## What's ZIP? @St John's Hospital

Issue 39, February 1st, 2020



Cultural Evening at St. John's National Healthcare Summit 2020, 10<sup>th</sup> January 2020. Classical dance by Mrs. Kritika Balaji (cancer survivor)

#### **EDITORIAL TEAM:**

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St John's National Academy of Health Sciences St John's Medical College Hospital, Bengaluru



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<sup>\*</sup> We now present a fully interactive menu. It works best with Adobe reader application (on computers, mobile phones and tablets)







## MESSAGE FROM THE EDITORIAL TEAM

#### Dear All!

We are pleased to release the thirty ninth issue of "What's Up? @ St John's Hospital" magazine today.

It brings us a lot of joy to share that St. John's Medical College Hospital is now NABH Accredited. As we are all aware tremendous determination, commitment, diligence and hard work is required for an achievement of this order. We would like to congratulate all the staff, faculty, heads of the department, quality team and the Administrators. This accreditation is a testimony to the existing high quality healthcare provided by St. John's Medical College Hospital.

The present issue of the magazine provides a lot of important updates happening in the campus. We bring to you an interesting story of an young girl who survived after a grievous assault in survivor's corner. Also not to miss is the St. John's Watchdog which busts the myth of plastic in antidiabetic tablets.

Please feel free to communicate with us to publish your achievements. Feedback on any section of the magazine is welcome. We are happy to evolve to meet the needs to our beloved readers. Happy Reading!!

Editorial Team



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# UPDATES THIS MONTH SEXUAL AND REPRODUCTIVE HEALTH AWARENESS DAY 12th February 2020

## <u>SEXUALLY TRANSMITTED INFECTIONS(STIS) – RELEVANCE IN THE</u> <u>PRESENT HEALTH SCENARIO</u>

Sexual and Reproductive Health Awareness Day is held annually on 12<sup>th</sup> February. This day is an opportunity to raise awareness about sexual and reproductive health issues and to educate to reduce the spread of sexually transmitted infections. Dr. Ishwar Bhat (Professor, Department of Dermatology) writes about sexually transmitted infections (STIs) in the present issue of magazine.

#### What are STIs?

STIs refers to a group of infections with varied etiological agents that share one characteristic — the *route of transmission* of the infective organism is through sexual contact. When these infections result in clinical manifestations they are referred to as Sexually Transmitted Diseases (STDs). They need to be differentiated from reproductive tract infection which is a broader term that refers to any infection of the reproductive tract including not only STDs that involve the reproductive tract but also those infections of the reproductive tract acquired through non sexual routes. Eg. gynecological infections resulting from unsafe labour practices.

### What are the etiological agents?

There are about 30 STIs. These include those caused by:

- Bacteria (Ex: Syphilis, Gonorrhoea, Chancroid etc)
- Viruses (Ex: Herpes genitalis, Genital warts, Hepatitis B/C and HIV)
- Fungal (Ex: Candidiasis)
- Protozoal (Ex: Trichomoniasis)
- Ectoparasites (Ex: Pthirus pubis)

Many of these infections eg. HIV are also transmissible through other routes, but sexual transmission is often the predominant route of infection.

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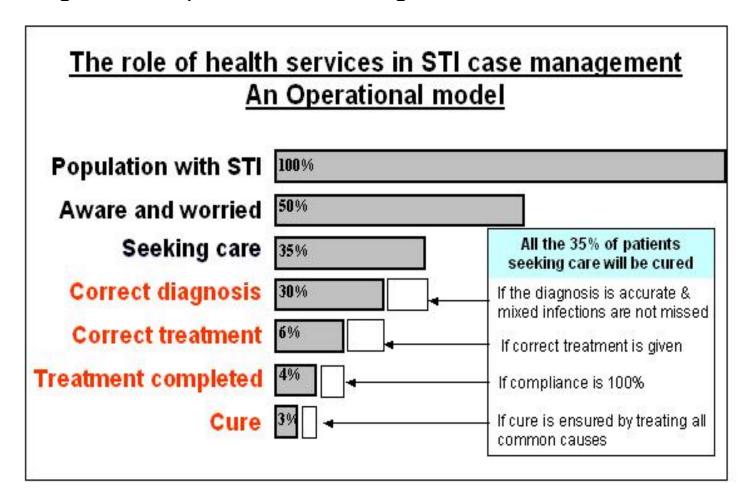


## SEXUAL AND REPRODUCTIVE HEALTH AWARENESS DAY contd...



#### How big is the problem?

STIs are typically an "iceberg disease". For every case that is detected, at least 10 cases are estimated to be active in the community. WHO estimates that globally about 333 million STI cases are prevalent with 1 million new cases being added on every year. At least 50 % of these cases are seen in sexually active age group of 15-26 years, hence the adolescent age group is at maximum risk. The following graph represents an estimate of the "ground reality" that exists in management of STIs



### What are the common manifestations of STIs/STDs?

Some of the common symptoms that patients with STIs can present with are as follows:

- Ulcers in the genital area- eg syphilis/chancroid
- Urethral/vaginal discharge –eg gonococcal/non gonococcal urethritis
- Vesicles in the genital area eg herpes genitalis
- Papules in the geniatal area- genital warts/ molluscum contagiosum etc
- Inguinal/scrotal swelling
- Lower abdominal pain in women- pelvic inflammatory disease

Importantly, more than 50% of all STIs may remain asymptomatic. Untreated, these asymptomatic cases can still cause enormous morbidity and constitute a reservoir of infection that is infective to others.

