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# **JOURNAL OF THE VIVEKANANDA INSTITUTE OF MEDICAL SCIENCES**

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Original articles should not normally exceed 2000 words and should not have more than 6 tables or illustrations; they should report original research. Case reports should be limited to 600 words, with one table or illustration, and not more than five references. Letters should not exceed 400 words, and must be signed by each author. Articles on the organisation, operation and planning of medical care should be limited to 1500 words, with not more than four tables or figures.

Each manuscript should be arranged in this

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The Title page should have the title of the article, concise and informative; initial(s) and surname of each author, with the highest academic degrees (not more than two degrees and/or diplomas) of each author, their designation and department alongside.

The second page should repeat the article title and carry the abstract and key words.

Appropriate scientific nomenclature giving both genus and species should be italicised, with an initial capital and abbreviation for genus only, after a full spelling at first mention, thus: *Mycobacterium Tuberculosis*, the Myco. Tuberculosis. Drugs should be given their approved names, not their propriety names. Spelling should conform to the Oxford English Dictionary.

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Peer review is the heart of scientific publication. The Editor wishes to place on record the contributions of the following VIMS Faculty who have provided their time for peer review of the submissions:

Dr. Achintya Das (Professor, Dept. of Surgery)

Dr. Prabuddha Mukherjee (Associate Professor, Dept. of Medicine)

Dr. Ajitesh Roy (Assistant Professor, Dept. of Medicine)

Dr. Pranamita Ray (Assistant Professor, Dept. of Pathology)

Dr. Debjani Sinha Ray (Assistant Professor, Dept. of Radiology)

Dr. Suman Das (Visiting Surgeon, Maxillofacial Unit).

The Editor also wishes to thank Dr. Shaoni Sanyal, Senior Resident, Dept. of ENT Head Neck Surgery, for editorial assistance.

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## Editorial

### **Life in The Time of COVID 19**

I was in the UK in February 2020 when news of the spread of a new respiratory syndrome akin to SARS and MERS began to emerge from China. Later we would be told the outbreak began in the Wuhan province of China in December 2019. On my flight back from Newcastle to Kolkata via Dubai a handful of passengers were wearing blue surgical masks, but that was it. India reported its first case on 30<sup>th</sup> January, 2020 and by the time I returned there was supposed to be thermal screening of passenger arriving by international flights at all major airports. There was no evidence of this as I left Kolkata airport for home on February 23<sup>rd</sup>. The World Health Organisation (WHO) declared COVID 19 caused by novel corona virus SARS-CoV-2 a pandemic on 11<sup>th</sup> March, 2020. National lockdown was declared by the Union Government of India on March 23<sup>rd</sup> 2020 – and I think it is no exaggeration to say our lives changed forever.

Overnight we had to bring in systems and guidelines to both protect our own health and allow examination and treatment of patients. Very quickly we became experts on the differences between masks rated N95 and FFP3, correct donning and doffing procedures for PPE, and how to minimize aerosol generation during a procedure. As time went by we were bombarded with scientific papers and forwarded social media posts leaving a wake of confusion. An analysis in the respected scientific journal Nature, published in December 2020, estimated that more than 2,00,000 scientific journal articles and preprints related to the pandemic had been published by early December 2020.

We were also bombarded with webinars – at one point, in May or June 2020 there were 4 or 5

ENT related webinars happening every week. We quickly became conversant with Zoom, Microsoft Teams and Google Meets. The West Bengal University of Health Sciences asked all Institutes to introduce online teaching to make up for the deficit in resident training.

The residential doctors at the hospital stoically accepted the demands placed upon them of COVID duty and, in spite of all the challenges, the hospital remained open, providing service throughout the lockdown period.

Every Department had, of necessity, to find new ways of doing things, with guidance provided by a nodal committee constituted by the authority. In this issue of the Journal of the Vivekananda Institute of Medical Sciences, we will read about the ways in which our colleagues in the Departments of Obstetrics and Gynaecology, and ENT Head Neck Surgery faced the first wave of COVID 19, as well as the views of some residents regarding online teaching.

At the time of writing the above we were firmly in the grip of the second wave, which stretched the health system of our country to the limit. With lessons learnt first time around the Seva Pratishthan adapted as best as it could to live up to its name and provide service. Now, with the second wave receding and restrictions gradually being relaxed, we have time to evaluate what we did, what we could have done better, and what we should do next time around. With the publication of this issue we have cleared the backlog for preceding years, and now have to publish the 2 issues for 2021 to keep the Journal up to date. I appeal to all Faculty, Visiting Physicians and Surgeons, Senior and Junior residents, to submit papers for the forthcoming issues.

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Ranjan Raychowdhury, Executive Editor; Professor, Department of ENT & Head Neck Surgery, RKMS, VIMS

## **Clinical Audit of Health Services in The Department of Obstetrics and Gynaecology at The Ramakrishna Mission Seva Pratishthan During The Covid 19 Pandemic**

Babita Saha<sup>1</sup>, Arunabha Das<sup>2</sup>, Ashish Seal<sup>3</sup>, Goutam Giri<sup>4</sup>, Abhijit Ghosh<sup>5</sup>, Ayesha Khan<sup>6</sup>

### **Abstract :**

The emergence of novel coronavirus, termed SARS-CoV-2, and the potentially life-threatening respiratory disease that it can produce, COVID 19, has spread rapidly across the globe creating a massive public health problem. The Department of Obstetrics and Gynaecology was faced with major challenges at the outbreak of the COVID 19 pandemic. Initial planning was necessary to restructure and reshape our activities in order to provide COVID related care as well as to ensure safety of both patients and health workers. The most important measures included use of facemask, rational use of PPE, systematic screening and dedicated spaces for COVID 19 cases. In this article we have shared our experience in adapting our obstetrical and gynaecological care to this sudden crisis and evaluated our performance over the last one year.

The total number of deliveries from June 2020 to June 2021 was 1847. Among them only 78 (4.2%) women were COVID positive. We had tested all pregnant women near term or in labour before admission. COVID positive obstetric patients were managed according to standard protocol. Caesarean section rate was higher during this pandemic and NICU admission of newborns was slightly higher than previous years.

As there is limited data on the effect of COVID 19 in pregnancy at present, our management protocol must be updated from time to time to provide better care.

