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Prolongamento do intervalo QT: a importância da Farmacovigilância

O intervalo QT é uma medida eletrocardiográfica da repolarização miocárdica. Um intervalo prolongado está associado a risco aumentado de desenvolvimento de arritmias ventriculares potencialmente fatais. Valores de QT superiores a 500 ms associam-se a elevado risco de *torsades de pointes* ou taquicardia ventricular polimórfica. Múltiplos fatores podem contribuir para o prolongamento do intervalo QT, incluindo suscetibilidade genética, distúrbios eletrolíticos e o uso de certos medicamentos.

Com efeito, **diversas classes de medicamentos, como antiarrítmicos, antipsicóticos, antidepressivos e alguns antibióticos**, têm sido implicadas no prolongamento do intervalo QT. Estes medicamentos induzem o prolongamento do intervalo QT, através de mecanismos diversos. Por exemplo, quinolonas e macrólidos como a moxifloxacina e a eritromicina, respetivamente, bloqueiam os canais de potássio cardíacos, levando ao atraso da repolarização ventricular. A interação entre medicamentos com potencial de prolongamento do intervalo QT que são metabolizados pelo **citocromo P450 3A4** e fármacos que inibem esta enzima é também um fator de especial relevo.

A prevenção do prolongamento do intervalo QT associado a iatrogenia medicamentosa é fundamental para a redução do risco de arritmias potencialmente fatais. É crucial **identificar doentes de risco aumentado** por fatores genéticos ou condições preexistentes, como insuficiência cardíaca ou síndrome congénita do QT longo. A avaliação regular do intervalo QT nos doentes a quem foram prescritos medicamentos que afetem a repolarização cardíaca pode ser feito recorrendo a métodos simples como o ECG de 12 derivações em repouso e a monitorização por Holter.

A deteção precoce desta RAM deve levar a uma **intervenção imediata**: devem ser equacionados a descontinuação ou ajuste da dose do medicamento suspeito, sendo que as anomalias eletrolíticas, especialmente a hipocaliemia e a hipomagnesemia, devem ser corrigidas.

A **notificação** do prolongamento do intervalo QT é essencial para uma farmacovigilância eficiente, visto que a sua ocorrência pode não ser imediatamente aparente durante os ensaios clínicos, uma vez que estes excluem frequentemente indivíduos com doenças cardíacas preexistentes. No entanto, a ocorrência tardia de *torsades de pointes*, de outras arritmias ventriculares potencialmente fatais, ou mesmo de morte súbita, pode tornar difícil estabelecer uma relação causal clara entre medicamento e reação adversa, o que poderá explicar em parte a subnotificação desta RAM.

Inês Jordão

Leia mais **aqui** sobre intervalo QT, medicamentos e risco de arritmia

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DCI Medicamento	Público-alvo	Que comunicação? Data de publicação *online*
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Compilado por Patrícia Catalão

A seguir: Concluímos a divulgação de pósteres do programa científico do evento comemorativo do 30º aniversário do INFARMED, I.P., Farmacovigilância Envolver o Cidadão. Neste Número: dados de farmacovigilância relacionados com contrafação de medicamentos para a disfunção erétil e revisões dos perfis de segurança de*i mmune checkpoint inhibitors* agentes anti-TNFα e tirzepatida. Finalmente, tendo como caso exemplar a esclerose múltipla, um olhar sobre uma dificuldade clínica comum: o diagnóstico diferencial entre falta de eficácia e manifestação da história natural da doença.

THE ERA OF FAKE MEDICINES:
PHARMACOVIGILANCE DATA OF COUNTERFEIT MEDICINES USED IN ERECTILE DYSFUNCTION

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INTRODUCTION & AIMS: Substandard and falsified (SF) medicines are a public health problem almost overworld (1). SF medicines can be classified into 3 categories: substandard, unregistered/unlicensed, and falsified medicines. The regular use of SF medicines can lead to therapeutic failure or drug resistance as well as unknown adverse events, thus constituting a significant risk to the public health. There are several therapeutic classes that have been counterfeited mainly antiretrovirals. Notwithstanding, counterfeit medication used for the treatment of erectile dysfunction (ED) has also emerged in the illegal market. Among these SF medicines, sildenafil citrate is one of the most prevalent examples (2).

