MAY— AUG 2021 Volume 6, Issue 2

Sanjivini 2021
THE VIJAYA AUSHADHI

A Triannual Official Publication of

VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN

Approved by AICTE, PCI, Affiliated to JNTUK & An ISO 9001:2015 Certified Institution

SRK FOUNDATION VIJAYAWADA

A Newsletter on Pharmacy Practice

Dear reader,

Hope you and your family are safe and following social distancing, and other Covid protocol. We are going through unprecedented crises in human history, humanity has never seen such a pandemic in the last 100 years. It is so devastating to hear that about 33 million died across the globe. However, the great scientific achievement in 2021 was the development of several vaccines in less than one year and evidence shows that people who are vaccinated are far less likely to spread Covid -19. So, it is mandatory that all of us must rule out all the apprehensions regarding vaccination and must get vaccinated. Vaccination procedures may evolve soon for the young generation too and let us pray for the world to be a safe planet for living.

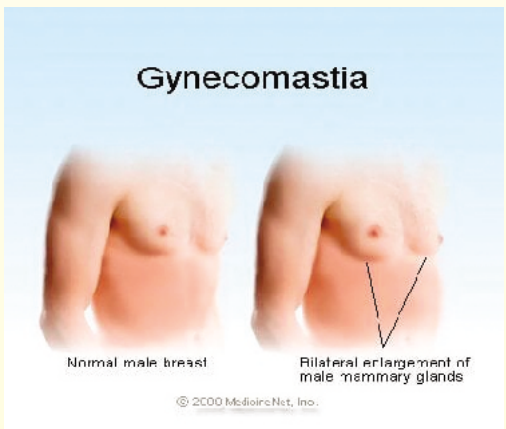
I encourage all the readers to get vaccinated and fight back against the disease.

"Tough times never last, but tough people do."

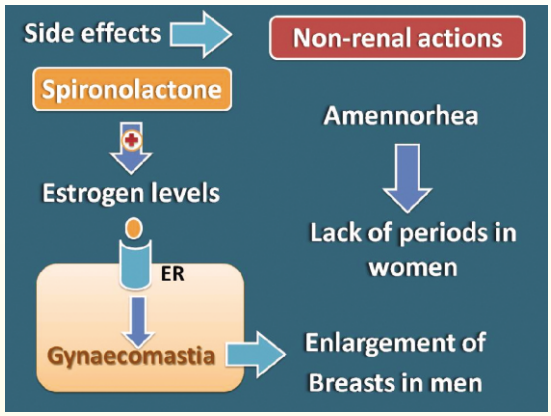
SPIRONOLACTONE-INDUCED GYNECOMASTIA

Drug-induced gynecomastia accounts for about 20%–25% of all new cases in adults. Gynecomastia is clinically defined as benign enlargement of male breast due to proliferation of glandular component with deposition of fat. It usually occurs due to imbalance between actions of estrogen and androgen on the breast tissue. The causes for gynecomastia can be either physiological (neonatal, pubertal, or involutional) or pathological condi-tions (drug induced, endocrine disorders such as testicular, adrenocortical, or pituitary tumors, hyperthyroidism, and nonendocrine causes such as cirrhosis, starvation, stress, and renal failure).

Spironolactone is a potassium-sparing diuretic



used to treat high blood pressure and heart failure. can cause gynecomastia by multiple mechanisms. It blocks the androgen receptors and prevents the binding of testosterone and dihydrotestosterone. It decreases testosterone production from testes by inhibiting enzymes 17α-hydroxylase and 17, 20-desmolase. In addition it displaces testosterone from sex hormone-binding globulin, and enhances the metabolic clearance of testosterone. It increases the levels of estrogen by enhancing