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## SEXUAL AND REPRODUCTIVE HEALTH AWARENESS DAY contd..



#### **Management of STIs**

The importance of effectively managing STIs is twofold. Firstly, the STIs themselves left untreated can cause enormous morbidity and even mortality hence the need for early intervention. Secondly, the link to the most dreaded of the STIs, namely HIV! Presence of an STI indicates high risk behavior in the individual and provides an opportunity to counsel for behavior modification. Also, presence of an STI like genital ulcer enormously increase the risk of HIV transmission.

The following measures are recommended to reduce the burden and transmission of STIs in society:

- Counseling young adults/adolescents about importance of abstinence and responsible sexual practices.
- Spreading community awareness about STIs and the need to seek prompt treatment.
- Vaccinations for certain STIs like HPV/ Hepatitis B.
- Awareness of presenting symptoms of STI among medical personnel to maximize case detection and therapy.
- Use of appropriate therapy for particular STIs, including Syndromic case management.
- Counseling and educating patients regarding abstinence & safe sexual practices, and encouraging them to avail ICTC services for HIV testing.
- Ensuring treatment and counseling for sexual partners.
- Training medical graduates in eliciting appropriate sexual history from patients and providing education about abstinence & responsible sexual practices.

Do You Want to Access all the previous issues of the Magazine? CLICK BELOW

What's Ap?

@St John's Hospital



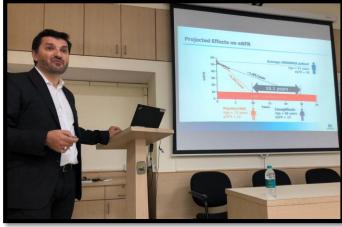




## **Department of Endocrinology**

21<sup>st</sup> December 2019 – The Department of Endocrinology organised a meeting in the campus with Dr. Vlado Perdovic, Nephrologist (previously executive director of the George Institute, Australia, Dean at Medicine). UNSW He discussed findings of the recently published CREDENCE trial and addressed cardiovascular, renal and safety issues of SGLT2 inhibitors. The meeting was departments of attended by Nephrology and Cardiology as well. .





### 1980 MBBS Batch - Reunion

5<sup>th</sup> January 2020 – 1980 MBBS Batch had a mini reunion in the campus of St. John's National Academy of Health Sciences Bengaluru.











## **Department of Medicine**

6<sup>th</sup> January 2020 – Department of Medicine organised a guest lecture on 'Health Economics Prospects of Family Medicine in India' by Dr. Sasidharan (Professor, Department of Family Medicine, Calicut Medical College).



### ST.JOHN'S NATIONAL HEALTHCARE SUMMIT 2020

St. John's National Healthcare Summit 2020 was held from 9<sup>th</sup> to 11<sup>th</sup> January 2020 in St. John's campus. The first day was pre-conference workshops in six separate halls led by experts in Costing of Hospital Services, Surface Anatomy in Physiotherapy, Continued Renal Replacement Therapy, ECMO, Mould room techniques in radiotherapy and Quality control in Medical Laboratory Accreditation. The conference on 10<sup>th</sup> and 11<sup>th</sup> had more than 750 participants who were health and allied healthcare professionals, industrial organizations, entrepreneurs and students from Healthcare/Hospital Administration, Physiotherapy, Lab Technology, Medical Imaging Technology, Radiotherapy, Renal Dialysis Technology, Perfusion Technology, Operation Theatre Technology and Anaesthesia Technology. The summit was inaugurated by Dr. (Col). Sunil Rao, CEO of Sahyadri group of hospitals, Pune.





More than 20 research paper presentations and many poster presentations were made in this summit by faculty, researchers and students from about 15 institutions across the nation. Exhibition stalls and demonstration of online learning platforms attracted many participants.

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## ST.JOHN'S NATIONAL HEALTHCARE SUMMIT 2020 contd..

The cultural evening of the summit was made memorable by classical dance performance by a cancer survivor. It was inaugurated by Mr. Arshad Rizwan (MLA, Shivajinagar). This summit was organized under the initiative of the AHS departments headed by the vice-dean Dr. Geraldene Menezes. Fr.Dr.John Thekkekara and Dr. Annie Thomas gave leadership for this summit as the organizing chairperson and secretary respectively.





Acknowledgement: Rev. Fr. John Varghese Thekkekara (Professor and Head, Department of Hospital Administration, SJAHS)

## St. John's Medical College Hospital is now NABH Accredited

11<sup>th</sup> January 2020 – St. John's Medical College Hospital has now been granted NABH Accreditation. The Accreditation is effective from 11<sup>th</sup> January 2020 till 10<sup>th</sup> January 2023.