Herein, it is presented a brief analysis that aimed to identify and describe the cases (including the adverse drug reactions) related to counterfeit medication indicated for the treatment of erectile dysfunction (ED).

METHODS: This analysis was carried out based on EudraVigilance data for all Individual Case Safety Reports (ICSRs) obtained in the context of post-authorization monitoring for active substance(s) belonging to the ATC group G04BE used in the treatment of ED. The search was based on ICSRs which included at least one of the following preferred terms (PT): Counterfeit product administered; Product counterfeit; Product label counterfeit; Product packaging counterfeit; Suspected counterfeit product; Adulterated product; Product tampering or Suspected product tampering (3).

RESULTS & DISCUSSION: According to the EudraVigilance database, 77% ICSRs of counterfeit products were from non-European Union countries whereas 23% corresponded to European Union (EU) countries, mainly Germany. Most cases were reported on 2012/13 and only few were reported in the last three years probably due to the COVID-19 pandemics (**Fig.1**).

About 60% of ICSRs were considered as serious adverse drug reactions (ADR), among which 19.4% and 5.8% led to hospitalization and death, respectively (**Table 1**). Sildenafil followed by Tadafil were the most prevalent medicinal products that were reported. Nevertheless, it should be highlighted that only 29.7% of searched PT terms corresponded to "counterfeit product administered" while most cases (47.7%) were related to "suspected counterfeit product" which reveals that most data still need further investigation. About 46.5% ICSRs of searched PT terms were coded with "ineffective drug" or similar and 68% were coded with at least one physiopathologic adverse drug reaction (ADR), mainly headache, as reported in literature and product information of these therapeutic drugs.

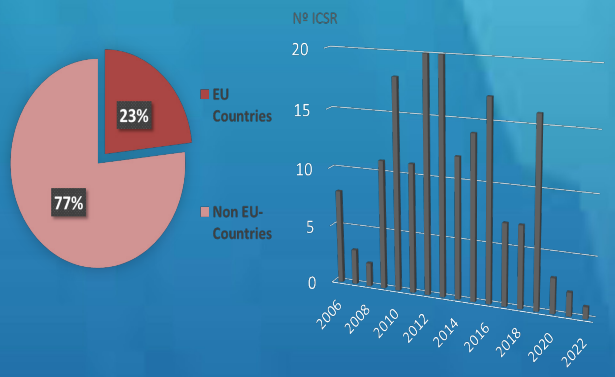

Fig.1. Representation of the number of ICSRs of counterfeit products for ED from EU and Non EU- countries since 2006 to 2022.

Table 1. Summary of main variables correspondent to searched PT of ICSRs of counterfeit products for ED from EU and Non EU- countries since 2006 to 2022 (Note: % Rounded values).

VARIABLES			%
Sex		Male	92.4
		Female	1.7
		Unknown	5.8
Seriousness		Yes	59.9
		No	34.3
		Not known	5.8
Seriousness criteria		Death	5.8
		Life risk	2.9
		Hospitalization	19.4
		Other	71.8
PT	***Counterfection***	Suspected counterfeit product	47.7
		Counterfeit product administered	29.7
		Product counterfeit	22.1
		Product Tampering	0.6
	Efficacy	Drug ineffective	46.5
	ADR	Headache	4.7
		Erection increased	2.7
		Dizziness	2.4
		Myocardial infarction	2.0
		Malaise	2.0
		Nausea	2.0
		Loss of consciousness	2.0
		Hypertension	1.7

