

### FROM THE PEN OF THE PRESIDENT...

Dear All,

The corona catastrophe continues to take its toll. But the IMPA continues its usual CPD activities and the AGM was postponed for a little while. The year January started on a positive note of membership performance at a high level no less than WHO – I am referring to the appoint of one of our respected members Dr Palitha Abeykoon's appointment as a special envoy for the WHO Director General. This while no doubt is a feather in the cap for Dr Palitha Abeykoon but for us at IMPA this brings honor and recognition as a powerful body of membership comprising esteemed individuals. Congratualations Dr Palitha. It is also heartening to record here the many congratulatory messages sent by the membership through the official email.

In view of the current corona vaccination initiatives and many undercurrents we in the IMPA with the help of esteemed public health colleagues plan to get the priority status in vaccination programmes for our membership too.

As this will be the final President's message for the year ending 2020 I wish to thank Dr Hazari and Ms Champa for the yeoman service which they have rendered tirelessly.

#### Dr. Ananda Perera

President IMPA

#### COVID-19: RISKS AND SIDE EFFECTS OF VACCINATION-VACCINE IS SAFE

Vaccines are safe and save lives. The rapid development of COVID-19 vaccines has people asking questions. Here is an overview of the reactions and side effects you can expect.

Millions of people worldwide have received the vaccination against the coronavirus. Vaccines

have been found safe and approved by health authorities in many countries.

At the same time, many people are ambivalent because, while they want to protect themselves against infection, they also fear possible side effects from vaccination. They have doubts as to whether the vaccines are actually safe, given the rapid pace of development, and whether possible side effects have been adequately studied.

So what vaccine reactions are normal, and what side effects are possible?

#### Normal vaccination reactions

It is normal to have certain reactions after a vaccination: There may be redness, swelling or pain around the injection site. Fatigue, fever, headache and aching limbs are also not uncommon in the first three days after vaccination.

These normal vaccine reactions are usually mild and subside after a few days. They show that the vaccine is working, because it stimulates the immune system and the body forms antibodies against the infection that is only "feigned" by the vaccination.

Accordingly, such typical vaccination reactions have also been reported after receiving the BioNTech-Pfizer, Moderna, AstraZeneca and the Russian Sputnik V vaccines, which are already in use.

#### Rarely serious side effects

In addition to the typical vaccination reactions, there were also individual cases of sometimes severe side effects after vaccination, such as allergic shocks, which were reported in detail. But these are isolated cases.

Overall, the approved vaccines are safe, according to the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the World Health Organization (WHO); otherwise, they would not have authorized the vaccines.

Some of the new vaccines – so-called mRNA vaccines – are different from the established vaccines: they do not contain weakened or killed viruses. Instead they contain only a blueprint for a component of the COVID-19 pathogen.

Others are so-called vector vaccines that use harmless adenoviruses (such as cold viruses

that only affect chimpanzees) as transporters to introduce the surface protein of SARS-CoV-2, the spike protein, and thereby trigger the immune response.

Here is an overview of the risks and side effects of the commonly mentioned vaccines:

#### The Biontech-Pfizer vaccine

During the approval phase, no serious side effects occurred with the BNT162b2 vaccine developed by companies BioNTech of Germany and Pfizer of the US. The typical vaccination reactions such as fatigue and headache were less frequent and weaker in older patients.

However, since this mRNA vaccine has been in use, a few patients had a severe allergic reaction immediately after the injection. One patient in the USA and two Britons even went into anaphylactic shock, associated with reddening of the skin and shortness of breath.

Since these individuals either had no previous illnesses or were not known to be allergic to certain vaccine ingredients, the British Medicines and Healthcare products Regulatory Agency (MHRA) warned in particular people who are allergic to certain vaccine ingredients, or have already suffered an anaphylactic shock, against getting the vaccination.

The manufacturers do not see any direct connection to the vaccination in the case of a US physician with no previous illnesses who died from a brain hemorrhage due to immune thrombocytopenia 16 days after receiving the vaccination. This occurs when the immune system reduces the number of platelets.

Headlines were made when 33 people in Norway died a few days after the first vaccination, all of whom were more than 75 years old and had severe underlying diseases. While manufacturers are still investigating the causes, the Norwegian Health Authority has changed its instructions for vaccinating older, frail people against COVID-19. In the future, doctors are to decide individually whether the benefits of vaccination outweigh the risks of side effects.

#### The Moderna vaccine

The mRNA-1273 vaccine from US company Moderna is also a gene-based vaccine that is very similar in principle to the one from BioNTech/ Pfizer.