Congratulations to quality department, administrators, faculty and staff of all the departments.

Director of SJNAHS Rev. Dr. Paul Parathazham sent out a congratulatory message to all the staff on this regard.





## M. Sc in Nurse Practitioner for Critical Care - Inauguration

16<sup>th</sup> January 2020 – M.Sc in Nurse Practitioner for Critical course (NPCC) was inaugurated in the college of Nursing. The program was preceded by the Director, SJNAHS, Rev. Dr. Paul Parathazham, Associate Director Hospital, Rev. Fr. Pradeep Kumar Samad, Rev. Sr Ria Emmanuel (Chief of Nursing Services), Dr. Sanjiv Lewin (Chief of Medical Services), Mrs. Reena Menon (Principal College of Nursing)



## **Dr. Arpana lyengar was** awarded ACCRI Award

24<sup>th</sup> and 25<sup>th</sup> January 2020 – Indian Society of Clinical Research (ICSR), 13<sup>th</sup> Annual Conference in Mumbai, Dr. Arpana Iyengar (Professor, Department of Paediatric Nephrology) was awarded ACCRI National Award for Excellence in Academic Clinical Research.



The study was 'Determining the optimal dose of cholecalciferol supplementation in children with chronic kidney disease, an open label multicentre randomised controlled trial' was authored by A lyengar (PI), N Kamath, Hamsa V, J Sharma, J Singhal, S Uthup, S Ekambaram and R Shroff.

### Dr. Denis Xavier in High level Expert Committee - ICMR

Dr. Denis Xavier, (Vice Dean, SJMC, Head, Division of Clinical Research and Training, SJRI) is now member of High level Expert Committee of Indian Council of Medical Research (ICMR) under the chairmanship of Prof. Vinod Paul (Member, Niti Ayog, New Delhi). The purpose of the committee is to prioritize research areas for India. The committee is convened by Director General of ICMR. Congratulations to Dr. Denis Xavier.



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## ST.JOHN'S NATIONAL ACADEMY OF HEALTH SCIENCES

## Food Fest 2020

23<sup>rd</sup> January 2020, St. John's National Academy of Health Sciences in collaboration with trained nurses association of India (St. John's unit) organised Food Fest 2020. The event was organised with a nobel cause of







## FRIDAY CLINICAL MEETING

13th December 2019

## A young male presents with skin manifestations, worsening muscle pains & foot drop associated with multiple joint pains and swelling

**CLINICAL PATHOLOGICAL CASE DISCUSSION** 

Discussants: Dr. Divya Jacob, Senior resident, Dept. of General Medicine. Supported by Dr. Jovis (Radiology) and Dr. Parul Jain (Pathology)

#### **SUMMARY OF THE CASE:**

- 27 year old male no comorbidities; 1 month ago had history of swelling over dorsum of left hand with severe pain and rise of local temp; treated with antibiotics.
- 1 week later, he developed hyperpigmentation of right hand and flexor aspect of right forearm; fever and symmetrical polyarthralgia; treated with oral steroids but got only partial relief.
- In SJMC hospital: Skin examination revealed discoloration and an erythematous nodular/ plaque like lesion over the dorsum of the left hand; left hand swelling extending up to distal one third of forearm with rash over left forearm; nodular plaques with eschar like lesion over right limb; ecchymotic patches over both arms; discoloration of right dorsum of 2nd and 3rd fingers, swollen DIP and PIP joints with painful restriction of movements; all muscles were tender; continued to have high grade fever and developed bilateral foot drop with paraesthesia in both lower limbs; treated with steroids and discharged. On two week follow up, he had worsening pain and swelling of bilateral hands, increasing discoloration of fingers, including pre gangrenous changes of the right 2nd digit and noticeable proximal muscle weakness.





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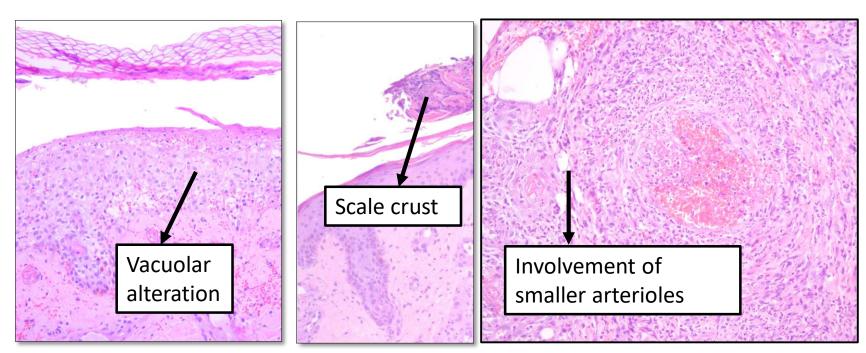
## FRIDAY CLINICAL MEETING

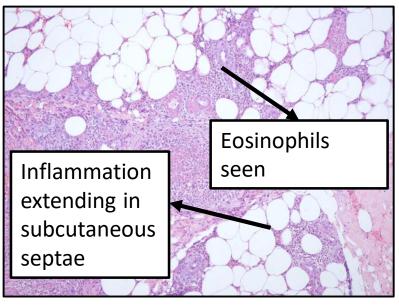
#### **CLINICAL PATHOLOGICAL CASE DISCUSSION**