CONCLUSION: Overall, these results showed that both counterfeit medicines used for ED and the respective ICSRs clearly deserve to be monitored. Nevertheless, there are still limited data regarding the prevalence of these medicines (among many others) and their impact in terms of ADR. Moreover, as many of those SF medicines (including herbal supplements formulated with this type of drugs) are ordered online and not always detected in customs besides several patients still do not report the ADR probably due to a stigma perspective, this reality represents a real challenge for pharmacovigilance monitoring. A special and shared effort should be undoubtedly welcome from all health authorities synchronized with other governmental systems in order to overcome this huge challenge and detect the SF medicines´ market at "real time", thus ensuring the main goal on public health – the use of safe medicines.

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Immune checkpoint inhibitors and cardiac events

A pharmacovigilance database analysis

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INTRODUCTION

The development of immune checkpoint inhibitors (ICIs) was a turning point in cancer therapy. ICIs rely on the immune system to be effective, and it is also through the immune system that their main adverse drug reactions (ADRs) arise [1]. In this context, myocarditis is relevant due to its relation to the mechanism of action, incidence, and difficulty of diagnosis. However, meta-analyses performed on cardiac toxicity induced by ICIs [2] showed that other cardiac disorders could have a higher incidence, redirecting the discussion.

OBJECTIVE

Contribute to this topic with the characterization and analysis of cardiac events reported to the Portuguese National Pharmacovigilance System and related to the use of ICIs.

METHODS

Retrospective analysis of individual case safety reports (ICSRs) reported to the Portuguese National Pharmacovigilance System, since 28 December 2010 (reporting date of the first ICSR of interest) until 30 November 2022.

ICSRs inclusion criteria:

- ICIs reported as suspect/interact drug;
- Had at least one ADR belonging to the primary MedDRA system organ class (SOC) "Cardiac Disorders".

The cardiac diseases reported were grouped into the categories used in clinical practice [3].

RESULTS

Total of 799 ICSRs

33 cases had at least one ADR encompassed by the primary MedDRA SOC "Cardiac Disorders" corresponding to a total of 38 ADRs.

21 types of cardiac disorders reported	
Arrhythmias	n=16 (42%)
Pericardial disorders	n=10 (26%)
Myocarditis	n=4 (11%)
Coronary artery disease	n=3 (8%)
Heart failure	n=2 (5%)
Cardiomyopathy	n=2 (5%)
Others	n=1 (3%)

31 (94%) ICSRs were classified as serious. Of these:

n=12 (36%) Clinically important
n=6 (18%) Hospitalization occurred or was extended
n=2 (6%) Assessed as life threatening
n=11 (33%) Patient died

CONCLUSIONS

- This study follows up on the possible association of ICIs and cardiac events other than myocarditis, with a higher impact than initially expected by their mechanism of action.
- The seriousness of cardiac ADRs and the progressive increase in patients on ICIs therapy reinforce the need for further studies on the mechanism and pattern of cardiac events manifestation in this setting.
- For this purpose, pharmacovigilance databases add an important complement to the safety analysis performed in clinical trials.

References: [1] Haanen J et al. Annals of Oncology. 2022; 33: 1217-1238; [2] Dolladille C et al; European Heart Journal. 2021; 42: 4964–4977; [3] Lyon R et al. European Heart Journal. 2022; 43: 4229–4361

The pharmacogenomic biomarkers and safety profile of immunosuppressive medicinal products anti-TNF-α

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Background: Anti-TNF-α agents are generally well tolerated, with minor common adverse effects and not needing drug discontinuation. However, serious adverse effects have occurred, the most common being of severe infections. Pharmacological therapy has side effects, which can lead to non-adherence to medication by users. Thus, it is important to ensure the efficacy and safety of this therapy. This is achieved by identifying pharmacogenomic biomarkers that can predict the response of these immunosuppressive medicines, preventing the occurrence of adverse reactions, toxicity, or lack of efficacy.