During the clinical trials, participants tolerated the vaccine well, according to the manufacturer and testing authorities. The usual vaccination reactions were only mild or moderate and didn't last long. However, almost 10% of those vaccinated with mRNA-1273 experienced fatigue, according to an interim report by an independent surveillance panel.

Severe allergic reactions to the Moderna vaccine are "rare," according to the US Centers for Disease Control and Prevention (CDC). The CDC is basing that assessment on the documentation of 4,041,396 doses of the vaccine that were administered between December 21, 2020 and January 10, 2021. A total of 108 allergic reactions were recorded, but only 10 recipients went into anaphylactic shock. The CDC reported that none of the allergic reactions led to death.

A very small number of people who received the Moderna vaccine experienced facial nerve paralysis. However, it is still unclear whether these reactions are actually related to the core ingredient of the vaccine. It is possible that the side effects were not triggered by the mRNA, but by lipid nanoparticles that serve as carriers for the mRNA and are later broken down by the body.

Isolated cases of facial paralysis, mostly temporary, occurred sporadically during the clinical trials of the BioNTech/Pfizer and Moderna vaccines, but also during ongoing vaccinations in Israel.

#### The AstraZeneca vaccine

At the British-Swedish company AstraZeneca, an

incident during clinical trials in September caused a stir because one person suffered inflammation of the spinal cord after vaccination. The trial was briefly halted until an independent panel of experts determined Otherwise, only typical vaccination reactions such as pain at the injection site, muscle pain, headache and fatigue occurred with the vaccine from AstraZeneca. Again, vaccine reactions were less frequent and milder in older people. This is a vector vaccine.

#### The Russian Sputnik V vaccine

As early as August 2020, the vector vaccine Gam-COVID-Vac (Sputnik V) was approved in Russia, but without waiting for phase III trials involving tens of thousands of subjects. Sputnik V uses two differently modified adenoviruses (rAd26-S and rAd5-S).

There have been considerable reservations worldwide about the vaccine developed by the Gamaleja Research Center in Moscow because the Russian government issued an emergency use authorization after a phase II trial. Furthermore, scientists reviewing the study voiced concern about possible manipulation of the data.

Nevertheless, Sputnik V is already being used not only in Russia but in many other countries, including Belarus, the United Arab Emirates (UAE), India, Brazil and Argentina.

that the inflammation was probably not related to the vaccination.

On January 2, Russian Health Minister Mikhail Murashko told journalists that more than 1.5 million doses had been delivered to Russian regions and more than 800,000 people had been vaccinated.

According to the Russian Health Ministry, only the usual vaccination reactions, such as headaches or fever, have been registered so far. In Argentina, typical vaccination reactions occurred in 317 of a total 32,013 vaccinated people, according to the Argentinian Health Ministry. There have been no reports of severe side effects following Sputnik V vaccination. Nevertheless, reservations are apparently high in Russia as well. According to a Reuters report, 52% of 3040 Russian doctors and other health professionals stated in a survey, conducted by the "Doctor's Handbook" mobile application and quoted by the RBC daily, that they would not be vaccinated with Sputnik V due to insufficient data.

#### Weighing the benefits and risks

All risks and side effects registered so far are only snapshots of the past months – this must be noted despite all the excitement about the rapid vaccine development. Nothing is yet known about possible long-term effects of the individual vaccines. Only the long-term studies that accompany the vaccinations worldwide and will continue since approval will provide clarity.

In principle, the decision is always based on a risk-benefit assessment, said Christian Bogdan, director of the Institute for Clinical Microbiology, Immunology and Hygiene at Erlangen University Hospital, who is also a member of the Standing Committee on Vaccination (STIKO) at the Robert Koch Institute (RKI).

To the German Press Agency, he made the following calculation: If an elderly person has a

20% chance of dying from a coronavirus infection, and at the same time the risk of getting a severe side effect of the vaccination is 1:50,000 or even less, "I would accept that risk," he said.

So far, there is a lack of information about rare, possibly severe side effects, for example in rare pre-existing conditions or in certain risk groups such as specific allergy sufferers.

Such side effects only become apparent after many people have been vaccinated and after a longer observation period. "There is therefore a residual risk," said Bogdan. "How high that is will have to be examined in the coming months and years."

When it comes to children, Bogdan said they shouldn't be vaccinated. Their risk of dying from COVID-19 is close to zero, he said, and they still have a very long life ahead of them.

Women who are pregnant or breastfeeding should also not get vaccinated as a precaution, according to Bogdan, based on current data.

A recommendation from the US Center for Disease Control (CDC), however, does not rule out vaccinating pregnant or breastfeeding mothers with mRNA vaccines after medical examination and consultation.