Persistent leucocytosis (36.99 thou) and thrombocytosis (6 lakh and 48 thou). ANA, ANCA, PR3 ELISA, MPO ELISA, myositis autoantibody panel were all negative. HIV/HBsAg/HCV were negative. APLA was also negative. RF/Anti CCP – negative

Differential Diagnosis during the discussion after history, examination and blood investigations and imaging:

- A. Essential mixed cryoglobulinemia
- B. Medium vessel vasculitis: Polyarteritis nodosa (PAN)
- C. Sweets syndrome i.e. acute febrile neutrophilic dermatosis
- D. Infections particularly Rickettsial spotted fevers.





Histopathology report was suggestive of cutaneous polyarteritis nodosa. There were Scale crust and basal vacuolar alteration in epidermis, involvement of small arterioles and perivascular neutrophilic infiltrates in dermis and widening of septae, congestion of blood vessels, inflammatory infiltrates in subcutis. (PC: Dr. Parul Jain)







## FRIDAY CLINICAL MEETING

#### **CLINICAL PATHOLOGICAL CASE DISCUSSION**

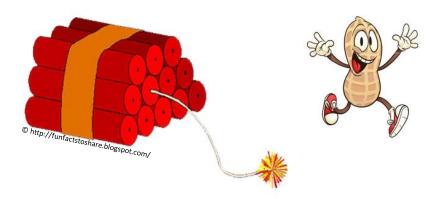
#### **TAKE HOME MESSAGES**

- Dermatology faculty opined that lesion on the thigh was not eschar (as eschar are necrotic and black) but more likely deep seated nodules.
- Rheumatologists differed from the histopathological diagnosis of cutaneous PAN and vouched for systemic PAN and opined that cutaneous PAN is very unlikely to cause such systemic symptoms of myopathy and neuropathy where there are no cutaneous lesions on skin.
- Secondary Livedo reticularis is now more properly called livedo racemose
- Mutations in adenosine deaminase 2 (identified in early onset familial PAN)
  was sent to PGI Chandigarh and was negative (treatment for this is
  different from PAN and needs TNF inhibitors as first line); ADA 1 is
  associated with primary immunodeficiency.
- Though microaneurysms was reported absent in the CT done in SJMC, rheumatologists suggested "prying eyes" are needed to spot those.

## Did You Know?

Peanuts are used in manufacturing dynamite! Dynamite is made from Nitroglycerine. Nitroglycerine, also known as trinitroglycerin, and glyceryl trinitrate, is an oily, explosive liquid made by nitrating glycerol. Glycerol is made of.......Peanut oil!

REF: Foododdity.com







## 13 13 6 17 57 & Rhyme Chime...

## The knee Pop

- Dr Benzeeta Pínto (Asst. Prof. Clín immunology and Rheumatology)

There was a time, my life was a song
The patella, femur and tibia, they all got along
I ran, I jogged, I danced with such poise
But soon they began to make some noise
Crack, pop, grate, what's all this fuss
The doc saw my knee, said crepitus

They rubbed each other the wrong way Good ol' cartilage couldn't keep them at bay

Femur told the patella you are always in my face Why don't you realize I need some space?

The quadriceps tried to mediate but soon got worn
The ligaments would have tried but they were already torn

The big burly synovium now laughed in glee My knee swelled up in this unusual melee I tried many things but all in vain Oh say hello to chronic pain

Some Chinese healer stuck needles into me My neighbor told me try physiotherapy I even got a bee-sting, if you get the gist Then someone suggested "rheumatologist"

Díd he do better ít's really hard to say Let's leave doctor-bashing for another day

Maybe it's time to slow down in life How I dread the thought of going under the knife

Symptomatic treatment isn't it just a lure C'mon science buck up, where is the cure?







## Team of The Month

## **Drivers of the Transport Department**

Driving requires a lot of skill, and not everyone can do it and it isn't admired enough. Drivers make an important contribution to the everyday success of our institution. The transport department has 11 drivers who work in 24 hour shifts to ensure efficient working of several departments. Their list of duties ranges from driving officials of the academy, ambulance service, during medical camps and student postings, transporting materials to various laboratories, picking up doctors on call during night duty, transferring dead bodies in case of medico legal cases along with tractor services in the garden and much more. Mr. Raja Rao, Assistant Security officer and Transport officer is incharge of the drivers, he makes sure that all departments seeking the assistance of drivers are satisfied with the services provided.

We are extremely glad to have such dedicated drivers who go beyond their duty timings to fulfill the needs of the academy, and appreciate their work and contribution to the academy.



In the photo above: Mr. Narayan Rao, Mr. Madeshan, Mr. Jyothisha, Mr.Suresh Kumar, Mr. Srinivas, Mr. Sathish, Fr. Vimal and Mr. Raja Rao. Absent: Mr.Annimuthu, Mr.Tony, Mr.Sebastian, Mr. Alexander and Mr. Santhosh.





