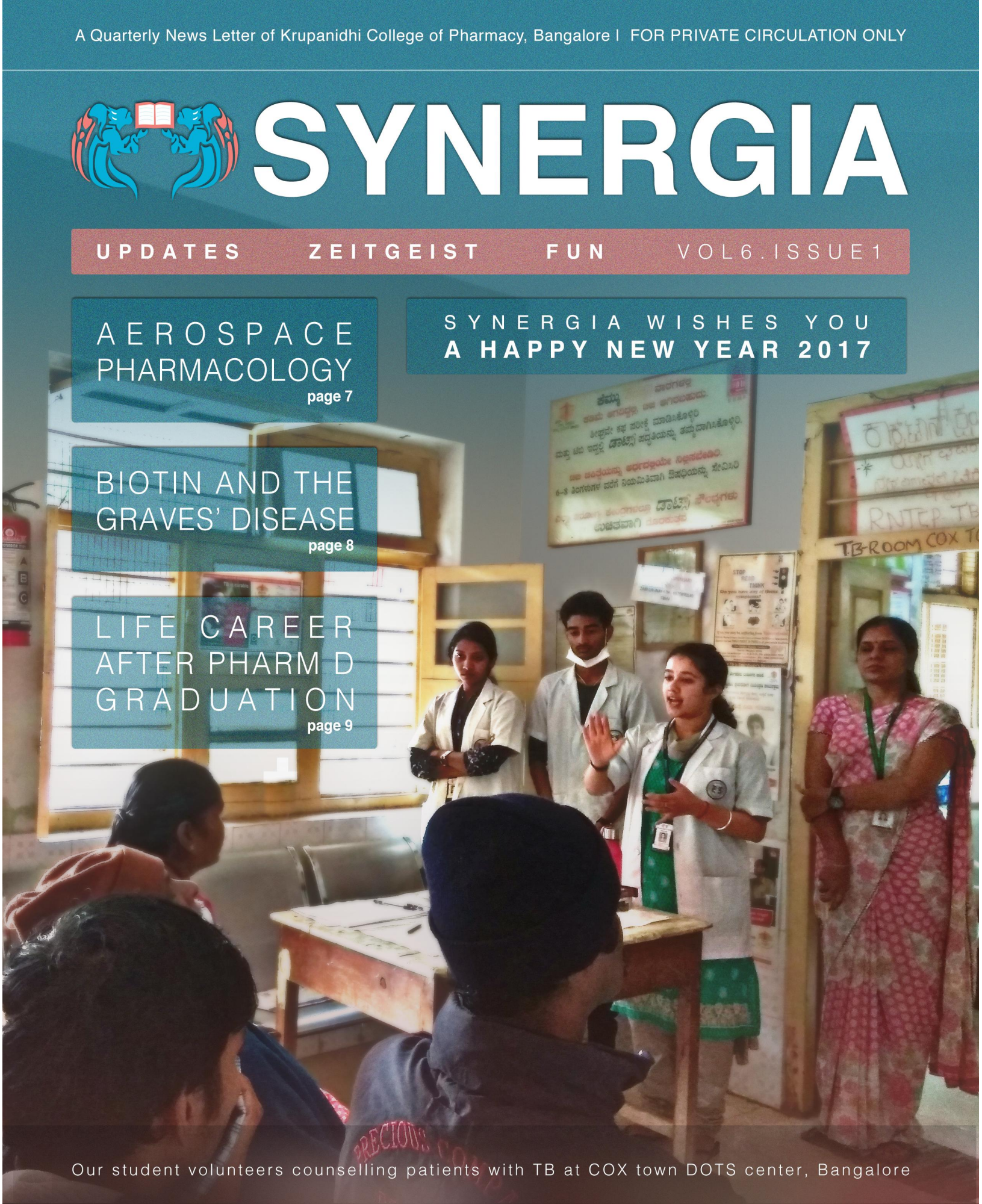
A Quarterly News Letter of Krupanidhi College of Pharmacy, Bangalore I FOR PRIVATE CIRCULATION ONLY

SYNERGIA

UPDATES ZEITGEIST FUN VOL6.ISSUE1

SYNERGIA WISHES YOU
A HAPPY NEW YEAR 2017



Our student volunteers counselling patients with TB at COX town DOTS center, Bangalore

Please send your contributions, feedback and suggestions to : synergia.kcp@gmail.com