peripheral conversion of testosterone to estradiol. The antiandrogen action of spironolactone responsible for the development of gynecomastia depends on the dose and duration of treatment and is usually bilateral. A study conducted by Roseet al. has reported that 6 out of 16 patients with hypertension treated with spironolactone developed gynecomastia. They also found low blood testosterone levels and higher estradiol levels among these patients compared to controls which confirms hormonal imbalance as the causative factor for spironolactone-induced gynecomastia. Deepinder and Braunsteinet al. observed 10% of 1663 heart failure patients who received 25 mg/day of spironolactone for 24 months have developed gynecomastia. Stopping the offending agent resolves the problem and thereby can save the patient from embarrassment, anxiety, physical discomfort of investigations, and surgical procedure. Patients should be informed about this side effect while prescribing this drug and alternatively eplerenone can be used.

Source:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5846220/
https://www.cmaj.ca/content/176/5/620.2
https://www.iosrjournals.org/iosr-jdms/papers/Vol18-issue11/Series-1/H1811015659.pdf

SRK FOUNDATION VIJAYAWADA
VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN

A Primer on Covid-19 Vaccines

Vaccinology provides another opportunity for pharmacists to prove their mettle. Vaccine researchers are looking at several ways to present the SARS-CoV-2 antigen in such a way that it does not cause infection but stimulates the immune system to produce circulating antibodies and creates cell memory against this antigen. The target of most vaccine researchers is to use the RNA gene or subunit of the spike protein S of the SARS-CoV-2 virus for stimulating the production of antibodies. A successful vaccine would generate enough antibody immunoglobulin G in the blood and immunoglobulin A in the mucosa. Both these types of immunoglobulins antibodies help destroy the single-stranded positive-sense RNA virus SARS-CoV-2 that causes Covid-19.

Covaxin (from Bharat Biotech) provides 6 micrograms per 0.5 ml of the whole virion inactivated SARS-CoV-2 virus strain NIV-2020-7070, where NIV stands for National Institute of Virology. Aluminum hydroxide gel in the Covaxin vial helps in vaccine efficacy and other inactive ingredients in the vial are required for the stability of the vaccine. The whole inactivated virion technology is also used in the production of seasonal influenza vaccines, rabies vaccines, and hepatitis A vaccines. Covaxin is given in two doses each of 0.5 ml, 4 weeks apart. The efficacy of Covaxin as per phase 3 data is 77.80%, this data has been submitted to DCGI.

Covishield manufactured by Serum Institute of India (SII), Pune is based on viral vector technology for the SARS-CoV-2 virus by Oxford University and AstraZeneca. World-over the vaccine is popular as the AZ-Oxford vaccine or AstraZeneca Oxford vaccine. In this technology, the DNA virus adenovirus is used as a vector or carrier of the RNA gene that produces the spike protein of SARS-CoV-2. So the DNA of the adenovirus that is found in chimpanzees is taken, genetically engineered with the help of special enzymes, so that only the viral RNA gene portion that codes for the spike protein of the SARS-CoV-2 virus, gets fused into the chimpanzee adenovirus DNA. The generic name of Covishield is ChAdOx nCoV-19 coronavirus vaccine (recombinant). Each dose of Covishield is 0.5 ml, and each dose provides ChAdOx nCoV-19 coronavirus vaccine (recombinant) 5 X 1010 viral particles (vp).

After Covishield is injected into a person the adenovirus gets into the human host cell. The virus is broken down and the recombinant DNA gets into the nucleus of the host cell. The spike protein is manufactured by the host cell ribosome and this goes to the surface of the host cell. Immediately T lymphocyte cells break down this abnormal host cell with spikes, and the spike protein fragments stimulate B lymphocytes to produce specific antibody immunoglobulin M and G that help destroy the spike protein antigen. Thus, when a vaccinated individual is exposed to the SARS-CoV-2 virus in society, the B lymphocytes produce corresponding antibodies that help destroy the SARS-CoV-2 virus that has entered the human body.