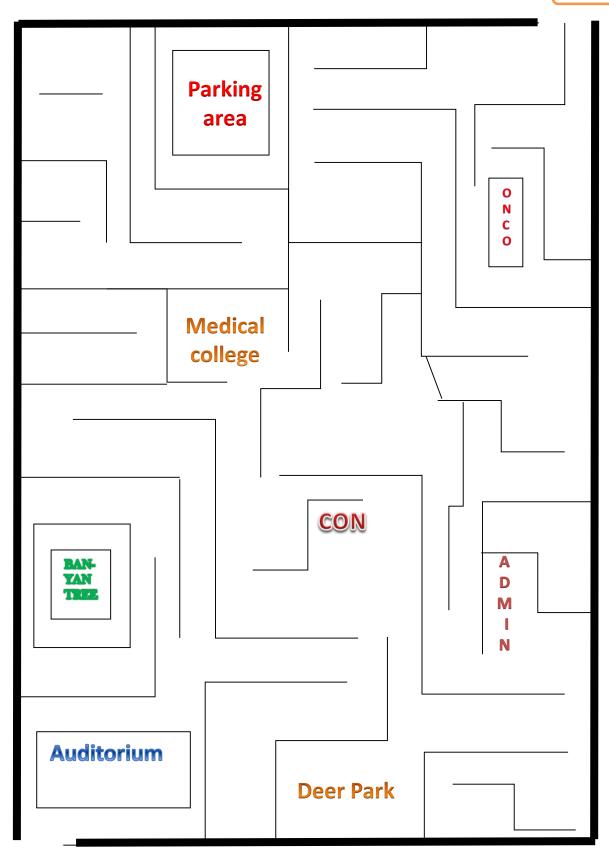


## GREY Matters!



SJNAHS: Roadmap Level 1: Easy

ENTRY





CLICK HERE FOR ANSWERS







## LAUGHTER IS THE BEST MEDICINE...



My husband talks in his sleep. Unfortunately, he also snores, so I sometimes give him the wifely elbow. "What?!" he demanded one night, still mostly asleep.

"Turn over—you're snoring," I said.

He did as instructed and while doing so muttered, "That's nothing; you should hear my wife snore."



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A patient came to the hospital with a burned right hand. As the doctor took down his medical history, he asked the injured man, "Do you smoke?"

"Yeah, a pack and a half a day," said the patient.

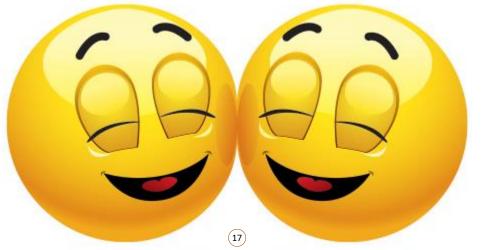
Concerned, the doctor told him, "You should consider quitting." "No, it's OK," said the patient. "I smoke with my left hand."

I visited the Air and Space Museum...Nothing was there.





Q: What do you call an alligator wearing a vest?A: An Investigator!





**Readers Digest** 



## **SURVIVOR'S CORNER**

By Dr. Saudamini Nesargi

This month's survivor corner is extra special as it is written by the 'survivor' herself!

A young lady telephoned a few days ago enquiring about donation details for the Child for Life Fund (CFL). After sending the details, I asked her what prompted her to donate to CFL. She said that she was a beneficiary of St. Johns and that 'it gave her life'. Curious, I asked for details, found her experience to be extremely inspiring and asked her to write about it. This is the story in her own words, with minor editing.

It was a Monday afternoon in a small town in Andhra Pradesh when I, a young girl studying in the 9<sup>th</sup> standard was on my way home from school. I was stabbed by a schoolmate who was upset that I had rejected his friendship. I was repeatedly stabbed in the chest and abdomen and also sustained wounds on my arms while trying to defend myself. I was taken to a nearby hospital but not even basic first aid was provided as it was a medicolegal case. I then had to travel over 5 hours to finally reach St. John's at midnight.

Immediately my wounds were cleaned and stitches put. They stopped the bleeding in the chest area and two pipes were attached to arm pits to clean out the clotted blood. I soon got better and was allowed to eat. Unfortunately, it was found that the food and other stomach contents were leaking into the pipes from my chest. An x ray taken showed two holes in the diaphragm. I was operated, and though the surgery was successful, it required 27 days including ICU stay and ventilation before I was sent home.





## SURVIVOR's CORNER contd...

Five months later, there was a swelling on my sutures for which I went to the hospital. As this was quite unexpected, I was advised a biopsy and surgery, but this was deferred as I had board exams coming. Instead, regular dressings were done until the surgery. Over the course of the next five months, I had 11 surgeries as there was a constant re- accumulation of pus and repeated infections, including a pneumonia and bladder stones. Each of these 11 surgeries required some post op ICU stay and some required post op ventilation.

Finally, after a wait of 3 years, a scan was done which showed that a rib where I was stabbed was infected. The doctors planned to remove the infected rib, but this couldn't be done as there was too much blood loss during surgery. It was the toughest part of my recovery as I was dependent on medicines for sleeping, so the doctors sent me home with the drain bags. Finally in the last operation the rib was removed and miraculously I felt better the very next day!