FDA APPROVALS

BRAND NAME (ACTIVE INGREDIENT)	INDICATION	SPONSOR	APPROVAL
Eucrisa (Crisaborole) Ointment	Atopic Dermatitis	Pfizer	December 2016
Zinplava	Treatment of recurrent Clostridium difficile infection	Merck	October 2016
Vemlidy (tenofovir, alafenamide)	Chronic hepatitis B	Gilead Science	November 2016
Intrarosa (Prasterone vaginal insert)	Moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause	Endoceutics	November 2016
Soliqua 100/33 (insulin glargine and lixisenatide injection)	For the treatment of inadequately controlled type II diabetes	Sanofi Aventis	November 2016
Xultophy 100/3.6 (insulin degludec and liraglutide injection)	For the treatment of inadequately controlled type II diabetes	Novo Nordisk	November 2016
Spinraza (nusinersen) Injection	Spinal Muscular Atrophy	Biogen	December 23, 2016
Carnexiv (carbamazepine) Injection	Seizures	Lundbeck Inc.	October 7, 2016

SOURCE: Centerwatch, USFDA, Current as on 31 December 2016, Complied by Rejitha Thomas. Asst Prof, KCP

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EXPERT REVIEW

NATIONAL LIST OF ESSENTIAL MEDICINES

WHO's definition of essential medicines is that "Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness." In India there are uncountable numbers of medicine formulations available; many of these are similar in therapeutic action, however some may be more expensive albeit many inexpensive medicines are highly effective. Apart from, medicines which are known to be therapeutically ineffective, irrational or even may be harmful are commercially available. An estimated 20000 pharmaceutical companies in India produce over 50000 formulations that are freely available in the market. Over 100 brands of paracetamol, omeprazole and Amoxicillin either alone or in combination with another medicine exist in Indian medicine retail market. Hence there is a need to select essential medicines from the innumerable medicines available in the market. It is a paradox that many non-essential and, even adulterated medicines are available yet there is a shortage of essential medicines particularly in the developing countries including India. The WHO essential medicine concept that focus on people in the developing countries is that a that focus on people in the developing countries is that a limited range of carefully selected essential medicines leads to better health care, better medicine management and lower cost. In October 1977, WHO published the first model essential drugs list (EDL) of 186 individual drugs, in the wake of 1975 World Health Assembly's call on focusing attention on essential medicines of good quality at reasonable cost. The EDL, advocated by WHO, was a guideline and was based on the principle that some medicines were more essential than others on the contrary many medicines in developing countries were not useful. In the past 40 years , 19 times revisions in the list have been carried out (on an average every two years). The name of the list, 2003 onwards, has also changed, from essential drugs list (EDL) to essential medicines list (EML). The current version, the 19th WHO EML, was published in 2015 that contained about 414 individual medicines. There is also a "WHO Model List of Essential Medicines for Children", whose fifth edition was also published in 2015. The WHO EML represents the most compelling international compilation of essential medicines for public health. Each country is encouraged by WHO to prepare their own national lists taking into consideration local priorities. Over 150 WHO member countries have adopted a national list of essential medicines. Major international agencies (UNICEF, UNHCR) prepare their medicines catalogue on the basis of the WHO model list. The WHO model EML forms basis for WHO model formulary, International Pharmacopoeia, basic quality tests and development for reference drug standards. National List of Essential Medicines of India (NLEM): The first national essential drugs list, prepared by the Ministry of Health and Family Welfare, Government of India in 1996, contained 279 medicines. The list was modelled on the WHO EDL pattern, and followed the general principles enunciated by WHO in the preparation of the list. The second revision was carried out in 2003, contained 354 medicines. The current revision has been published in 2015. It has 376 individual medicines. The national list of essential medicines implies that the medicines included in it are adequate to meet the common contemporary health needs of the general population of India.

KNOW MORE

"As of 2016, at least 156 countries have created national lists of essential medicines based on the WHO's model list.The national lists contain between 334 and 580 medications and the WHO updates the Model List of Essential Medicines every two years"

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CASE REPORT

CASE REPORT ON DRUG INDUCED INTRAOCULAR BLEEDING

Adverse reactions are life threatening conditions associated with significant morbidity and mortality. Intraocular hemorrhage is bleeding (hemorrhage) into the eyeball . It may be the result of physical trauma (direct injury to the eye) or medical illness. Severe hemorrhage, particularly when leading to rising pressure inside the eye. Different causes can cause bleeding in different locations. Drugs that may cause the Eye to Hemorrhage:

- Aspirin, may exaggerate bleeding of the eye, and usually surgeons recommend discontinuing aspirin for at least a week before eye surgery
- Venlafaxine
- Amphotericin B
- Cholesterase inhibitors
- Pentoxifylline, prescribed for to improve circulation
- Anti-coagulants
- NSAIDS, including OTC pain relievers

The following diseases may be associated with intraocular bleeding:

- Sickle cell anemia
- Diabetes
- Retinal detachment
- Ebola
- Macroaneurisma retinal
- Optic neuritis
- Diabetic retinopathy

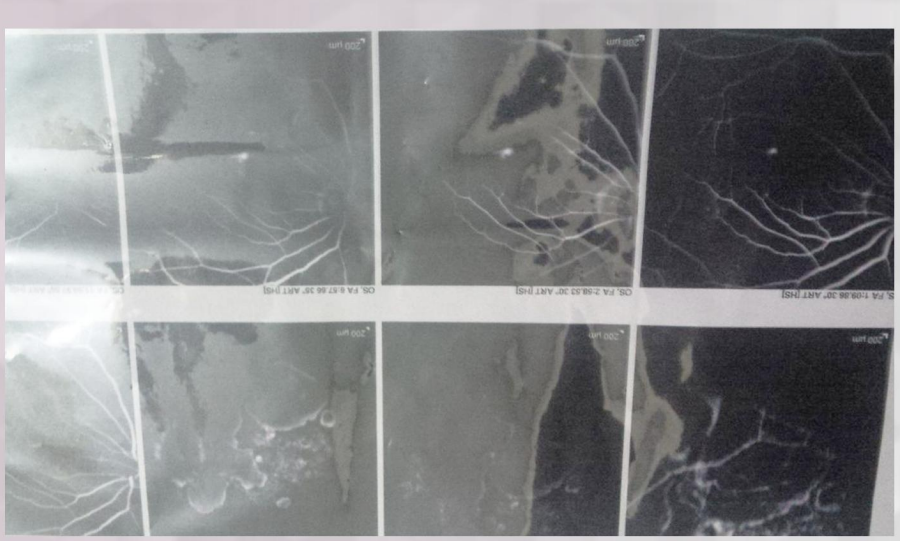
CASE REPORT

Here is a case report that describes a 72 yr old female patient from Kerala who was administering Tab. Pradaxa (Dabigatran etexilate mesylate-an anticoagulant)150 mg once daily at night after food.

The patient had a history of chest pain , chest tightedness and shortness of breath for which she was prescribed with medication pradaxa for prevention from stroke. She is been also taking Tab. Vilzem CD-90mg since 2 years prescribed by a cardiologist for an irregular heart rhythm. Four months later she was not able to read letters properly, it appeared vertical, She also consulted her general physician wherein she complained about her problem for which the physician told to have an eye check up as she is a geriatric patient. When she had an eye check up,the ophthalmologist confirmed that she was having intraocular bleeding and an increase in orthostatic blood pressure. Later she reverted back to her general physician and she was advised to discontinue the suspected drug pradaxa.

DISCUSSION

Intraocular hemorrhage is just one of several bleeding events associated with Pradaxa. The risk of internal bleeding is an acknowledged risk with any blood-thinner. However, in the case of pradaxa , it is the leading cause of death. According to the Food and Drug Administration (FDA), the drug is linked to thousands of adverse events, including 542 that were fatal. In addition, the Institute of Safe Medication Practises reported that Pradaxa was linked to more deaths and njuries in 2011 than any of the 800 other drugs it reviewed.



TOMOGRAPHY OF THE LEFT EYE

TOMOGRAPHY OF LEFT EYE

Anterior segment exams revealed bilateral spontaneous hyphema and fibrin accumulation. Observation of the posterior chamber by tomography showed vitreous hemorrhage and choroidal detachmentbilaterally. No evidence of additional intraocular inflammation was present.

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DRUG REVIEWS

ROLE OF SIDEROPHORE ON MEDICAL APPLICATIONS

INTRODUCTION

Siderophores are small, high-affinity iron chelating compounds secreted by micro-organisms such as bacteria, fungi and grasses Iron is essential for almost all life for processes such as respiration and DNA synthesis Siderophores are amongst the strongest binders to Fe3+ known, with enterobactin being one of the strongest of these. Because of this property, they have attracted interest from medical science in metal chelation therapy, with the siderophore desferrioxamine B gaining widespread use in treatments for poisoning and thalassemia.