Objectives: The main goal of this project was to identify, describe, characterize and classify the scientific evidence associated with the use of pharmacogenomic biomarkers in the treatment of autoimmune diseases with anti-TNF-α agents.

Methods: The work was developed in two phases: i) a search for pharmacogenomic biomarkers in the summaries of products characteristics (SmPC) of anti-TNF-α agents; and ii) a systematic literature review based on the data obtained in the first phase, with the principal objective of finding studies in international literature that could describe and characterize the biomarkers founded before and possibly identifying other relevant biomarkers. The second phase is in process. Finally, the levels of evidence and recommendation grades will be classified for every study.

Results: As preliminary results, 7 anti-TNF-α agents (L04AB) were identified on the ATC/DDD Index 2023, but only 3 of them have marketing authorization in Portugal. In the phase I search, any pharmacogenomic biomarker was identified during the SmPC screening. For phase II, in the systematic literature review, the search is based on the following query: (((efficacy) OR (effectiveness)) AND ((safety) OR (surveillance) OR ("adverse drug reactions")) AND (("Tumor necrosis factor-alpha (TNF-alpha) inhibitors") OR ("anti-TNF-alpha") OR ("Anti-tumor necrosis factor (TNF)-alpha") OR ("anti-TNF-α drugs"))). The systematic review screening is in progress, with a view to identifying relevant information about pharmacogenomic biomarkers and classifying the evidence levels and recommendation grades.

Conclusions: Most pharmacogenomic variants are not studied or acknowledged by the pharmacogenomic tests and still need more scientific research that confirms their usefulness, namely to innovative medicines like anti-TNF-α agents. Besides, genotyping of patients is not common clinical practice. According to the potential biomarkers identified during the systematic literature review, a set of recommendations should be proposed.

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Tirzepatide: a systematic review

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Introduction

Type 2 Diabetes is a chronic and metabolic disease characterized by hyperglycemia due to inadequate insulin secretion or to insulin resistance . The ideal therapies are those capable of reducing blood glucose levels with a lower risk of hypoglycemia and weight gain

GLP-1 receptor agonists (GLP-1 RAs) have been first approved in 2005, which have proven very effective and now they are the first-choice injectable drugs for the treatment of Type 2 Diabetes

Type 2 Diabetes and Tirzepatide

More recently, it has been hypothesized that the combination of GLP-1 RAs with GIP receptor agonists (GIP RAs) would provide more effective glycemic control along with a significant weight reduction effect. A new drug – Tirzepatide -was developed based on a synthetic peptide that acts as an agonist of both GLP-1 and GIP receptors, producing a greater insulin response

Some studies have highlighted the safety and efficacy of two incretins in the control of glycemia and body weight. Since diabetes is a complex pathology, in many cases has associated co-morbilities, it is important to deepen the study of the safety of Tirzepatide to prevent and predict possible adverse events

Objectives

To define, evaluate and summarize information from relevant studies on Tirzepatide, its efficacy and any adverse events it may cause

This systematic review allows to have an updated summary of the scientific evidence about this new antidiabetic drug

Methods

A literature search was conducted in PubMed/Medline, up to February 20, 2023

Using the following medical subject heading terms and keywords: (tirzepatide) AND (“type 2 diabetes”) AND (“randomized controlled trial”)

A table and a concept map were created to summarize the collected data, following the PICO criteria

Results

Of the 174 items, 47 were selected as they corresponded to the selection criteria

Randomized controlled clinical trials or articles in which the safety profile of the drug was analysed in people with Type 2 Diabetes treated with Tirzepatide or other comparator agents

Treatment and severe adverse events were analyzed in all Randomized Controlled Clinical Trials and were compared with other antidiabetic agents or with a placebo

In most cases, the incidence of Tirzepatide effects was higher when compared to the placebo, but similar to the other antidiabetics