After the last operation in 2007 and treatment till 2008, I have completed my MBA and am working. I am also a certified Yoga teacher.

I thank my Mom, Dad, sister who were and are my support system, the doctors and nurses at St. who have been beside me in this journey to recovery.





## St John's WATCHDOG



## Plastic in anti-diabetic tablets?

**Overview** – In this issue, we examine the veracity of a recently viral video where an individual (presumably customer) in a pharmacy store claims that the tablets contained in a blister pack that he's holding contain plastic and are therefore harmful. Video was also made sensational by several TV news channels!

Content of video – A person holds up a blister pack of a brand of medication named Gemer DS containing the anti-diabetic fixed dose formulation, Metformin sustained release + Glimepiride. The person starts alleging that a diabetic patient (acquaintance of his) who was prescribed this brand and procured from a Medplus pharmacy outlet in Bangalore started causing a 'health upset'. So he proceeded to 'test' the tablets by trying to dissolve them in water. The tablets did not dissolve for more than 8 hours, and in fact started bloating up. This, the person alleges, proves that the tablets contain plastic. He replicates this 'test' in the pharmacy in front of the pharmacist.











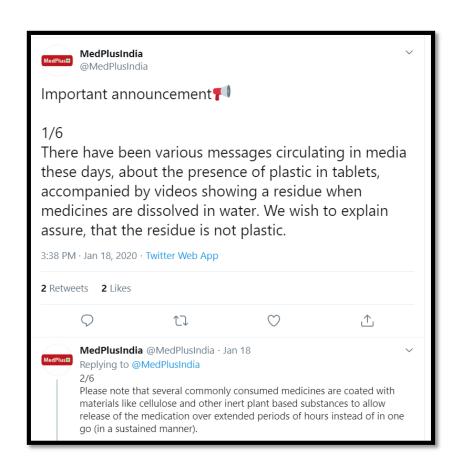
## St John's WATCHDOG

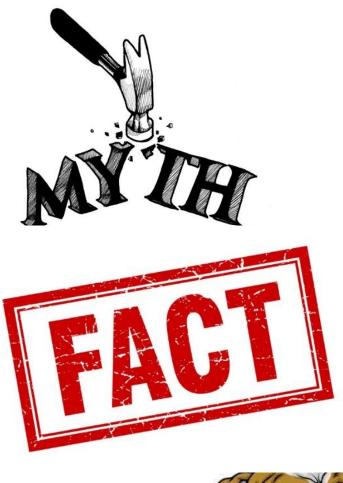


## Antidiabetic Medications contain Cellulose – Not Plastic!

**FACTS** – Medplus India clarified the following through a Twitter feed and a webpage –

- To enable the release of active medicine in a gradual manner, the tablets contain cellulose based polymers.
- These cellulose based polymers swell up when they come in contact with water or the gastric juice of the stomach. This process enables the slow release of the medicine. The cellulose is then easily excreted.
- Hence, if this tablet is immersed in water, the swollen cellulose fragments tend to look like plastic, since it does not dissolve in water.
- Cellulose based polymers have been tested and approved for use and human consumption by various regulatory agencies and is safe for human consumption.











## THE QUOTABLE OSLER

### A Calm life is necessary for continuous work.

The truth that lowliness is young ambition's ladder is hard to grasp, and when accepted harder to maintain. It is so difficult to be still amidst bustle, to be quiet amidst noise; yet...the calm life [is] necessary to continuous work for a high purpose.









My Jowish Loarning

### Appreciate your blessings and advantage.

It is a common experience that men do not always appreciate their blessings and advantages. Those who are the best off are the least sensible of it.

REF: The Quotable OSLER: Edited by Mark E Silverman, T. Jock Murray, Charles. S Bryan



## MEDICINE DIS MONTH

A Bird's Eye View....

#### Tranexamic acid for adults with acute traumatic brain injury.

Tranexamic acid reduces surgical bleeding and decreases mortality in patients with traumatic extracranial bleeding. Intracranial bleeding is common after traumatic brain injury (TBI) and can cause brain herniation and death. A multicentric randomised CRASH 3 trail with 12,737 patients tested the efficacy of Tranexamic acid in reducing the head injury related deaths. the risk of head injury-related death was 12.5% in the tranexamic acid group versus 14.0% in the placebo group. The risk of head injury-related death reduced with tranexamic acid in patients with mild-to-moderate head injury (RR 0.78) but not in patients with severe head injury (RR 0.99). It was concluded that tranexamic acid is safe in TBI and reduces deaths.

-Lancet. 2019;394(10210):1713.

### Medical versus Surgical Treatment for Refractory Heartburn.

Heartburn that persists despite proton-pump inhibitor (PPI) treatment is a frequent clinical problem with multiple potential causes. Patients who were confirmed to have reflux related heart burn were randomly assigned to receive surgical treatment (laparoscopic Nissen fundoplication), active medical treatment (omeprazole plus baclofen, with desipramine added depending on symptoms), or control medical treatment (omeprazole plus placebo). 67% of the patients undergoing surgery had >50% decline in the GERD related QOL scores proving surgery to be most effective as compared to other two interventions...