MEDICAL APPLICATIONS

•Siderophores have applications in medicine for iron and aluminum overload therapy and antibiotics for improved targeting.

Understanding the mechanistic pathways of siderophores has led to opportunities for designing small-molecule inhibitors that block siderophore biosynthesis and therefore bacterial growth and virulence in iron-limiting environments.

•Siderophores are useful as drugs in facilitating iron mobilization in humans, especially in the treatment of iron diseases, due to their high affinity for iron.

One potentially powerful application is to use the iron transport abilities of siderophores to carry drugs into cells by preparation of conjugates between siderophores and antimicrobial agents.

Because microbes recognize and utilize only certain siderophores, such conjugates are anticipated to have selective antimicrobial activity.

•Microbial iron transport (siderophore)-mediated drug delivery makes use of the recognition of siderophores as iron delivery agents in order to have the microbe assimilate siderophore conjugates with attached drugs. These drugs are lethal to the microbe and cause the microbe to apoptosise when it assimilates the siderophore conjugate.

Through the addition of the iron-binding functional groups of siderophores into antibiotics, their potency has been greatly increased. This is due to the siderophore-mediated iron uptake system of the bacteria.

•A Trojan horse strategy based on siderophore–drug complexes holds great promise in several medical applications.

•Siderophore-based therapeutics have potential in the treatment in iron overload.

•The ability of bacteria to develop resistance to antimicrobial agents poses problems in the treatment of numerous bacterial infections. The Trojan horse concept involves the use of bacterial iron uptake systems to enter and kill bacteria.

•Several studies have shown that siderophore–drug conjugates make it possible to design antibiotics with improved cell transport and reduce the frequency of resistance mutants. Growing interest in siderophore –drug conjugates for the treatment of human diseases including iron overload, cancer, and malaria has driven the search for new siderophore–drug complexes. This strategy may have special importance for the development of iron oxide nanoparticle-based therapeutics.

•Inhibitors of bacterial siderophore biosynthesis are also promising new antimicrobial agents.

•Iron chelation by siderophores causes robust responses in host cells through gene expression changes involved in apoptosis, mitophagy, hypoxia, and the production of inflammatory cytokines.

DID YOU KNOW?

"Siderophores are amongst the strongest soluble Fe3+ binding agents known"

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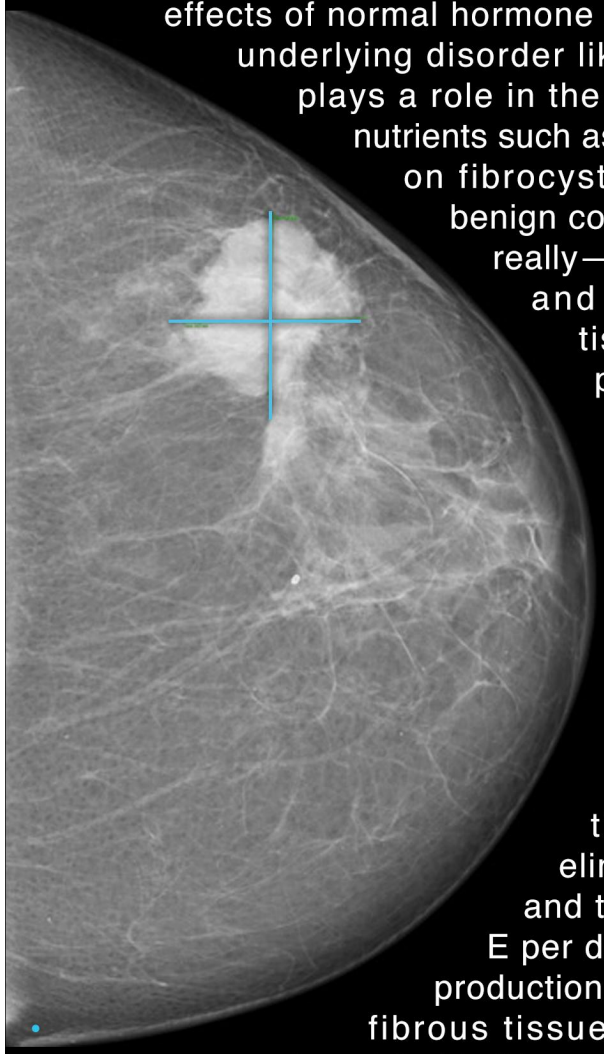
BODY HEALTH