Hence, vaccinated individuals seldom suffer severe Covid-19 and hospitalization. Covishield is given in two doses, the second dose is 6 to 8 to 12 weeks after the first dose. Covishield efficacy rate is generally reported as 73.43% but some studies have said

that it is up to 100%. With a dosing interval of 12 weeks, the efficacy rate of Covishield is 78.79% as reported.

Sputnik 5 Covid-19 vaccine invented by Gamaleya National Center of Epidemiology & Microbiology, Russia - a leading center for virus research, their competence is on adenovirus vector technology. However, they use the human adenovirus and not the chimpanzee adenovirus. The efficacy claim of Sputnik 5 is reported from 91% to 97.6%. Sputnik 5 is a two-dose vaccine (the second dose uses a different adenovirus vector than the first dose to enable beer efficacy), dose interval is 3 weeks. Single-dose Covid-19 vaccine Sputnik Light is the first dose of Sputnik 5 and is also said to generate a good level of antibody production for a protective effect from Covid-19.

The specific mRNA that codes for the SARS-CoV-2 spike protein is presented by the Pfizer mRNA vaccine brand name Comirnaty and Moderna's mRNA vaccine. When the mRNA vaccine is injected into a person - the vaccine mRNA is wrapped in a lipid nanoparticle – this is taken up by host cells. The mRNA goes directly to the host cell ribosome (protein factory) and the spike protein is manufactured.

Biological Evans, Hyderabad is on the verge of launching an antigen recombinant protein (subunit of the spike protein) based vaccine in collaboration with Baylor College of Medicine, the USA at a projected cost of Rs. 110 per dose, this too is a two-dose vaccine (28 days apart). The brand name of this vaccine is Corbevax.

Zydus Cadila is using a plasmid DNA technology platform, however, this technology platform has not been used widely in vaccine production. The spike protein RNA gene is combined into the circular plasmid DNA of certain bacteria – the recombinant plasmid thus created is injected intradermally. The brand name of these three-dose vaccines is Zy-CoV-D. In the Covid-19 vaccine constellation, work is on for an oral vaccine too! A company by the name ORAVAX (Israel – India partnership), is creating an oral vaccine with a triple antigen VLP (virus-like particle). Early analysis showed an efficacy of 66.6% for the three-dose vaccine.

As per WHO the efficacy threshold for any COVID-19 vaccine is 50%. In current pandemic times, the benefit outweighs any risk associated with vaccination. Hence, taking the vaccine is most vital to avoid severe COVID infection and restore routine living.

Source:
https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines?adgroupsurvey

VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN

SRK FOUNDATION VIJAYAWADA

REGULATORY NEWS

COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19)

Risk of thrombosis with thrombocytopenia syndrome (TTS)

The Committee for Medicinal Products for Human Use (CHMP) has recommended that COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) (Vaxzevria®) must not be given to anyone who has had thrombosis with thrombocytopenia syndrome (TTS). COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) is a vaccine for preventing COVID19 in people aged 18 years and older. As TTS requires specialist treatment, health-care professionals should consult applicable guidance and/or specialists to diagnose and treat the condition. Also, health-care professionals should check for signs of thrombosis in any person who has thrombocytopenia within three weeks of vaccination and should advise people to seek urgent medical attention if they have any symptoms suggesting thrombosis or thrombocytopenia.

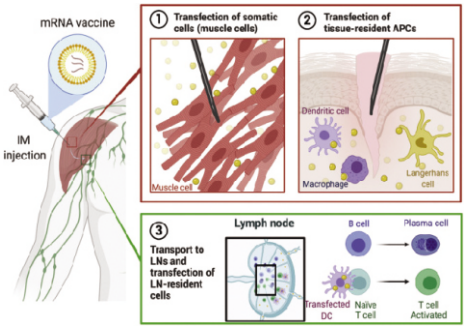
Reference: Reference: EMA, 21 May 2021 (www.ema.europa.eu) (ipc.gov.in)

Tozinameran, COVID19 vaccine mRNA

Risk of myocarditis

The PRAC has requested more detailed information on myocarditis and pericarditis from the marketing authorization holder of tozinameran. This should be included in the next pandemic summary safety report before considering if any other regulatory action is needed. Additionally, the PRAC has requested the marketing authorization holder for COVID19 vaccine mRNA (mRNA 1273) (COVID-19 vaccine Moderna®) to also monitor for cases of myocarditis and pericarditis and to the provide a detailed analysis.