- Spechler SJ et al N Engl J Med. 2019;381(16):1513.

## Effects of tranexamic acid on death, disability, vascular occlusive events and other morbidities in patients with acute traumatic brain injury (CRASH-3): a randomised, placebo-controlled trial





The CRASH-3 trial collaborators\*

#### Summary

Background Tranexamic acid reduces surgical bleeding and decreases mortality in patients with traumatic extracranial bleeding. Intracranial bleeding is common after traumatic brain injury (TBI) and can cause brain herniation and death. We aimed to assess the effects of tranexamic acid in patients with TBI.

Methods This randomised, placebo-controlled trial was done in 175 hospitals in 29 countries. Adults with TBI who were within 3 h of injury, had a Glasgow Coma Scale (GCS) score of 12 or lower or any intracranial bleeding on CT scan, and no major extracranial bleeding were eligible. The time window for eligibility was originally 8 h but in 2016 the protocol was changed to limit recruitment to patients within 3 h of injury. This change was made blind to the trial data, in response to external evidence suggesting that delayed treatment is unlikely to be effective. We randomly assigned (1:1) patients to receive tranexamic acid (loading dose 1 g over 10 min then infusion of 1 g over 8 h) or matching placebo. Patients were assigned by selecting a numbered treatment pack from a box containing eight packs that were identical apart from the pack number. Patients, caregivers, and those assessing outcomes were masked to allocation. The primary outcome was head injury-related death in hospital within 28 days of injury in patients treated within 3 h of injury. We prespecified a sensitivity analysis that excluded patients with a GCS score of 3 and those with bilateral unreactive pupils at baseline. All analyses were done by intention to treat. This trial was registered with ISRCTN (ISRCTN15088122), ClinicalTrials.gov (NCT01402882), EudraCT (2011-003669-14), and the Pan African Clinical Trial Registry (PACTR20121000441277).

Results Between July 20, 2012, and Jan 31, 2019, we randomly allocated 12737 patients with TBI to receive tranexamic acid (6406 [50·3%] or placebo [6331 [49·7%], of whom 9202 (72·2%) patients were treated within 3 h of injury. Among patients treated within 3 h of injury, the risk of head injury-related death was  $18 \cdot 5\%$  in the tranexamic acid group versus  $19 \cdot 8\%$  in the placebo group (855 vs 892 events; risk ratio [RR] 0.94 [95% CI 0.86-1.02]). In the prespecified sensitivity analysis that excluded patients with a GCS score of 3 or bilateral unreactive pupils at baseline, the risk of head injury-related death was 12.5% in the tranexamic acid group versus 14.0% in the placebo group (485 vs 525 events; RR 0.89 [95% CI 0.80-1.00]). The risk of head injury-related death reduced with tranexamic acid in patients with mild-to-moderate head injury (RR 0.78 [95% CI 0.64-0.95]) but not in patients with severe head injury (0.99 [95% CI 0.91-1.07]; p value for heterogeneity 0.030). Early treatment was more effective than was later treatment in patients with mild and moderate head injury (p=0.05) but time to treatment had no obvious effect in patients with severe head injury (p=0.73). The risk of vascular occlusive events was similar in the tranexamic acid and placebo groups (RR 0.98 (0.74-1.28). The risk of seizures was also similar between groups (1.09 [95% CI 0.90-1.33]).

**Interpretation** Our results show that tranexamic acid is safe in patients with TBI and that treatment within 3 h of injury reduces head injury-related death. Patients should be treated as soon as possible after injury.

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#### Introduction

Each year, worldwide, there are more than 60 million new cases of traumatic brain injury (TBI). Road traffic crashes and falls are the main causes and the incidence is increasing. Intracranial bleeding is a common

complication of TBI and increases the risk of death and disability.<sup>2</sup> Although bleeding can start from the moment of impact, it often continues for several hou **CONTENTS** injury.<sup>3,4</sup> Ongoing intracranial bleeding can lead to raised intracranial pressure, brain herniation, and death.



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\*Members listed at end of paper For the Arabic translation of the abstract see Online for appendix 1

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For the Urdu translation of the abstract see Online for appendix 7

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## Randomized Trial of Medical versus Surgical Treatment for Refractory Heartburn

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#### ABSTRACT

#### **BACKGROUND**

Heartburn that persists despite proton-pump inhibitor (PPI) treatment is a frequent clinical problem with multiple potential causes. Treatments for PPI-refractory heartburn are of unproven efficacy and focus on controlling gastroesophageal reflux with reflux-reducing medication (e.g., baclofen) or antireflux surgery or on dampening visceral hypersensitivity with neuromodulators (e.g., desipramine).