Vitamin E, No Caffeine Key in Preventing Breast Lumps

Breast growth begins during embryonic development, and cycles of female breast growth continue throughout puberty, during pregnancy, and over the course of each menstrual cycle. In some cases, breast growth can lead to the development of breast lumps, which can occur as side effects of normal hormone cycling, or might indicate an underlying disorder like a breast tumor. Your diet plays a role in the health of your breasts, and nutrients such as vitamin E can have an effect on fibrocystic breast disease (FBD), a benign condition – not even a disease, really— that can cause breast lumps and cyst to develop in breast tissues. Cysts are fluid-filled pockets; lumps are solid masses. These developments can lead to inflammation, causing the breast toswell and become painful. The pain can range from mild to severe. FBD is very common, occurring in perhaps 20 to 40 percent of women prior tomenopause. Here are two recommendations that help most women: eliminate caffeine from the diet and take 400 to 800 IU of vitamin E per day. Caffeine stimulates overproduction of cellular products, such as fibrous tissue and cyst fluid. One study found that FBD symptoms improved in more than 97 percent of women who avoided caffeine entirely and in 75 percent of those who reduced their intake. Good results have also been reported with vitamin E supplementation.



Nutrition Fact

"One cup of brewed coffee (8 oz) contains about 70–140 mg of caffeine, or about 95 mg on average"

TOP 10 FOODS RICH IN VITAMIN E

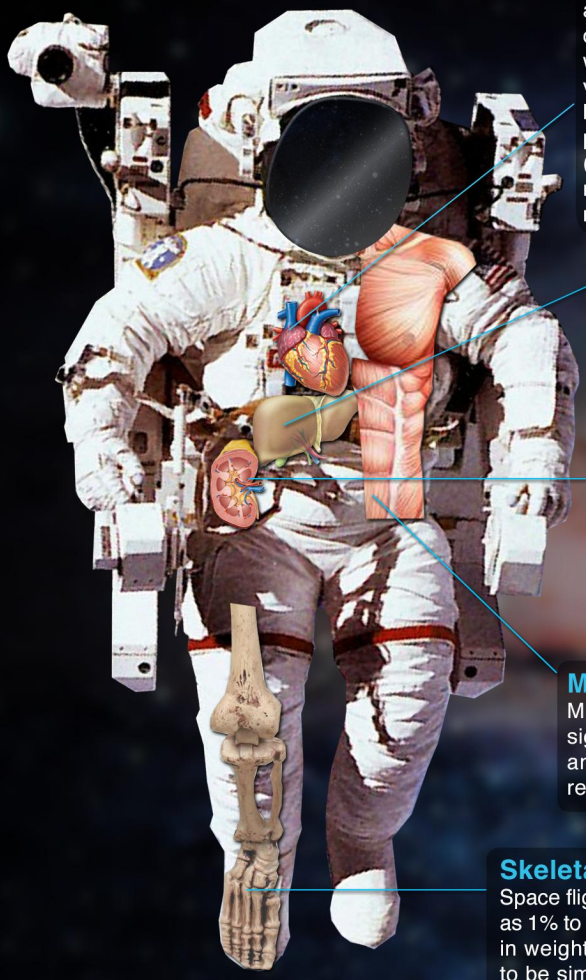
1. **Almonds** — 1 ounce: 7.3 mg (27% Daily Value)
2. **Spinach** — 1 bunch: 6.9 mg (26% Daily Value)
3. **Sweet Potato** — 1 Tb spoon: 4.2 mg (15% Daily Value)
4. **Avocado** — 1 whole: 2.7 mg (10% Daily Value)
5. **Wheat germ** — 1 ounce: 4.5 mg (17% Daily Value)
6. **Sunflower seeds** — 2 Tb spoon: 4.2 mg (15% Daily Value)
7. **Palm Oil** — 1 Tb spoon: 2.2 mg (11% Daily Value)
8. **Butternut squash** — 1 cup, cubed: 2 mg (7% Daily Value)
9. **Trout** — 3 ounce: 2 mg (7% Daily Value)
10. **Olive oil** — 1 Tb spoon: 2 mg (7% Daily Value)

• *Image source: medscape.com*

Physiological, Pharmacokinetic, Pharmacodynamic Changes

During Space Flight

The space environment provides several challenges: variable gravity; constant radiation; extreme temperature and pressure, these challenges in human induce physiological changes that may lead to pharmacokinetic and pharmacodynamic changes of drug administered to crew in space shuttle.



