas stations and convenience stores. Relatively few regulations address dietary food supplements which, require no prior quality control or clinical trials before being made commercially available. Products labelled as natural, herbal and/or non-synthetic seems to take them off the radar and into the good books of consumers. Some manufacturers have been known to include medications or other synthetic compounds in dietary supplements in order to produce the desired results [1]. Products often have no labelling in regards to dosing or maximum permitted use. This increases the potential for overdose and toxic side effects as individuals seek to attain desired results. Several recent reports cite the presence of medications and synthetic compounds in herbal supplements claiming to improve sexual performance. Compounds such as sildenafil citrate, tadalafil, vardenafil hydrochloride trihydrate [2-4], but also synthetic analogues such as piperidenafil, acetildenafil, methisosildenafil, homosildenafil, hydroxyhomosildenafil, thiohomosildenafil, thiosildenafil, and thiomethisosildenafil have been reported [5-9]. Many of these compounds remain clinically unproven in terms of efficacy and safety and may pose serious health risks. Patients with preexisting conditions such as coronary artery disease, stroke, hypertension, and diabetes may be at increased risk of serious life-threatening complications if products are used without physician consultation as occurred in this case that led to lifethreatening bradycardia and heart block.

CONCLUSION

The market has been inundated with herbal supplements that may be adulterated with drugs or analogs that may put the public at risk for adverse health effects or death. The lack of regulation and standardization in the production and distribution of these supplements poses a significant risk to consumers as well as healthcare professionals who may not be aware of patients' herbal supplement use. Therefore, it is important to inform healthcare professionals and the public about the potential for product adulteration and the potential for severe side effects. In the event of an adverse reaction, toxicological analysis is recommended as well as communication with the U.S. Food and Drug Administration and/or other authorities. Reporting each adverse event will increase the awareness of adulteration and promote the regulation of these products.

CONFLICT OF INTEREST

None

DISCLOSURES

None

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