#### **METHODS**

Patients who were referred to Veterans Affairs (VA) gastroenterology clinics for PPI-refractory heartburn received 20 mg of omeprazole twice daily for 2 weeks, and those with persistent heartburn underwent endoscopy, esophageal biopsy, esophageal manometry, and multichannel intraluminal impedance–pH monitoring. If patients were found to have reflux-related heartburn, we randomly assigned them to receive surgical treatment (laparoscopic Nissen fundoplication), active medical treatment (omeprazole plus baclofen, with desipramine added depending on symptoms), or control medical treatment (omeprazole plus placebo). The primary outcome was treatment success, defined as a decrease of 50% or more in the Gastroesophageal Reflux Disease (GERD)—Health Related Quality of Life score (range, 0 to 50, with higher scores indicating worse symptoms) at 1 year.

#### **RESULTS**

A total of 366 patients (mean age, 48.5 years; 280 men) were enrolled. Prerandomization procedures excluded 288 patients: 42 had relief of their heartburn during the 2-week omeprazole trial, 70 did not complete trial procedures, 54 were excluded for other reasons, 23 had non-GERD esophageal disorders, and 99 had functional heartburn (not due to GERD or other histopathologic, motility, or structural abnormality). The remaining 78 patients underwent randomization. The incidence of treatment success with surgery (18 of 27 patients, 67%) was significantly superior to that with active medical treatment (7 of 25 patients, 28%; P=0.007) or control medical treatment (3 of 26 patients, 12%; P<0.001). The difference in the incidence of treatment success between the active medical group and the control medical group was 16 percentage points (95% confidence interval, –5 to 38; P=0.17).

#### CONCLUSIONS

Among patients referred to VA gastroenterology clinics for PPI-refractory heartburn, systematic workup revealed truly PPI-refractory and reflux-related heartburn in a minority of patients. For that highly selected subgroup, surgery was superior to medical treatment. (Funded by the Department of Veterans Affairs Cooperative Studies Program; ClinicalTrials .gov number, NCT01265550.)

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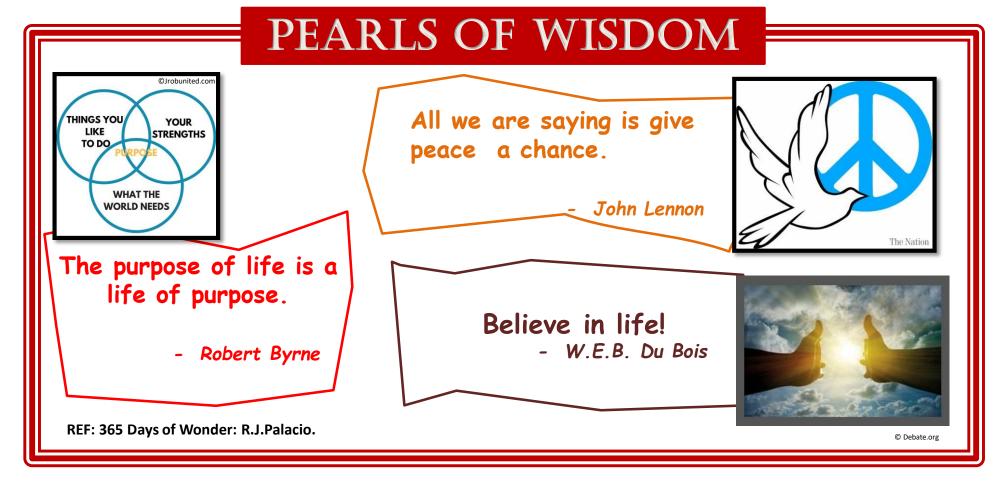
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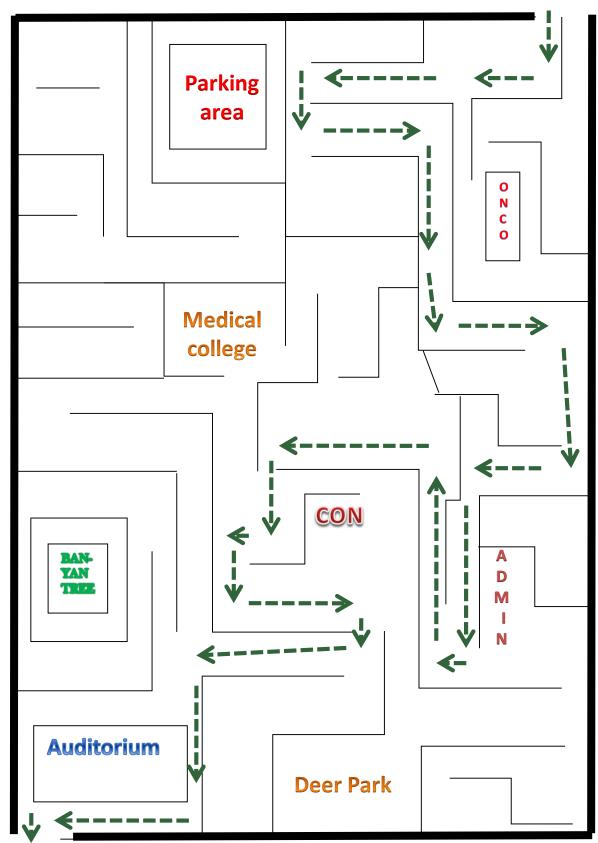


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