Cardiovascular System

Orthostatic intolerance is observed in most astronauts after returning to Earth and is a consequence of cardiovascular adaptation to weightlessness. Postflight stroke volume, left ventricular end diastolic volume, and estimated left ventricular mass decreased compared to preflight, while heart rate and mean blood pressure (both systolic and diastolic) were elevated and remained higher than preflight levels during the mission

Enzymes

Activities of leucine aminopeptidase, acid phosphatase, adenosine triphosphatase, and glucose-6- phosphatase, Hydroxymethylglutaryl -CoA (HMG-CoA) reductase showed a transient increase.

Excretory System

The urinary sodium, potassium, and chloride increased, while serum osmolality and sodium and the excretion of sodium, potassium, and water are decreased.

Muscular System

Muscle strength, tone, and endurance decreased significantly during space flight, both in humans and animals. 37% decline in muscle mass was reported after one week.

Skeletal System

Space flight results in loss of bone mass, loss of as much as 1% to 2% per month of bone mineral density, especially in weight-bearing bones, a condition that is suggested to be similar to disuse osteoporosis.

Immune System

Reduction in T-cell counts and a decrease in natural killer (NK) cell concentration and functionality, in cell-mediated immunity, altered cytokine production and constant levels of immunoglobulins. Increased susceptibility to infection under space flight conditions. The possibility of having altered ability to heal from bacterial and certain fungal, viral, and parasitic invasions.The activity of white blood cells, such as lymphocytes, macrophages, and natural killers, and drugs that have these cells as their pharmacological targets, such as interferons, colonystimulating factor (CSF), and other cytokines was affected during space flights.

Endocrine System

Alterations in hormone levels during space flight are strongly related to stress and the cardiovascular adaptive response to the microgravity environment. During long space flights (> 2 weeks), cortisol levels are increased, and adrenocortotropic hormone (ACTH) and insulin are decreased. Postflight, angiotensin, aldosterone, thyroid-stimulating hormone (TSH), and growth hormone (GH) levels are also increased. Microgravity also stimulates functional activity of the parathyroid and suppresses the thyroid C cells, which affects the production of parathyroid hormone and calcitonin, respectively.

ADSORPTION

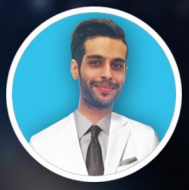
Alternations in salivary levels, Gastric emptying due to changes in particle size discrimination by the stomach, which is ependent on the force of gravity. increase the transit rate along the small intestine by decreasing the dimensionless ratio of gravitational forces to viscous forces In zero gravity. therefore, these alterations in GI emptying and intestinal transit rate could lead to inefficient absorption and erratic plasma levels.

DISTRIBUTION

Physiological changes, such as the decrease in total body water (TBW) and plasma volume (PV), and the muscle loss may alter the volume of distribution of drugs, this will have an impact on the plasma and tissue concentrations achieved after the administration of a drug in space and, depending on the magnitude of the change, will require that a completely new dosing scheme be designed to avoid sub-therapeutic or toxic concentrations.

METABOLISM and EXCREATION

The amounts of cytochrome P-450 isoforms and other enzymes decreased during space flight and simulated microgravity, which suggests that xenobiotic metabolism, may also be altered by space flight. Altered nutritional or energy requirements may have effects on urine excretion of drugs, and dehydration may result in changes in urine excretion of drug.Ion channels are gravity sensitive.Gravity directly influences the integral open-state probability of native ion channels (porins) incorporated into planar lipid bilayers. In microgravity, the openstate probability is decreased, while in hypergravity, it was increased47.



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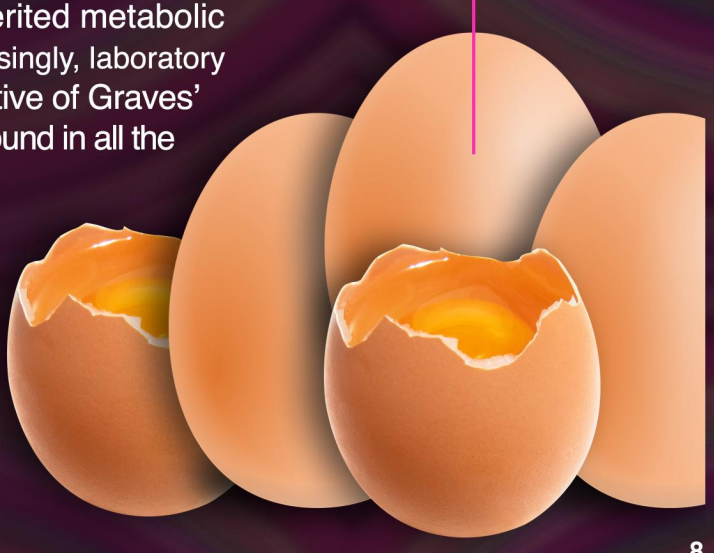
ALERT - DRUG REVIEW

