Drug & Poison Information Center Bulletin
Faculty of Pharmacy - Tanta University

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Inside this issue:

A recent study reveals the origins of cancer immunotherapy-induced myocarditis

Highlights from a recent study, published Nov. 6 in Nature, led by Harvard Medical School (HMS) researchers at the Broad Institute of Massachusetts Institute of Technology (MIT), Harvard and Massachusetts General Hospital. The study uncovers the immune basis for heart-muscle inflammation in patients receiving cancer immunotherapy. The findings point to an immune response different from the one directed at the tumor. Results can inform precision-targeted therapies that treat the heart inflammation but preserve the immune response against the cancer.

Background:

Cancer immunotherapy has redefined the treatment of many cancers, however, in a small number of patients this life-saving approach leads to a dangerous heart-muscle inflammation called myocarditis. Why and how this happens has remained unclear, hampering efforts to prevent and treat this at times fatal complication when it arises. New research shows that immune cells and connective-tissue cells in the heart muscle appear to be driving the immune response that triggers the heart inflammation.

Furthermore, the team identified notable changes in the blood that may predict the likelihood of a patient with myocarditis dying from it. Importantly, the findings provide the first evidence for an immune reaction in the heart that is distinct from the immune response aimed at the tumor. A new clinical trial at Mass General is testing an arthritis drug to treat immunotherapy-related heart inflammation, aiming to develop more targeted therapies for checkpoint inhibitor-induced myocarditis.

Identifying the molecular fingerprints of myocarditis :

The new findings are based on an analysis of blood, heart, and tumor tissue samples from patients who developed myocarditis while receiving immune checkpoint inhibitors (ICIs), a type of the immunotherapy class therapy.

The heart tissue showed: Upregulation of molecular pathways that help recruit and retain immune cells involved in inflammation. Patients with active disease also had greater abundance of clusters of cytotoxic T cells, dendritic cells, and inflammatory fibroblasts.

In the blood: The team found fewer immune cells called plasmacytoid dendritic cells, dendritic cells, and B cells, while mononuclear phagocytes were present in higher numbers. The team also analyzed the T-cell receptors in tissue from affected hearts were distinct from those seen in tumors. There was also no evidence that T-cell receptors recognized a heart-muscle protein involved in contraction called α-myosin, previously reported as a pivotal antigen driving immune checkpoint therapy-induced myocarditis. These results suggest that the T-cell receptors most abundant in affected heart tissue recognize undetermined antigens.

The researchers aim to identify the antigens involved in the heart and in the tumor and determine whether they are normal proteins, mutated tumor proteins, foreign particles such as viruses, or something else.

The pattern of T-cell subtypes in the blood indicated which individuals were more likely to succumb to myocarditis, suggesting that a blood test could one day be used to flag patients at increased risk who should be monitored closely or avoid immunotherapy altogether. The team also found T cells in the peripheral blood that originated in the heart and correlated with severity of disease. Those findings open the door to developing a diagnostic blood test that could replace invasive heart biopsies for patients suspected of having myocarditis.

References:

- *Blum SM, Wright G, Patel B, et al. Immune responses in checkpoint myocarditis across heart, blood, and tumor. Nature. 2024. doi:10.1038/s41586-024-08105-5.*

- *Harvard Medical School. How cancer immunotherapy fuels heart inflammation in some patients. Available at: https://hms.harvard.edu/news/how-cancer-immunotherapy-fuels-heart-inflammation-some-patients. Accessed in November, 2024.*

Ph. Bassant M. Mahboub, PhD. cand.

FDA updates GLP-1 label with pulmonary aspiration warning

On November 5, the US Food and Drug Administration (FDA) updated the labels for all glucagon-like peptide 1 receptor agonists (GLP-1 RA) with a warning about pulmonary aspiration during general anesthesia or deep sedation. The affected drugs include: semaglutide (Ozempic, Rybelsus, Wegovy); liraglutide (Saxenda, Victoza); and the dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 tirzepatide (Mounjaro, Zepbound).

According to the new label: "Rare postmarketing reports describe pulmonary aspiration in patients receiving GLP-1 receptor agonists undergoing elective surgeries or procedures requiring general anesthesia or deep sedation who had residual gastric contents despite reported adherence to preoperative fasting recommendations.

Available data are insufficient to inform recommendations to mitigate the risk of pulmonary aspiration during general anesthesia or deep sedation in patients taking these drugs. It is unclear whether modifying preoperative fasting recommendations or temporarily discontinuing them could reduce the incidence of retained gastric contents. Instruct patients to inform healthcare providers prior to any planned surgeries or procedures if they are taking a GLP-1 RA.

Patient information:

The Medication Guide section of the label includes new additions. Patients are advised to inform their healthcare provider if they are scheduled to undergo surgery or other procedures that use anesthesia or deep sedation.

They are alerted that the GLP-1 RAs they are taking may cause serious side effects, including food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sedation.

Patients are advised to tell all their healthcare providers that they are taking a GLP-1 RA before they are scheduled to have surgery or other procedures.

In the Patient Counseling section of the label, physicians are advised to inform patients about the risk for pulmonary aspiration during general anesthesia or deep sedation, as follows: "Inform patients that, the drug may delay the stomach's emptying rate leading to complications with anesthesia or deep sedation during planned surgeries or procedures.

References:

- *FDA updates GLP-1 label with pulmonary aspiration warning. Available at: https://www.medscape.com/viewarticle/fda-updates-glp-1-label-pulmonary-aspiration-warning-2024a1000k84. Accessed November, 2024.*
- *New FDA warning added to popular weight loss drugs.. Available at: https://www.webmd.com/obesity/news/20241106/new-fda-warning-added-popular-weight-loss-drugs. Accessed in November, 2024.*

Ph. Mai Mousa, PharmD., PhD. Cand.