#### **DIVERTICULAR DISEASE** GPs point of view

Dr. Shalinie Fernando MBBS(COL), DFM, MD in Family medicine SLMC Reg No: 17135 Designation: Senior Registrar, Ministry of health

# Left lower abdominal pain with bloating and constipation, A common presentation in the elderly.

Mrs. KL a 67 year old housewife, a mother of one child, presented to The Medical Clinic giving a history of left sided lower abdominal pain for the last 3 to 4 weeks. The pain was a mild to moderate intensity dull ache associated with bloating and discomfort which is more after meals. On further inquiry it was revealed that she had been having on and off constipation for the past two to three years, to which she had taken an aurvedic preparation. She denies passage of blood or mucous per rectum. There was no of loss of appetite or loss of weight.

She did not have any medical problems in the past and nor was she on any long term medication. A Total Abdominal Hysterectomy (TAH) was done due to menorrhagia, when she was at the age of 48 years.

She was worried that these symptoms would be due to a serious illness and she wanted an abdominal scan to exclude any serious pathology.

On examination she was a well looking, neatly dressed lady with a satisfactory level of self-care but anxious regarding her condition. Her conjunctivae were pink and she did not have signs of localized or generalized lymphadenopathy.

Abdominal examination elicited mild tenderness on deep palpation over the left iliac fossa (LIF). There were no palpable intra-abdominal or pelvic masses. Rest of the abdominal examination as well as the examination of other systems were normal. Digital rectal examination was also found to be normal.

#### Differential Diagnosis (DD) considered in Mrs. KL

- Diverticulitis
- Large bowel malignancy ( colorectal carcinoma)
- Inflammatory Bowel Disease(IBD)
- Irritable Bowel Syndrome(IBS)

#### Arriving at a working diagnosis

The most probable diagnosis according to the history and examination is diverticulitis. Age of the patient, typical history of LIF pain associated with abdominal bloating and discomfort, altered bowel habits with on and off constipation for years, makes diverticulitis highly possible in her. But when considering her age and alteration in bowel habits, large bowel malignancy must be excluded as a sinister cause. IBD though one of the DD is a rare possibility in this scenario. IBS which comes under the differential diagnosis, due to the presentation of abdominal pain, discomfort and bloating after meals, is rather unlikely to develop at this age and is a diagnosis of exclusion.

#### Management done at the Family Practice clinic

Patient education regarding the condition - Patient was given a reasonable explanation about the possible cause of her symptoms alleviating her fear of a cancer.

Considering her concerns and expectations an

abdominal ultrasound scan was ordered.

A course of omeprazole and domperidone was prescribed as symptomatic treatment. Paracetamol was given to relieve pain.

#### Discussion

#### DIVERTICULAR DISEASE

Formations called diverticula are key components of diverticular disease. Diverticula are pouches that occur along digestive tract, most often in, colon particularly the sigmoid colon. The term diverticulosis indicates the presence of diverticula.

These pouches are form when weak spots near the blood vessels in the intestinal mucosa balloon outwards due to the increased intraluminal pressure with thickening of the muscle layer. An alternative explanation is the cholinergic denervation with increasing age which leads to hypersensitivity and increased uncoordinated muscle contraction. When these pouches become inflamed, or bacteria gather in them and cause an infection, it is termed diverticulitis. Diverticular colitis refers to inflammation on the folds in areas of diverticulosis. This occurs when feces obstruct the neck of the diverticulum causing strangulation and bacterial growth leading to inflammation. It is perhaps better to use the more general term diverticular disease, as often it is difficult to be sure whether the diverticula are inflamed.

While it was rare before the 20<sup>th</sup> century, diverticular disease is now one of the most common health problems in the Western world. It's a group of conditions that affect the digestive tract. Diverticulitis is the most serious type of diverticular disease. Diverticulitis often requires treatment because it typically causes symptoms and can lead to serious health complications.

#### Disease progression

Diverticula themselves can be harmless. Having diverticula that aren't infected or inflamed, is diverticulosis. This condition typically causes no symptoms and doesn't need treatment.

If diverticulosis does cause symptoms, it's called symptomatic uncomplicated diverticular disease (SUDD). The good news for people with diverticulosis is that only 10 to 20 percent of people with this condition progress to SUDD. And of those, about 4 percent get acute diverticulitis. It typically takes about 7 years for this progression to diverticulitis to occur. And of the 4 percent of people with diverticulitis, only 15 percent have complications. An episode of diverticulitis, can recur as an acute, or short-term, problem. However, that's not a definite. According to a study about assessment of risk for recurrence in diverticulitis, in those who have had one episode, around 39 percent of individuals have another acute attack within five years. And the same study had found that the first attack is typically the worst one. This may be because scar tissue builds up in the diverticula and helps prevent future perforations. But for some, diverticulitis can progress into a chronic, or long-term, problem. For these people, the condition can be much more serious. Surgery to remove the diseased tissue is generally considered.