**Keywords :** SARS-CoV-2, COVID 19, Pandemic, Obstetrics & Gynaecology care, Pregnancy outcome

### **Introduction :**

The novel coronavirus COVID 19 has turned into a global public health crisis and it has worst-hit all the aspects of society especially the health care system. There has been a rapid increase in cases and deaths since it was identified in Wuhan, China in early December 2019.<sup>[1]</sup> There are limited reports on the impact of COVID 19 infection during pregnancy however there is a perception that pregnant women may be susceptible to develop more severe symptoms after infection with respiratory viruses due to physiological changes to their immune and cardiopulmonary systems.<sup>[2]</sup> Subsequent studies indicate that the clinical course of COVID 19 pneumonia in pregnancy is similar to that in non-pregnant women.<sup>[3,4]</sup> In addition, pregnant women do not have a higher risk of contracting COVID 19 infection or suffering from more severe disease than other adults of similar age.<sup>[5,6]</sup> The uniqueness of COVID 19 infection is the high rate of acquiring infection and incomplete understanding of transmission of infection.

The Department of Obstetrics and Gynaecology (OBG) is a part of Ramakrishna Mission Seva Pratishthan, Vivekananda Institute of Medical Sciences, Kolkata, a multidisciplinary postgraduate teaching hospital. The Obstetric division comprises a labour ward with

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approximately 3500 births per year and the Gynaecology division handles its own procedures, postsurgical care and emergency cases.

Awareness was raised about the issue of COVID 19 at the end of March 2020 in West Bengal. After the declaration of pandemic worldwide, a complete lockdown was declared in the state from 22nd March 2020. At the beginning of pandemic our hospital had neither the facilities nor the necessary resources to test the patients for SARS-CoV-2 infection. As a result we managed patients symptomatically, and transferred high risk patients to COVID designated facilities. Almost all departments had to reschedule their daily activities by reducing or cancelling non-urgent procedures for the benefit of COVID related care. The Department of OBG, dedicated to women's health, was no exception. This was however a double challenge for maintaining safe circuit for pregnant women as well as reducing other non-urgent activities.

COVID 19 may rapidly cause severe pneumonia and we had anticipated the acute shortage of ventilators, high flow oxygen therapy and the need for triage. Although there had been a few, sporadic, reports of exacerbation of disease or foetal disorders in pregnancy due to COVID, we knew that pneumonia in pregnancy can generally be severe because of the physiological changes that occur during pregnancy.<sup>[2]</sup>

#### **Education of the Health Personnel :**

The medical staff of our department were kept up to date with the latest information about the clinical features, diagnosis, management, complications as well as the hospital protocols regarding isolation, proper donning and doffing of the PPE kit, COVID testing, initial screening

of the patient attending the outdoor and emergency etc. Education of the patients and their caregivers was also needed regarding the methods of hand hygiene, selection & proper use of face mask, coughing etiquette, clinical features & transmission of COVID infection. Pregnant women were instructed to stay at home, avoid densely populated areas and also asked to seek medical advice in the event of any fever, cough, dyspnoea, weakness, loss of taste & smell sensation, diarrhoea etc.

#### **Establishing an Expert Committee & Management Strategy :**

An expert committee was established for diagnosis, planning of management and decision making. Committee members were from the Departments of General Medicine, Obstetrics & Gynaecology, Paediatric Medicine, physicians from ICU, Anaesthesia, Radiology etc. To prevent cross infection separate channels for patient transport were made for COVID and non-COVID patients and also for health personnel. Medical personnel were instructed to wear gown, mask, face shield, cap and medical latex gloves while caring for patients in the indoor and outdoor. Pre-examination screening was done by paramedical staff at the entrance of the outdoor premises and emergency.

#### **Antenatal Care :**

Intrauterine pregnancy confirmation and antenatal care are essential for pregnant women. However, we had to reduce hospital visits and cancel some of the visits to avoid further spread. Sometimes we had to discontinue the pregnant woman's regular visits and provide medical advice over the telephone for those who had a history of travel or close contact with COVID positive cases. The following visits were recommended:

- i) around 11 to 13 weeks for USG confirmation of intrauterine viable pregnancy with measurement of nuchal translucency, routine blood and urine investigations and blood pressure measurement
- ii) around 20 to 24 weeks for anomaly scan and oral glucose tolerance test
- iii) The third trimester routine visit every 2 weeks was changed to 3 to 4 weeks interval.

Certain surveillances such as blood pressure recording, foetal movement count, uterine height, foetal heart rate monitoring could be done at home or at nearby community hospitals. Patients were encouraged for frequent visits only if any complications arose.

#### **Admission Protocol of Pregnant Patients:**

Pregnant women may be COVID positive though asymptomatic.<sup>[7]</sup> It was, therefore, necessary to test every pregnant woman on admission to distinguish between COVID positive and negative patients and to improve the management protocol in this pandemic situation. The nursing and paramedical staff were asked to screen the epidemiological history and symptoms; record the temperature, and measure the oxygen saturation of all patients visiting the Department. Suspect patients were directly transferred to the fever clinic. After admission only one caregiver was allowed and asked not to leave the hospital during hospitalisation. Other people were not allowed to enter the obstetric department without permission. Patients who needed admission, but with the possibility of COVID infection, were kept in an isolation ward and nasopharyngeal swab for RT PCR sent for confirmation. Emergency patients such as vaginal bleeding, premature rupture of membrane, patient in labour were directly referred to the obstetric department. In some cases, delivery or surgery needed to be

performed before ruling out COVID infection. For that purpose, an isolation delivery room was arranged.

#### **Management of Child Birth of Suspected / Confirmed Covid Patients :**

A special isolation delivery room and operation theatre equipped with newborn resuscitation equipment was prepared. A plan for a separate intrahospital transport channel (i.e., corridor, elevator) was prepared for the positive patients. The anaesthetists and paediatricians were informed to attend the delivery room/OT in advance to ensure sufficient time for them to don PPE and complete protective preparation. All health personnel were instructed to strictly implement the proper hand hygiene along with all protective measures while handling suspected or confirmed COVID cases. The mode of delivery was preferably caesarean section unless labour progressed rapidly. This was to prioritise the maternal & child health care as well as for the safety of medical staff. In order to reduce the risk of transmission, anaesthetists also preferred regional anaesthesia over intravenous sedation or general anaesthesia. After delivery, mothers were shifted to the isolation ward along with the newborn as per the opinion of paediatrician. Newborns of COVID positive mothers were tested routinely after 48 hrs of delivery. Mothers were treated with standard protocol of postpartum care along with vitamin C, zinc, and multivitamins. For symptomatic patients we used hydroxychloroquine, azithromycin, aspirin, heparin, steroids and remdesivir as per the advice of physicians and updates from the national ICMR guidelines.