The adverse events encountered

Were, mainly, gastrointestinal ones with dose-dependent increased odds of nausea, vomiting and diarrhea, like those experienced by patients treated with GLP-1 RAs	Hypoglycemia has also been considered and occurred in some patients receiving Tirzepatide, with a lower incidence when compared with other drugs such as insulin glargine	Other adverse events included injection site reactions, pancreatitis, cholecystitis, hypersensitivity and mortality, all these had a low incidence and some of these events were not always attributable to the treatment

Conclusions

- This review is useful to have a general picture of the safety of the new antidiabetic drug Tirzepatide, approved in the United States in 2022.
- This review contributes to SDG 3 of the United Nations 2030 agenda.
- Since the only data available so far are the results of randomized controlled clinical trials , it is important to understand and know the possible adverse effects that may occur during the treatment.
- As the target patients are frail subjects, who often have pathologies related to diabetes that worsen the clinical situation, it is essential to minimize treatment-related and severe adverse events that can compromise the patient's health, such as severe hypoglycemia and pancreatitis.

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Disease manifestation or therapeutic ineffectiveness?

THE EXAMPLE OF MULTIPLE SCLEROSIS

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INTRODUCTION

- Multiple sclerosis (MS) relapses are triggered by a combination of several factors and often cause some anxiety in the patient [1], especially if they coincide with a recent change in therapy.
- When the manifestation of disease can result from several factors, it can be very difficult to differentiate the cases in which there is ineffectiveness of therapy [1].
- According to the rules for coding adverse drug reactions (ADRs) in pharmacovigilance, when a lack of efficacy is coded, its manifestation should not be coded at the same time.

This is a concern identified in clinical practice and pharmacovigilance.

METHODS

- Retrospective analysis of individual case safety reports (ICSRs) reported to the Portuguese National Pharmacovigilance System.
- Between 1 January 2011 and 31 December 2021.
- Criteria for inclusion of ICSRs:
  - At least one of the DMTs for MS was identified as a suspect/interacting drug;
  - Therapeutic indication included a MedDRA term encompassed by the high level term (HLT) "multiple sclerosis acute or progressive";
  - At least one ADR covered in HLT "multiple sclerosis acute or progressive" and/or HLT "therapeutic and non-therapeutic responses".

OBJECTIVES

Characterise and analyse the cases reported to the Portuguese National Pharmacovigilance System whose ADRs are the manifestation of the disease and/or the lack of efficacy of disease-modifying therapies (DMTs) in MS.

RESULTS

Total of 3,952 ICSRs

With at least one of the DMTs for MS identified as a suspect/interacting drug and its therapeutic indication included a MedDRA term encompassed by the HLT "multiple sclerosis acute or progressive".

The three drugs most reported were:

Interferon beta-1a (n=248)
Interferon beta-1b (n=123)
Fingolimod (n=99)

Of these cases:

633	Had an ADR only covered in HLT "acute or progressive multiple sclerosis"
22	Had an ADR only convered in HLT "therapeutic and non-therapeutic responses"
59	Had both HLTs

ICSRs classified as serious: 48% (n=343)
Principal seriousness criterion - **Clinical importance 68% (n=232)**

CONCLUSIONS

The difficulty to draw a line between what is a disease manifestation and what is an ADR of treatment ineffectiveness is reflected in the overlapping of adverse reactions codification.

This overlap adds "noise" to the pharmacovigilance system and could lead to interpretation biases.

This question is particularly relevant in MS and, in clinical practice, this may have implications in medication adherence and therefore in disease progression.