Biotin ingestion imitating Graves' Disease

Biotin is known as vitamin B7 which is water soluble and widely used in over-the- counter as a dietary supplements. The major natural sources of biotin are eggs, almonds, nuts, legumes and milk. It is an important component of enzymes in the body that help in metabolism of certain substances like fats, carbohydrates and others. Biotin is used for preventing and treating biotin deficiency associated with pregnancy, long-term tube feeding, malnutrition, rapid weight loss, hair loss, brittle nails, skin rash in infants, seborrheic dermatitis, diabetes and mild depression . Overall, aside from instances where biotin may be deficient in alcoholism, some epileptic drug therapies, and overconsumption of raw egg whites. There isn't a good laboratory test for detecting biotin deficiency, so this condition is usually identified by its symptoms, which include thinning of the hair (frequently with loss of hair color) and red scaly rash around the eyes, nose and mouth. Nervous mouth. Nervous system symptoms include depression, exhaustion, hallucinations, and tingling of the arms and legs. There is some evidence that diabetes could result in biotin deficiency. Apart from its administration in nutritional deficiency, biotin plays an important role in the therapy of several inherited metabolic diseases e.g. biotin–thiamine responsive basal ganglia disease and biotinidase deficiency. Moreover, biotin is frequently used as a supportive treatment in patients with disorders of mitochondrial energy metabolism. In these patients, doses are considerably higher (2 to 15 mg per kilogram of body weight per day) than the dietary reference intake in children (5 to 25 µg per kilogram per day). The amount in over-the-counter dietary supplements varies considerably (up to 10 mg per tablet). In a recent study published int he New England Journal of Medicine, six children receiving high dose biotin treatment in the context of inherited metabolic diseases.Surprisingly, laboratory results suggestive of Graves' disease were found in all the patients during routine examination: excessively elevated levels of free thyroxine (T4), total triiodothyronine (T 3), low levels of thyrotropin, and elevated levels of anti-thyrotropin receptor antibodies. Antithyroid medication was initiated in at least three childrens to treat biotin mimicked autoimmune hyperthyroidism. In a literature search, it revealed that biotin may interfere with the most commonly used thyrotropin and thyroid hormone assays. After discontinuation of biotin treatment, interference with laboratory tests has been reported to disappear within 8 hours. like wise in this study also thyrotropin and thyroid hormone levels were normalized 24 to 48 hours after the discontinuation of biotin, whereas levels of anti-thyrotropin receptor antibodies took up to 7 days to normalize.

Nutrition fact

"Egg is one of the foods that contains high amount of Biotin. Each egg contain 8 mcg of Biotin"



ALUMNI SPEAK

CAREER LIFE AFTER GRADUATION

I am the first batch Pharma D graduate of Krupanidhi college. The day I passed out I felt like I'm standing right in front of a long pathway, which was dark. I choosed to take the challenge believing in the knowledge I acquired during the six long years. I have dreamt of getting in to clinical research since the day I have joined the Pharm.D course, but I have no clue how to get there. In a very short time an opportunity knocked on my door and now I stand in a very responsible position as a Clinical Research Associate in one of the top companies in the world (Astrazeneca). Clinical Research Associate, this is one of the crucial role in the clinical trials. Clinical research is one of the subject in the course of pharma D, but trust me nobody could even imagine the practical scenario, and the importance of the ICH GCP Guidelines unless and until they are involved in trial. A CRA works on multiple trials and handles multiple responsibilities at site level and study level, right from the selection of the investigator and site to the close of the study. CRA otherwise called as monitor, this word itself determines the responsibility of a CRA, which is closely monitoring all the activities. The activities include Investigator/site selection, providing support for Ethics committee, regulatory submission, conducting site qualification visit, site initiation visit, site training visit, interim monitoring visits, site close out visit. Interim monitoring visits are conducted based on the trial requirement, which includes responsibilities like source data review, source data verification. In every monitoring visit a monitor verifies all the data of the patients enrolled in to the study and ensures that the patient meets all the inclusion and exclusion criteria, verifies the data entered in eCRF with the source data, resolves all the data entry related queries and also ensures the credibility of data. One of the most Challenging responsibility is to provide training to the investigator and the site staff on various aspects of clinical trial and also to ensure that the trial is conducted in accordance with the GCP guidelines. The experience I gained through out my course has helped me in communicating and working in close liaison with doctors. The responsibilities of a CRA are not limited, Since I'm working on trials in most critical patients there are some days where I wake up with a call from the doctor to report the death of the trial participant. All the SAE's in clinical trial should be reported to DCGI in 24hrs. As a CRA I have travelled to all major cities of India, I am working with the most reputed hospitals and with the most reputed doctors and handling hundreds of patients in various studies. I am really proud to be a CRA. Patient care starts with the right drug entering in to the market, as a Pharm D graduate I deliver patient care in India. Trust me our knowledge on therapy area makes us stand firm among the other pharmacy graduates, I still remember that one therapy area presentation which made me stand In this clinical research industry, so never loose your trust, your decision of choosing Pharma D is absolutely worth. Have patience and hold on to it.