#### **Post Partum Care:**

Asymptomatic COVID 19 positive mothers were

allowed to be roomed in, isolated from others. Temporary separation of baby from covid positive mothers was done if either was sick. Breast feeding was encouraged in all babies irrespective of covid status maintaining proper hand hygiene and wearing mask. All newborn of covid positive mothers were tested with RT PCR 48-72 hours post-delivery. Asymptomatic patients were discharged as per standard protocol.

### Statistical Records of Obstetrics and Gynaecology Department to See The Impact of Covid Infection

**Table 1: Total deliveries per year**

Year	Total deliveries
April 2016 to March 2017	3566
April 2017 to March 2018	3551
April 2018 to March 2019	3514
April 2019 to March 2020	3254
April 2020 to March 2021	1783

We have seen the total number of deliveries reduced by almost 50% during the pandemic. This may be because of lack of intent of the people to have pregnancy and lack of transport from rural to urban centres due to lockdown.

**Table 4: Outcome of babies of COVID +ve mothers**

COVID +ve newborn	Preterm	Intrauterine growth restriction	Low birth weight	Admission in NICU	Neonatal death	Intrauterine fetal death
08	18	06	17	23	0	01
10.2%	23%	7.6%	21.7%	29.4%	0%	1.2%

Out of 78 newborns, only 8 (10.2%) were detected COVID positive while tested routinely after 48 hrs of birth. We had no neonatal death for COVID positive mothers but we had 11 (0.6%) neonatal deaths amongst COVID negative mothers. There was only 1 intrauterine foetal death among the COVID positive mother and 13 among the COVID negative mothers.

**Table 2: Total gynaecological operations per year**

Year	No. of Operations
April 2018 to March 2019	784
April 2019 to March 2020	649
April 2020 to March 2021	269

The total number of gynaecological operations also came down drastically because we had postponed non-emergency procedures.

**Table 3: Caesarean section rate**

	LSCS	VD	TOTAL
COVID +ve	57(73%)	21(27%)	78
COVID-ve	1149(65%)	620(35%)	1769

The total number of deliveries from June 2020 to June 2021 was 1847. Among them only 78 (4.2%) women were COVID positive. Out of 78 deliveries, 57 (73%) were delivered by caesarean section (LSCS) and only 21(27%) were delivered vaginally(VD). Among the COVID negative patients, 65% underwent LSCS and 35% had vaginal delivery. In our hospital the overall caesarean section rate before this pandemic was 52%-55%. So, caesarean section rate was higher during this pandemic due to fear of spread of this highly infectious disease.

**Table 5 : NICU admission of newborns per year**

Year	No. Of newborns admitted in NICU following birth
April 2018 - March 2019	302 (8.6%)
April 2019 - March 2020	309 (9.4%)
April 2020 - March 2021	183 (10.2%)

Newborns admitted in NICU during this pandemic was slightly higher than previous years.

**Table 6 : Comorbidities of COVID +ve mothers**

Total COVID +ve mothers	Gestational diabetes mellitus (GDM)	Hypertension	Intrahepatic cholestasis of pregnancy (ICP)
78	17(21.7%)	05 (6.4%)	05 (6.4%)

Maximum COVID positive patients were delivered in August 2020 (probably peak of first wave) and May 2021 (peak of second wave). Out of 78 women only 6 (13%) had mild symptoms like fever, cough etc. No COVID positive mother was admitted in ICU. Initially in the month of April, 2020 we transferred 3 COVID positive asymptomatic mothers to designated hospital for delivery as the facilities for segregating and managing COVID positive patients were not prepared by that time. In the first wave we noticed that most of the pregnant COVID positive women were asymptomatic or mildly symptomatic and did not require hospitalisation except for obstetric reason. In the second wave we saw a few symptomatic mothers having high grade fever and cough; 3 patients admitted with respiratory distress required oxygen therapy in late second and third trimester but they recovered. Incidentally there were 2 maternal deaths during this period but they were not related to the current pandemic.

**Summary :**

- Although our hospital is not a designated COVID-19 centre, our study revealed that there was a high incidence of asymptomatic positive pregnant women. Hence all patients were treated with proper precautions.
- According to ICMR guideline, we tested all pregnant women near term or in labour before admission.
- COVID positive obstetric patients were managed according to standard protocol.

- Health care workers followed the standard guidelines during managing the patients like use of PPE kits, face shields, N95 masks etc.
- Caesarean section rate was higher during this pandemic and NICU admission of newborns was slightly higher than previous years.

**Conclusion :**

The contagiousness of SARS COV 2 and the high possibility of asymptomatic transmission constitute a true problem for health care management. The need to separate the affected

individuals whether patient or health care provider, is still valid. Every subject must be considered as potentially affected. Use of protective measures such as PPE kit, facemask etc. designated rooms for suspected or positive patients and systematic screening are essential to prevent spread of infection. On the basis of this management strategy, we have run our department. However, success of this strategy depends on sufficient medical resources and the

health care setting to some extent. Many of our doctors, nurses, paramedical and cleaning staff were infected and recovered. Now we have completed vaccination against COVID 19 of all staff members. At the present time, limited data is available on the impact of COVID 19 on pregnant women and their babies. So, our management protocol must be updated continuously with clinical evidence and knowledge about COVID 19.

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## **Covid 19 and Online Post Graduate Training in ORL- HNS: Initial Experience of An Indian Tertiary Centre**

Shaoni Sanyal<sup>1</sup>, Ranjan Raychowdhury<sup>2</sup>

### **Abstract :**

**Background :** The World Health Organisation (WHO) declared COVID 19 caused by novel corona virus SARS-CoV-2 a pandemic on 11<sup>th</sup> March 2020.

The identification of Aerosol generating procedures (AGPs) as major routes of iatrogenic spread of the virus effectively led to all elective ORL-HNS surgery being put on hold. The West Bengal University of Health Science advised all affiliated institutes to implement online teaching and training. We present our initial experience of online post-graduate training in ORL-HNS

**Methods :** This is a Qualitative descriptive study set in the Dept of ENT & Head-Neck Surgery at our institute. Microsoft Teams was chosen for the purpose of online teaching. The online academic schedule consisted of 4 one-hour sessions each week- journal club, seminar, lecture and surgical video. At the conclusion of each session an online feedback form was circulated on departmental academic group created on WhatsApp. At the end of each month, all the feedback regarding the classes was compiled and letters were sent out to all members who had presented in either of the academic activities.