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Materiais Educacionais publicados na ficha do medicamento no Infomed

Clique nas hiperligações para consultar

DCI Medicamento	Público-alvo	Que materiais? Data de publicação *online*
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Ácido desoxicólico *Belkyra*	**Médicos:** cirurgia plástica reconstrutiva e estética	Guia 06-10-2023
Ambrisentano *Ambrisentano Accord, Ambrisentano Generis*	**Doentes**	Cartão do doente 25-09-2023
Apixabano *Apixabano Teva*	**Médicos:** cardiologia, neurologia, medicina interna, medicina geral e familiar, hematologia/imuno-hemoterapia, anestesiologia, ortopedia, cirurgia vascular, gastroenterologia **Farmacêuticos:** diretores dos serviços farmacêuticos hospitalares	Guia do prescritor 13-09-2023
Capsaícina *Qutenza*	**Profissionais de saúde:** médicos de anestesiologia, oncologia e endocrinologia (unidades de dor) e profissionais de saúde (médicos e enfermeiros) que irão realizar a aplicação.	Guia de administração 02-10-2023
Eculizumab *Soliris*	**Médicos:** neurologistas hematologistas nefrologistas **Doentes**	**Guia para prescrição a doentes com:** doença do espectro da neuromielite ótica (NMO) miastenia gravis generalizada (MGg) refratária hemoglobinúria paroxística noturna (HPN) síndrome hemolítico urémico atípico (SHUa) Guia para doente/pais/cuidadores de doentes com MGg refratária 23-10-2023
Glofitamab *Columvi*	**Profissionais de saúde:** médicos de hematologia e oncologia, diretores dos serviços farmacêuticos hospitalares e diretores do serviço de enfermagem **Doentes**	Guia do profissional de saúde Cartão do Doente 07-09-2023

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DCI Medicamento	Público-alvo	Que materiais? Data de publicação *online*
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Óxido nítrico *InoxGEN*	**Profissionais de saúde:** médicos e enfermeiros das unidades hospitalares com valência de UCI de neonatologia, pediatria e cirurgia cardiotorácica	Guia para profissionais de saúde 06-09-2023
Patisiran *Onpattro*	**Médicos:** neurologistas especializados em doenças neuromusculares e/ou neurofisiologia dos centros envolvidos no tratamento da amiloidose hereditária mediada por transtirretina	Guia: utilização segura em contexto domiciliário
	Doentes	Guia: utilização segura no domicílio 19-10-2023
Pembrolizumab *Keytruda*	**Doentes**	Cartão do doente 21-10-2023
Ravulizumab *Ultomiris*	**Médicos:**	**Guia para doentes com:**
	neurologistas	doença do espetro da neuromielite ótica (NMO) miastenia gravis generalizada (MGg)
	hematologistas	hemoglobinúria paroxística noturna (HPN)
	nefrologistas	síndrome hemolítico urémico atípico (SHUa)
	hematologistas, nefrologistas e neurologistas	certificado de vacinação
	Doentes	**Guia para doentes com:** NMO MGg refratária HPN SHUa
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Materiais Educacionais publicados na ficha do medicamento no Infomed

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DCI Medicamento	Público-alvo	Que materiais? Data de publicação *online*
Teriflunomida *Teriflunomida Mylan*	**Médicos:** neurologistas	Guia
	Doentes	Cartão
		18-09-2023
Teriflunomida Sandoz	**Médicos:** neurologistas	Guia
	Doentes	Cartão
		21-09-2023
Tremelimumab *Imjudo*	**Doentes**	Cartão
		12-10-2023

Compilado por Patrícia Catalão

O que significam?

AIM Autorização de Introdução no Mercado – em inglês ***MA*** *Marketing Authorisation*

EMA Agência Europeia do Medicamento – do inglês *European Medicines Agency*

FI Folheto Informativo – em inglês *PL Patient Leaflet*

PRAC Comité de Avaliação do Risco em Farmacovigilância (da EMA) – do inglês *Pharmacovigilance Risk Assessment Committee*

RAM Reação Adversa a Medicamentos – em inglês ***ADR*** *Adverse Drug Reaction*

RCM Resumo das Características do Medicamento – em inglês ***SmPC*** *Summary of Product Characteristics*