Dr. Akshara Reddy
Clinical Research Associate
Astrazeneca Pharma (India) Limited

CENTER FOR PHARMACEUTICAL PROFESSIONAL ADVANCEMENT

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Changing strategies for new drug discovery genomic biomarker based translational research
10/11/2016

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Clinical Research- an overview
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2

Dr. Ramanand Nadig
Drug discovery to pre-clinical studies
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3

Dr. Harsha Doddihal
Clinical Research in Oncology
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4

Mr. Narendra Kamath
Bioanalytical aspects related to BA/BE studies
Dr. Subhash Gore
Pilot & Pivotal BA/BE studies, basics & correlations
BA/BE studies for the nasal sprays & inhalation drug products
Dr. Dinesh Shenoy
Biowaiver strategies for various drug products
BA/BE studies for the dermatological drug products
03/12/2016

5

Dr. Gopal Muralidharan
A new chemical entity's path to drug discover- many a slip between the cup and the lip
10/12/2016

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Prof. Chandramouli
Biosimilars- Regulatory Perspective and Update
17/12/2016

7

Dr. Rajendra. Sandur
Pharmacovigilance Demystifying the Concepts
17/12/2016

Continuous Pharmacy Education:
The role of Community Pharmacist in DOTS provision and TB care

NSS team organised Tuberculosis Awareness and Counseling for TB patients at various DOTS centers in Bengaluru (Tavarekara, Adugodi, Cox-town and Varthur)



DIABETES SCREENING & AWARENESS CAMP AT MULLUR VILLAGE

WORLD DIABETES DAY 14 NOVEMBER 2016

To commemorate the World Diabetes Day 2016, Volunteers under National Service Scheme (NSS) program organized free Diabetes Screening & Awareness Camp in Mullur village under the guidance and coordination of the NSS officer Rajeswari R, from Krupanidhi College of Pharmacy on 14th November 2016.


WORLD AIDS DAY

1ST December 2016

Patient counselling competition


BONE MARROW REGISTRY AWARENESS & DONOR ENROLLMENT PROGRAMME

Bone marrow registry awareness and donor enrollment programme was organised by NSS team, Krupanidhi College of Pharmacy, Bangalore, in association with "BMCDT- INFOSIS Foundation" on 28th December 2016. The students, faculty members and non teaching staff actively participated and volunteered for the Bone marrow donation enrollment. 3 ml of blood was drawn from all eligible donors with their written consent for HLA testing. All enrolled members are given with Certificate for being Donor under Bangalore Medical College Development Trust- Infosys Foundation. The registry will be available for free for any needy marrow recipients. Commendable response was there for the programme with 179 registrations. Kudos to the Management, Principal, NSS Coordinator and the entire team.

TEAM SYNERGIA

PATRON: Dr. Suresh Nagpal, Mrs. Geetha Nagpal, Prof. Sunil Dhamangini, Ms. Neha Nagpal, Dr. Samuel Paul Isaac **ADVISORY BOARD:** Dr. M D Karvekar, Prof. Prakash V Mallya, Dr. Raman Dang, Dr. Sonal Dubey Sharma, Dr. NM Mahesh **EDITORIAL TEAM:** Teena Nazeem, Vidya Alex , Rejitha Thomas I **EDITOR:** Rajeswari R **CONSULTING EDITOR & CREATIVE LEAD:** Chandramouli R I **CREATIVE PHOTOGRAPHY:** Ashutosh Sherestha Bana I **DESIGN AND LAYOUT:** Saman Sharifi