**Result :** Sixteen people participated in the online teaching programme designed by the department. The response rate of the survey was 81%. The preferred mode of access to Microsoft Teams was via laptop/ mobile (7/13). Connectivity was commonly achieved by using Wi-Fi (5/13) or Wi-fi and mobile internet (5/13). Most of the

problems were associated with connection to Microsoft Teams (5/13). Some respondents experienced issues with the audio (4/13) and visual quality (6/13).

All agreed that using an online platform for teaching was convenient and felt this mode ensured greater participation. Most agreed that the quality of interaction was much better in traditional classes as opposed to online classes. Trainees agreed that feedback regarding their presentations helped to improve performance.

**Conclusion :** Our experience suggests that online teaching can serve as an adjunct to traditional methods of teaching, but not replace it entirely

**Keywords :** Training Support, COVID 19, Faculty, Feedback

### **Introduction :**

The World Health Organisation (WHO) declared COVID 19 caused by novel corona virus SARS-CoV-2 a pandemic on 11<sup>th</sup> March 2020. The outbreak of COVID 19 started in the Wuhan province of China in December 2019.<sup>[1]</sup> The first case in India was reported on 30<sup>th</sup> January 2020. Latest figures state there are 9,78,042 active cases in India. This pandemic has brought about a paradigm shift in all aspects of our lives.

Medical education in all postgraduate specialties has been impacted. The Medical Council of India postponed the Final Year Examination of Post Graduate courses and delayed counselling for admission to Post graduate courses for the academic session 2020-2021.<sup>[2]</sup>

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<sup>1</sup>Senior Resident, Corresponding Author; <sup>2</sup>Professor, Department of ENT Head & Neck Surgery, RKMS, VIMS

The declaration of National lockdown by the Union Government of India on March 23<sup>rd</sup> 2020 was almost immediately followed by drastic curtailment of elective admissions and surgery across the country, as all resources were diverted towards diagnosis and management of COVID-19 patients, with obvious disruption of surgical training.<sup>[3]</sup> The identification of Aerosol generating procedures (AGPs) such as mastoid surgery, endoscopic sinus surgery and laryngoscopy as major routes of iatrogenic spread of the virus effectively led to all elective ORL-HNS surgery being put on hold.<sup>[4]</sup>

Faced with this situation the West Bengal University of Health Science advised all affiliated institutes to implement online teaching and training from April 2020.

We present our initial experience of online post-graduate training in ORL-HNS.

**Aim :**

To present our initial experience of post-graduate Training in ORL HNS at a tertiary medical institute in West Bengal during the COVID 19 pandemic.

**Methods :**

**Setting :** Department of ENT & Head-Neck Surgery at a Post graduate training institute in West Bengal.

**Type of Study :** This is a Qualitative descriptive study in three parts:

1. Description of online teaching activity
2. Feedback from the faculty (trainers) regarding perceived advantages and disadvantages of online training as assessed by a survey after 10 weeks
3. Feedback from the trainees regarding their

experience of online training as assessed by a survey after 10 weeks

**Description of Online Teaching Activity :**

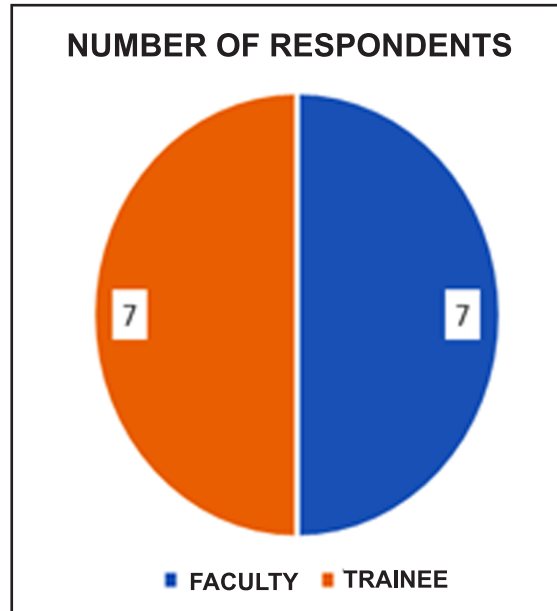
1. **Selection of platform :** For the purpose of online teaching, Zoom and Microsoft Teams were considered. At the time several issues with the security of the free to use Zoom platform were highlighted by the media so the free version of Microsoft Teams was selected. This has been found to be reasonably user-friendly by both senior and junior members of the department
2. **Online academic schedule :** At present the online academic schedule consists of 4 one-hour sessions each week- journal club, seminar, lecture and surgical video. The first two are resident led, while the lecture and surgical video are faculty led. The lectures and surgical video sessions were included to compensate for the lack of bedside clinical training and elective surgery. In addition, external online webinars for which advance information is available are also incorporated in to the schedule (e.g., online Journal Club by the State branch of the Association of Otolaryngologists of India)
3. **Online teaching session :** The call/ meeting is set up by the designated moderator ten minutes before the scheduled time to allow all participants to log in and the presenter to share his/her screen with the presentation. Once the presentation is completed the discussion is facilitated by the moderator to avoid simultaneous comments/answers. At the conclusion of each session an online feedback form is circulated on the departmental WhatsApp academic group. At the end of each month, all feedback regarding

the classes is compiled and sent to all presenters.

4. A major problem was uploading of teaching material (journal articles, Powerpoint™ presentations, surgical videos) to the Teams site, as this was dependent upon good internet connectivity, and there were concerns for how confidential such material would be once uploaded. It was decided to not upload any material and instead use the Screenshare function. For journal club the chosen papers were circulated via the WhatsApp group at the beginning of each month.