Does AI help physicians make better diagnosis? Research discovers

Based on a frightening new study that was published on November 15, 2024, the artificial intelligence (AI) cannot currently assist physicians in becoming better at diagnosing complex illnesses.

According to findings recently published in the journal JAMA Network Open, doctors' diagnostic accuracy was almost the same whether or not they were utilizing ChatGPT Plus. However, when the AI was given the freedom to diagnose itself, the researchers found that it performed better than doctors.

Dr. Andrew Parsons, a researcher at the University of Virginia School of Medicine, found that while AI alone can effectively assist in diagnosis, The involvement of a human physician may lead to a reduction in accuracy, suggesting that rigorous training is necessary. As part of the investigation, fifty physicians received case studies derived from real patients. These cases had data on laboratory test outcomes, physical assessments, and medical histories. .

Two randomly assigned doctors used ChatGPT Plus for diagnosis, while the other used standard reference sources and available information for patients' diseases.

According to the data, doctors who used ChatGPT gave an accurate diagnosis roughly 76% of the time, compared to roughly 74% for doctors who did not use AI. Researchers found ChatGPT group's diagnoses quicker and more accurate at over 92%, but warn that AI may perform worse when diagnosing patients on the spot compared to real-life case studies.

According to academics, further research is required to evaluate AI's capacity to identify medical issues, especially with regard to the treatment choices that follow a diagnosis.

References:

- *Can AI Boost Accuracy of Doctors' Diagnoses?. Available at: https://www.drugs.com/news/can-ai-boost-accuracy-doctors-diagnoses-122380.html. Accessed in November, 2024.*
- *Does AI Improve Doctors' Diagnoses? Study Finds Out . Available at: https://newsroom.uvahealth.com/2024/11/13/does-ai-improve-doctors-diagnoses-study-finds-out/. Accessed in November, 2024.*

Ph. Marwa E. Mohammed, PGCPD, M.Sc. Cand.

Novel drug approvals for the last months of 2024

As we approach the end of 2024, the pharmaceutical landscape has witnessed significant advancements with the approval of several novel drugs aimed at addressing a variety of health conditions.

What are "Novel" Drugs?

"Novel" drugs are new drugs never before approved or marketed in the U.S. These approvals reflect ongoing research and development efforts, showcasing the commitment of the medical community to improve patient outcomes and quality of life. In this overview, we will highlight the key novel drug approvals from the final months of 2024.

Drug Name	Active ingredient	Approval Date	Approved use
Orlynvah	sulopenem etzadroxil, probenecid	25/10/2024	To treat uncomplicated urinary tract infections (uUTI)
Vyloy	zolbetuximab-clzb	18/10/2024	To treat gastric or gastroesophageal junction adenocarcinoma
Hympavzi	marstacimab-hncq	11/10/2024	To prevent or reduce bleeding episodes related to hemophilia A or B
Itovebi	inavolisib	10/10/2024	To treat locally advanced or metastatic breast cancer
Flyrcado	flurpiridaz F 18	27/9/2024	A radioactive diagnostic drug to evaluate for myocardial ischemia and infarction
Cobenfy	xanomeline and trospium chloride	26/9/2024	To treat schizophrenia
Aqneursa	levacetylleucine	24/9/2024	To treat Niemann-Pick disease type C
Miplyffa	arimoclomol	20/9/2024	To treat Niemann-Pick disease type C
Ebglyss	lebrikizumab-lbkz	13/9/2024	To treat moderate-to-severe atopic dermatitis

For more details and in-depth information use this link or scan the **QR** code:

Novel Drug Approvals for 2024. Available at : https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2024. Accessed in November, 2024.

Ph. Bassant M. Mahboub, PhD. cand.

نوفمبر 2024

منشور
سحب

هيئة الدواء المصرية

اسم المستحضر	Tussinor syrup
رقم التشغيلة	M2028823
الشركة المنتجة	ماش بريمير
سبب التحذير	ذلك لكون المستحضر صادر له عدم مطابقة للتشغيلة الموضحة من قبل معامل هيئة الدواء
الإجراءات التصحيحية	سحب ووقف تداول وتحريز
نصائح للمستهلكين	في حالة الشك في المستحضر الصيدلى يتم الرجوع إلى هيئة الدواء المصرية سواء بالإتصال بالخط الساخن 15301 او الموقع الإلكترونى الخاص بالهيئة.

هذا التنبية خاص بالتشغيلات الواردة في المنشور فقط ولا ينطبق على تداول المستحضر بشكل عام

في حال وجود شكوى يرجى الرجوع للصيدلي للتأكد من العبوة او الاتصال على الخط الساخن ١٥٣٠١ او الابلاغ عبر الموقع الإلكتروني للهيئة www.edaegypt.gov.eg

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هيئة الدواء المصرية

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Vision

The vision of Tanta University DPIC is to improve national healthcare service through provision of evidence-based, unbiased, patient oriented drug information services & adverse drug reporting system.

Mission

* Responding to drug inquiries related to the use of the drug and providing the health care professionals and patients with drug information related to the patient's care to achieve the optimal use of the drug in addition to the provision of other toxicological managing information.
* Educational activities to support the rational optimal use of drugs as well, supporting research activities.
* Continuous medical education and training courses in various fields of pharmacy for students, undergraduates, postgraduate students, and researchers.
* Issuing a Drug Information Bulletin periodically to take a look at medical & pharmaceutical news.
* Supporting the National Pharmaceutical Vigilance Program by following up and monitoring side effects and problems related to use of pharmaceutical preparations within regional hospitals.
* Contributing to the establishment of various treatment protocols and prescription booklet services in regional hospitals.

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