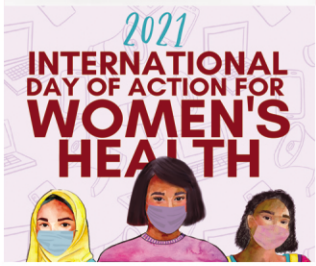
Reference : EMA, 7 May 2021 (www.ema.europa.eu)



Risk of facial swelling

The PRAC has recommended that the SmPC and the PIL for tozinameran (Comirnaty®) should be revised to include facial swelling in people with a history of injections with dermal fillers as an adverse reaction. Tozinameran is indicated for active immunization to prevent COVID-19 caused by SARSCoV-2 virus, in individuals 12 years of age and older. The PRAC reviewed the available evidence including cases of facial swelling reported to the European database for suspected adverse effects (EudraVigilance) and scientific literature. A causal association between the vaccine and the reported cases of facial swelling in people with a history of injections with dermal fillers was considered to be reasonably possible.

Reference: EMA, 7 May 2021 (www.ema.europa.eu)



NOVEL DRUG APPROVALS FOR 2021

DRUG NAME	ACTIVE INGREDIENT	APPROVAL DATE	USES
Empaveli	Pegcetacoplan	14.05.21	To treat paroxysmal nocturnal hemoglobinuria
Lybalvi	olanzapine and samidorphan	28.05.21	To treat schizophrenia and certain aspects of bipolar I disorder
Brexafemme	Ibrexafungerp	01.06.21	To treat vulvovaginal candidiasis
Aduhelm	Aducanumab-avwa	07.06.21	To treat Alzheimer's disease
Kerendia	Finerenone	09.07.21	To reduce the risk of kidney and heart complications in chronic kidney disease associated with type 2 diabetes
Bylvay	Odevixibat	20.07.21	To treat pruritus
Nexviazyme	Avalglucosidase alfa-ngpt	06.08.21	To treat late-onset Pompe disease
Korsuva	Difelikefalin	23.08.21	To treat moderate-to-severe pruritus associated with chronic kidney disease in certain populations

Source : https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021

VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN

Lockdown Activities

- On 21-06-2021, International Yoga day was celebrated virtually, Mrs. L. Santhi & Mr. L. Murali Krishna from yoga association of A.P addressed the virtual gathering and the students were made to do yoga according to the yoga protocol released by ministry of Aayush, Govt of India.
- Lockdown provided Pharm. D students with an ample opportunity to involve themselves in creating awareness to public through various social media platforms.
- Students presented posters, videos on the following topics : 05-05-2021 - World Asthma Day; 08-05-2021 -World Thalassemia Day; 05-06-2020 - World Environment Day; 07-06-2020 - World Food Safety Day; 26-06-2020 - International Day Against Drug Abuse and Illicit Trafficking.
- A webinar on Comprehensive prospects of PharmD; Drug Safety and Entrepreneurship was organized by the institution on 26th & 27th June 2021.
- A webinar on Research Methodology and Data Analysis was organized in the campus on 23th & 24th July 2021.
- On 31.07.21 Medi Healthcare Campus Placement Drive conducted by ASC Pvt Ltd for PharmD students at college campus. 17 students from our institution participated in the drive, out of which 5 students are shortlisted for the required positions.

To,

We are pleased to receive your feedback and suggestions :
The Editorial Board,
A Newsletter on Pharmacy Practice,
Vijaya Institute of Pharmaceutical Sciences for Women (VIPW),
Enikepadu, Vijayawada - 521 108, Ph: 7416560999