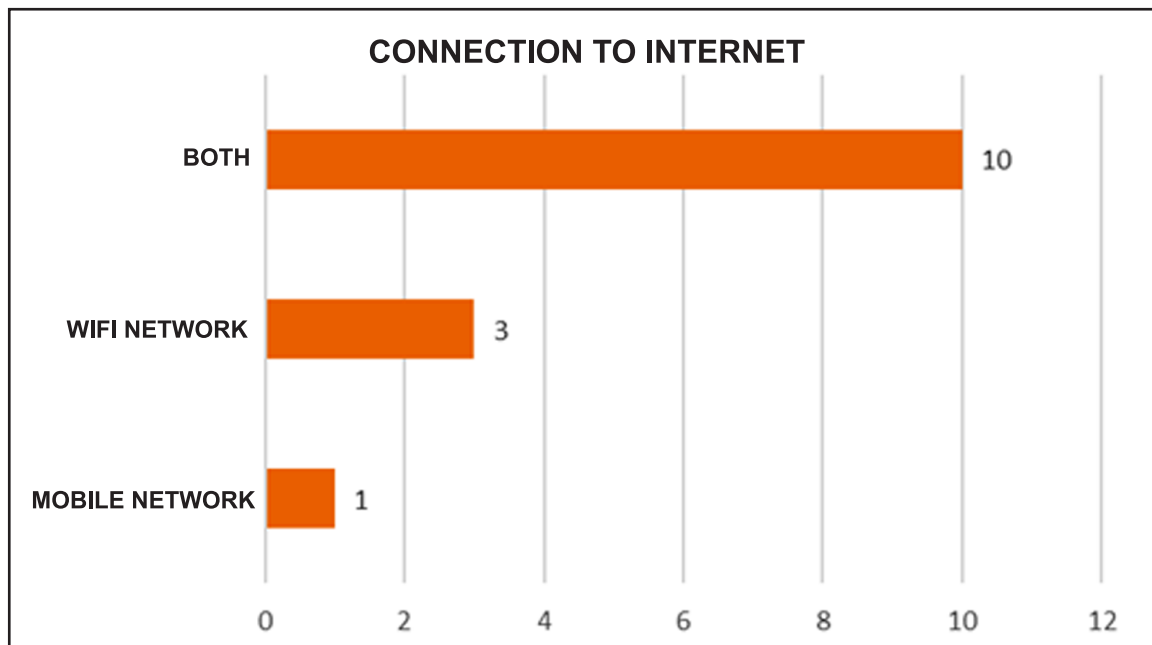
**Results :**

A total of 14 people responded to the survey. Half of them were trainees and the other half were faculty members. (Fig 1)



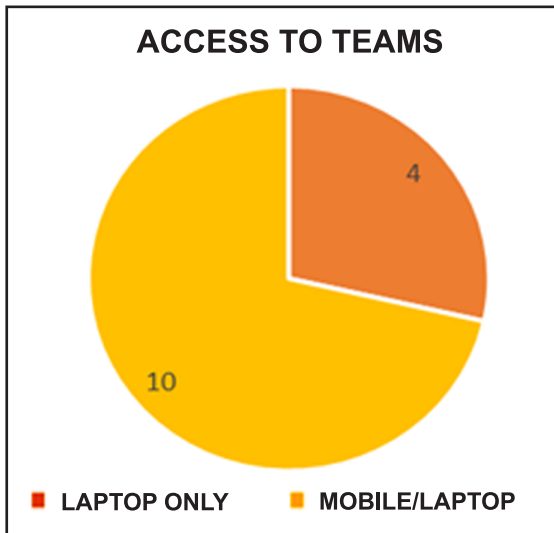
**Fig 1: Number of respondents**

Most respondents used both wi-fi or mobile connection (71%). (Fig 2)



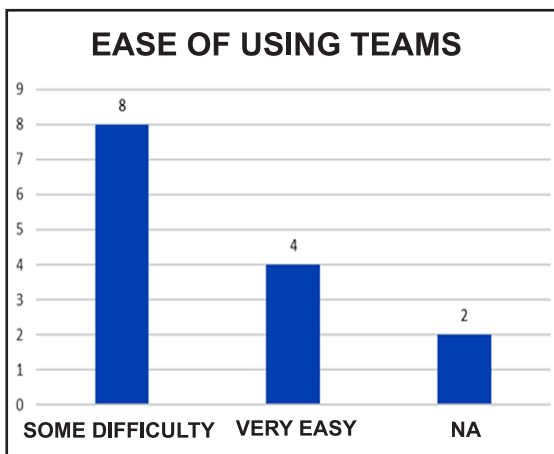
**Fig 2: Mode of connectivity**

Of the 14 respondents, only 4 exclusively used the laptop to access teams. (Fig 3)



**Fig 3: Mode of Access**

Some difficulty was faced by 57% (8 out of 14) of the respondents, in using Teams as an online teaching platform. Two respondents were only participants who did not present any academic sessions online. (Fig 4)



**Fig 4: Ease of using teams**

#### Feedback from The Faculty - Virtual vs Traditional Teaching

There are nine faculty members in our department. Six of them responded to the survey. Everyone agreed that online teaching was more

convenient. Two of the seven respondents felt this mode of teaching ensured greater participation. Save one all agreed that the quality of interaction was much better in traditional classes as opposed to online classes. It was felt that online classes were not a substitute for traditional teaching, especially in a surgical field. The faculty members also felt that the quality of the class was greatly dependant on the quality of internet signal. There was some concern regarding the feasibility of this method of teaching once the official lockdown was lifted and elective work resumed. Online teaching, being more structured than a small group discussion or ward round, requires development of engaging and varied content. Preparing lectures and surgical videos on a weekly basis requires time, which may not be possible once the elective workloads increase.

Most of the faculty (66.67%) were able to join Microsoft Teams using their mobiles/laptops and connect using wi-fi or mobile internet. Most of the faculty found it easy to use. There was some difficulty in uploading and downloading content, connectivity, audio and video quality.

#### Feedback from The Trainees - Virtual vs Traditional Teaching

All 4 Junior trainees and 3 Senior trainees responded to the survey. All trainees felt that online classes were more convenient in terms of accessibility and timing, but the dynamic nature of interaction was missing. The addition of surgical videos was appreciated by the Junior trainees. They all found feedback helpful to improve their performance. Participation of all members of the faculty during online seminars and journal club was appreciated. No trainee felt that online teaching in its present form could satisfactorily replace traditional teaching, especially that of clinical examination and surgical skills.

Most of the residents (71.42%) were able to join Microsoft Teams using their mobiles/laptops and connected using wi-fi or mobile internet. Most residents (86%) found it difficult to connect to Microsoft Teams, upload and download content. On occasion all residents faced issues with audio and video quality. They were familiar with other online platforms such as Zoom, YouTube, Facebook Live, Google Meet, Go to Webinar, and WebEx meet; Microsoft Teams was as user-friendly as these. One resident found Zoom easier to use than Microsoft teams.