#### Risk factors for diverticular disease

While there are several risk factors for diverticulitis, the key risk factor is age. Diverticulosis, the precursor to diverticulitis, is very common in older adults, especially those over 60. In people over age 70, 60 percent have diverticulosis, while 75 percent of people 80 years and older have the condition. However, young people have their own level of risk. A study on long term risk of acute diverticulitis among patients with incidental diverticulosis found during colonoscopy, found that the younger the patient is when receiving a diagnosis of diverticulosis, the higher your risk is of the condition progressing to diverticulitis.

#### Risk factors for the development of diverticulitis

A low-fiber diet: A lack of dietary fiber has long been suspected as a risk factor, but research has had conflicting results. Nevertheless, it's still thought by some to be related to the onset of diverticulitis.

**Heredity:** Diverticulitis seems to have a hereditary link. A study of siblings and twins proposes that more than 50 percent of potential risk of diverticular

disease comes from genetics.

**Obesity:** Being obese is a clear risk factor for diverticulitis. Research has shown that obesity raises the risk of diverticulitis and bleeding, but researchers aren't sure of the reason behind this link.

Lack of physical exercise: It's unclear if a sedentary lifestyle is a real risk factor. However, research suggests that exercise reduces the risk of diverticular disease. People who exercise less than 30 minutes a day appear to have increased risk.

**Smoking:** Research shows that smoking increases the risk of symptomatic and complicated diverticular disease.

**Certain medications:** Regular use of aspirin and other NonSteroidal Anti-Inflammatory Drugs (NSAIDs) may raise your risk of diverticulitis. The use of opiates and steroids appears to raise your risk of perforation, a serious complication of diverticulitis.

Lack of vitamin D: One study found that people with complicated diverticulitis may have lower levels of vitamin D in their system than people with uncomplicated diverticulosis. This study suggests that vitamin D levels seem to be related to complications of the disease, although the exact reason is unclear.

**Sex:** In people age 50 and younger, diverticulitis appears to be slightly more common in men than women. In people older than 50, it seems slightly more common in women.

#### Symptoms of diverticulitis

The most common symptoms of diverticulitis include.

- abdominal pain
- fever
- nausea
- vomiting
- increased urge to urinate, urinating more often than usual, or burning sensation while urinating
- constipation
- diarrhea (Blood in the stool, as well as bleeding from the rectum, can occur in both diverticulosis

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and diverticulitis).

#### **Diagnosis of diverticulitis**

A detailed history and clinical examination is vital in the diagnosis. Abdominal as well as Digital Rectal Examination is vital in this context. Following investigations are done to confirm the diagnosis.

- Full blood count
- imaging studied such as an abdominal ultrasound or an abdominal CT scan,
- urine full report
- stools occult blood
- stool test to check for GI infections
- pelvic examination in women to rule out gynecologic problems
- pregnancy test in women to rule out pregnancy
- Colonoscopy or Barium enema

#### **Complications of diverticulitis**

- Perforation and peritonitis
- Abscess formation
- Fistula formation
- Intestinal obstruction with strictures

#### Treatment of diverticulitis

Depends on the severity of the condition. If symptomatic uncomplicated or chronic diverticulitis,

- Rest
- Bowel resting with clear fluids and gradually incorporate into the regular diet with response.
- Broad spectrum antibiotic to cover both aerobic and anaerobic bacteria
- Pain relief with simple analgesic like Paracetamol . Avoid using NSAIDS.

If acutely ill with dehydration or failing ambulatory management

- In hospital management
- Intravenous fluids
- Parenteral antibiotics
- Parenteral analgesics

#### If complication occur

- Perforation and peritonitis Emergency laparotomy, colectomy and peritoneal cleaning
- Abscess drainage

• Fistula / strictures – surgical removal

#### **Reflective learning points**

Though diverticulitis is a common condition in the elderly possibility of a bowel malignancy should always be excluded in the elderly. And addressing patients concerns and expectations in situations like this is very important in patient satisfaction. This patient was sent for an USS scan abdomen according to her wish colonoscopy should ideally be done. Also dietary advice should have been given to her in order to avoid food items that will make her symptoms more such as dairy products, legumes, cabbage and cauliflower.

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\*vs placebo in acute neck pain † Pain at rest in acute neck pain

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Use as directed on pack. Do not exceed recommended dose and frequency, as excessive dosage could be harmful to the liver. If fever persists, consult your doctor. For adverse events reporting please call on 0112636341 or email on pharmacovigilance@gsk.com

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