### **Discussion :**

Clinical experiences are vital to the learning process, but social distancing norms and infection risk have significantly impacted traditional outpatient and ward teaching. Elective operations were halted from end of March to mid-June due to the national lockdown. In response to COVID-19 medical education has transitioned to rely on online formats entirely.

Online teaching presents reliable and reusable content in a format that is convenient to the learner. It transcends geographical boundaries and time zones. Besides providing content, the information presented can be enhanced by multimedia. The first reports of Web-based medical education appear in 1992.<sup>[5]</sup>

Virtual learning, so far had been used as an adjunct to the traditional methods of teaching in surgical disciplines. The National Board of Education has been conducting tele-learning in the form of case presentations and lectures for several years now. Another trend prevalent prior to COVID pandemic was sponsored clinical meets with live telecast of surgery.

Scagnoli et al in 2017 surveyed 96 undergraduate and graduate business major students regarding the utility of Video Lectures (VL).

Undergraduates considered VL useful based on how it helped in the completion of assignments, while graduate students perceived them as more relevant for their learning.<sup>[6]</sup>

After the declaration by WHO of a global pandemic on 11<sup>th</sup> March 2020, several authors from around the world have discussed the use of online teaching to mitigate the impact on surgical training.

In the USA, Chick et al described various modes by which surgical resident training could be maintained using innovative solutions such as the flipped classroom, online practice questions, teleconference and surgical video demonstration etc. They recommended a platform in which users could submit questions through a live chat function. In their opinion this decreased participant talk-over and allowed for a more fluid presentation. They also recommended the use of surgical videos to make up for loss of time in operating room. In addition, residents were encouraged to access freely available online content from various American surgical societies.<sup>[7]</sup>

They mentioned a number of limitations, such as some faculty struggling with novel technology, participants with poor bandwidth connections, and difficulty reviewing imaging. They felt these challenges could be overcome through an investment of time and effort by staff providers familiar with these techniques.

In Chile, Alvarez et al described how otolaryngology residents were expected to perform pre-established simulation training programmes for nasal endoscopic surgery and for myringotomy with ventilation tube placement. Teaching sessions such as Seminars (3 per week), conferences (4 per week), departmental meeting and curriculum modules (1 per week) as well as assessments were all moved to an online platform.

The initial programme was implemented in early April, when most patient activities had been suspended and residents were at home. Later, with increased workload, it was adjusted to a maximum of two seminars per week.<sup>[8]</sup> Otolaryngology residents from Australia, Canada, the US and the UK described the impact upon their training. In Australia unit meetings were held using programs such as Microsoft Teams or Zoom. In Canada teaching sessions were moved to online platforms and offered to residents across the country, rather than simply a home institution. Larger institutions in the United States partnered to form a collaborative multi-institutional education programme, offered throughout the day, every day.<sup>[9]</sup>

In the UK the Association of Otolaryngologists in Training (AOT) produced a new education calendar with a timetable of all ENT related webinars. ‘ENT Grand Rounds’ was started on 12<sup>th</sup> April covering important curriculum topics.<sup>[8]</sup> Comer et al in the US pointed out the risk of Covid Induced Limitations outlasting the cache of educational materials available to most centres. A two-year cycle of resident education could theoretically be exhausted in less than two months, resulting in significant repetition if only internal departmental lectures and lecturers were used. This could lead to educational fatigue of the residents, and teaching fatigue on the part of faculty within a single department. To avoid this, 3 multi-centre consortia have developed offering a web-based teleconferencing format for live lectures by faculty from numerous institutions across the US for a total 8 hours of lectures daily.<sup>[10]</sup>

In Africa, the Division of Otolaryngology at the University of Cape Town (UCT) began virtual academic meetings and ward-rounds using Zoom. An online academic programme, ‘UCT-Africa

Virtual ENT’, was started in April 2020. It provides open access to academic presentations and virtual academic ward rounds for all ENT departments in South Africa as well as other African countries including Zimbabwe, Ethiopia, Ghana, Tanzania, Uganda, Kenya, Malawi, Libya, Democratic Republic of Congo, Rwanda, Nigeria, Mauritius and Namibia.

A survey revealed that all eight South African ENT training centres were participating in the programme. Trainees from other African countries make up 46% of attendees. Over 90% of respondents stated that their training had been compromised by the COVID-19 pandemic, and 97% found learning on a virtual platform beneficial. Almost all respondents felt that such cross-institutional collaboration enhanced their learning and 90% agreed that such academic meetings should be formally incorporated into their training programmes. Most respondents were of the opinion that such a platform would provide sustainable educational in the future.<sup>[11]</sup> Our learning programme was conducted using Microsoft Teams. Each session was conducted by a designated moderator. This ensured ease of interaction.

Most respondents in our survey faced many limitations, such as difficulty with novel technology, poor bandwidth connections, and difficulty reviewing imaging. This was in agreement with the findings of Chick et al. In contrast to the training programme described Alvarez et al in Chile, our programme lacks simulation training. Our initial programme of weekly seminars, journal clubs, lectures and surgical videos was easily implemented during the national lockdown; but as normal duties resumed the increased workload required alteration of the schedule. This was similar to the experience in Chile. We agree with Chick et

al that preparation of online teaching material requires considerable investment of time and effort.

One of the short comings of our teaching programme is that it is limited to a single institute. Comer et al, noted that a two-year cycle of resident education could theoretically be exhausted in less than two months of online teaching. This could be overcome by creating a joint teaching programme with other departments, similar to the consortia suggested by them. However, in addition to our in-house teaching, trainees are encouraged to access ENT webinars organised by various national specialty associations (e.g., the Association of Otolaryngologists of India, Indian Academy of ORL-HNS, Foundation for Head and Neck Oncology etc) as well as online international workshops and meetings. This allows access to

high quality educational material from national and international experts.

Another issue relates to the use of the free version of Microsoft Teams: any uploaded material could possibly be accessed by outsiders hence all lectures and videos are presented by screen sharing rather than uploading to the site. As a consequence, the material is not available for trainees to review later.

### **Conclusion :**

Although the first reports of Web-based medical education appear in 1992<sup>[5]</sup>, the COVID 19 pandemic has forced ORL – HNS departments across the world to embrace online teaching and training. Our experience though small indicates several problems with this format, particularly with surgical training. We feel that post-Covid, there will remain a significant role for online training in tandem with more traditional methods.

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## Impact of Covid-19 on Otolaryngology Practice – An Institutional Experience

Saurabh Gupta<sup>1</sup>, Amitabha Roychoudhury<sup>2</sup>

### Abstract :

The COVID-19 crisis has had unprecedented impact on otolaryngology clinical practice. Due to lack of robust scientific recommendations on this subject, individual institutions created their own standard protocols, based on evidence and advisory from scientific societies. The way in which the emerging knowledge has helped us to deal with this ongoing crisis has been discussed.

Otolaryngology practice involves close contact with mucosa of the upper aerodigestive tract and therefore ENT surgeons and support para-medical staff are considered high risk for coronavirus transmission. Hence, specific protective measures for ENT clinical examinations, endoscopic procedures and surgeries during COVID-19 pandemic were recommended.

Cancellation of elective surgeries and decreased live doctor-patient interactions greatly affected resident education. Virtual learning with online lectures, seminars, surgical videos discussions were initiated to deal with academic challenges of the pandemic.

Knowledge and evidence about the impact of COVID-19 infection on otolaryngology clinical practice are increasing rapidly. In addition to patient management, safety of health care professionals should be the major priority as we continue to strive through this pandemic.

**Keywords :** SARS-CoV-2, COVID-19, Pandemic, Otolaryngology, Contamination, Aerosol, PPE

### Introduction :

The world is experiencing an unprecedented challenge due to the COVID-19 pandemic. The 2019 novel corona virus disease is a highly contagious disease spread by SARS-CoV-2 virus. It was declared a public health emergency by the World Health Organisation (WHO) in January 2020.

Human-to-human spread of Corona virus occurs mainly through respiratory secretions. Therefore, health care workers who are involved in the management of patients with diseases of the upper aerodigestive tract are highly susceptible to contract the disease during the pandemic. Dentists, otolaryngologists, head and neck surgeons, ophthalmologists, chest physicians, anaesthetists, intensive care specialists and speech therapists are vulnerable in particular. Therefore, it is imperative for these professionals to use special protective measures.<sup>[1]</sup>

As ENT surgeons, we are particularly exposed to viral transmission directly through mucus and aerosolized particles during clinical examination, endoscopies, surgeries, or other interventions in the head and neck area.

Evidence from China, Italy and the United Kingdom suggests that otolaryngologists are among the highest risk group of contracting the COVID-19 virus, especially when clinical examination and procedures are performed without using appropriate personal protective equipment (PPE).<sup>[2,3]</sup>

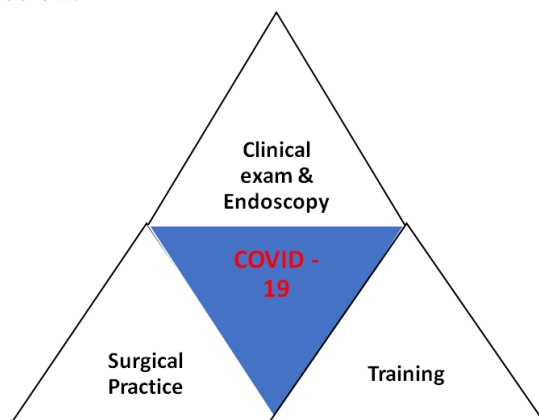
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Initially, lack of viable treatment or immunization against this virus dictated the Government to enforce social distancing. With “Lock Down” regulations and cancellation of elective surgeries, the number of non-emergency patients attending hospitals declined sharply.

In this article we attempt to focus on the impact of this disease on ENT practice, based on emerging evidence and published recommendations. A brief account of how a tertiary care hospital has handled the crisis with regard to ENT and Head Neck practice, and subsequent attempt to transit towards normalcy is also included.

The pandemic has severely affected all the aspects of ENT and Head Neck practices, as depicted below.



#### **Impact on Clinical ENT Examination :**

Any patient attending for consultation may be symptomatic or asymptomatic COVID positive. While performing clinical ENT examination, all patients should be considered potentially disease positive and appropriate precaution should be taken.

#### **1) Appointment System and Teleconsultation:**

Ideally, patients with time-sensitive, urgent, and emergency medical conditions such as head and neck cancers, airway emergencies, head and

neck abscesses, acute otitis media, acute mastoiditis, complicated sinusitis, sudden hearing loss, facial paralysis or facial trauma are expected to form the main bulk of OPD patients during such pandemic.<sup>[4,5]</sup> Our hospital set up did not permit prior appointment and prioritizing OPD appointments or teleconsultation. However, we restricted the number of patients seen in OPD, based on above criteria.

#### **2) Screening of Patients at Hospital/OPD**

**Entry :** All patients entering the hospital were centrally screened for history of respiratory illness with fever. Pulse oximetry and thermal screening was also done and patients with suspected viral illness were directed to the “Flu Clinic”. Patients with specific ENT problems only were registered for the ENT clinic. At the entrance of the ENT clinic, it was ensured that all patients were properly masked and no attendant was allowed into the OPD except for paediatric patients.

#### **3) OPD Room Setting :**

Standard recommendations suggested clinical ENT examination in a Negative pressure room. Since this was not feasible in our setup, we designated a non-air-conditioned room with efficient cross ventilation for OPD services. The room was fumigated every day at the end of the OPD hours. In all cases, the clinical examination was limited to the absolute necessary ones. Indirect laryngoscopy was avoided. Diagnostic nasal endoscopy and Rigid fibre-optic laryngoscopy were absolutely avoided in OPD and postponed for non-urgent indications.

#### **4) Personal Protection for Doctors & Health**

**Care Workers :** The appropriate protection followed was N95 mask, goggles or face shield, fluid resistant gown, surgical cap, and double gloves. The doctors would change gloves if they got soiled, and refrained from eating/drinking during OPD timings. Proper Donning and

Doffing areas were designated.

**5) Emergency Duties :** The hospital had designated areas for Covid and Non-Covid emergencies. All duties were undertaken with full protective gear. If the patient was later found to be COVID-19 positive, the trainees had to undergo RTPCR swab testing and quarantine if required.

#### **Impact on Endoscopic Procedures:**

Endoscopy in ENT is considered a high-risk procedure for the transmission of the SARS-CoV-2 virus.<sup>[6,7]</sup> Particularly, endoscopic examination of the nose and larynx are considered aerosol-generating procedures.<sup>[8]</sup> The virus appears to be present in the upper aerodigestive tract, with very high concentrations in the nasal cavity and nasopharynx.<sup>[9]</sup> It has also been shown that viral aerosol particles may remain in the air for up to three hours.<sup>[10]</sup> Routine endoscopy services were suspended during the initial stage of pandemic. However, it was performed in minor OT for patients with high priority e.g. epistaxis, suspected malignancy and airway obstruction. For laryngeal examination, flexible naso-laryngoscopy was preferred. This was done with full PPE (N95 or equivalent mask, water resistant gown/wear-on, face shield, head gear & double gloves) (Fig.1). COVID-19 RTPCR status was prerequisite prior to all elective endoscopies.



**Figure 1 Flexible Laryngoscopy with full protective measures**

#### **Impact on Operative Procedures :**

The European Rhinologic Society recommended suspension of all non-urgent ENT surgeries at the onset of the pandemic.<sup>[11]</sup> Endoscopic sino-nasal surgery, skull base and laryngological procedures in particular appeared to be high risk because of aerosol generation. The UK National protocol recommended that the surgeons use N95 mask, Personal protective equipment (PPE), glasses or full-face shield and double-gloving.<sup>[12]</sup> In addition, personnel in OT were to be restricted to the minimum.<sup>[12]</sup> The use of powered devices (Micro-debriders, High speed micro-motor drills) were to be avoided as these cause aerosolization of blood and other tissues.<sup>[13]</sup>

Patients with head and neck cancer were “time-sensitive” cases: surgery was essential and could not be avoided. Procedures without exposure of the mucosa, like neck or thyroid surgery, were considered at lower risk of aerosol generation.<sup>[14]</sup>

Tracheostomy is one of the most frequent urgent ENT surgeries. Due to the number of droplets and aerosols produced, tracheostomy and postoperative care (suctioning, wound dressing and tube changes) in Covid-19 patients were associated with a very high transmission risk to the entire health care team. Every patient requiring emergency tracheostomy was assumed COVID-19 positive as delaying the surgery while waiting for RTPCR test was not feasible.<sup>[15]</sup>

In COVID-19 patients, the decision of elective tracheostomy was considered only if absolutely necessary.<sup>[16]</sup> Tracheostomy in intubated patients was undertaken in patients with stable lung condition; not earlier than 2 weeks after intubation and preferably with negative RTPCR testing. It was avoided during periods of respiratory instability or high respiratory dependence.<sup>[17]</sup>

For tracheostomy we created a departmental protocol adapted from the UK national guidelines.<sup>[12]</sup> Postoperatively, the tube cuff was kept inflated; tube change was delayed, if possible, till RTPCR testing was negative. Tracheal tube suctioning was done with full PPE protection.

### **Departmental Tracheostomy Protocol**

- Full PPE to be used.
- Preferably to be done in operating theatre or adjacent room to ICU
- Use of cuffed and non-fenestrated tracheostomy tubes
- Under general anaesthesia with complete muscle relaxation to avoid coughing
- Experienced surgical team for minimizing exposure time
- Careful waste disposal after the procedure

We created a departmental Standard Operating Procedure for surgery guided by the above-mentioned recommendations. We took up biopsy for suspected malignancies, acute and chronic sino-nasal and mastoid disease with complications, head&neck surgeries for neoplastic diseases etc. Surgeries were performed by the most experienced member of the team. Our surgical team entered the operating room 15 minutes after the patient was induced and intubated.<sup>[18]</sup> Standard full PPE protection was followed for all surgeries.

Otologic surgery demands use of high-speed drills. Therefore, we draped the microscope with a transparent sheet to form a tent over the operative field to create a contained environment to minimize aerosol release during bone drilling. This was adapted from recommendations of

the American Neurotology Society.<sup>[19]</sup> For sino-nasal surgeries cold steel instruments were preferred and use of diathermy, micro-debrider and coblation was avoided.

All the protocols followed were the same for COVID-19 RTPCR negative and positive patients. The only difference was that positive patients were operated upon in the designated Covid Operating Room in the hospital.

### **Impact on Post Graduate Training :**

The pandemic has had a tremendous impact on training due to the substantial loss of training hours and significant psychological influence. To date, there is limited literature on how medical education should be handled amid a pandemic and how residents evaluate the implementation of such contingency planning.<sup>[20]</sup>

In general, the pandemic has caused considerable stress for resident ENT trainees in many aspects such as:

- Disruption of training
- Loss of clinical and operative exposure
- Tedious duties in Covid emergency and wards
- Fear of exposure despite PPE usage
- Lack of live interaction during case and paper presentations

On the other hand, positive aspects of the crisis are:

- increased acceptance of telemedicine
- adaptation to online teaching on virtual platforms
- extra time available for research work
- Ability to handle unprecedented crisis in medical practice

The cessation of elective surgery during this

time decreased the number of opportunities for ENT residents to learn in the operating room. Diminution in elective procedures also led to fewer pre-operative and post-operative patient visits causing less live experience with patients. Final year post graduate trainees and senior residents felt that the crisis was especially disruptive to their residency training, likely because they lost important opportunities to perform tasks more independently.<sup>[21]</sup>

It was reported that healthcare trainees had significant concerns for their safety and many of them had adverse emotional impact handling the pandemic.<sup>[22]</sup> Trainees had to isolate themselves from family members due to the fear of transmission of the disease.

In our institute, we devised a modified training program for junior and senior residents.

- All lectures, seminars and journal clubs were conducted on a digital platform where all trainees and faculties could take part from home or hostel
- To compensate for the lack of surgical exposure to the trainees, unedited surgical videos were screened by the faculty virtually on the digital platform

- With the initial peak of the pandemic declining, hands-on cadaver dissection exercises were resumed in the department
- The trainees were encouraged to present at state and national level virtual meetings and conferences

### **Conclusion :**

Covid-19 pandemic has been an unprecedented challenge for the medical community. As the pandemic is now slowing down all over the world, medical practice has adapted to the new normal. However, there are always concerns of a potential new wave of the pandemic which may again dampen the transition to the so-called normalcy. ENT as a speciality suffered a tremendous impact of this disease in clinical practice, surgical practice and postgraduate training. ENT surgeons and support staff are at particular risk for contracting the disease. Therefore, their protection is of utmost importance. We have navigated fairly well at our institute through the pandemic, striking a balance between safe practice and doing justice to our trainees. As the knowledge of Covid-19 pandemic is rapidly evolving, we need to keep ourselves updated with the new recommendations.

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## Survey of Undergraduate Training in ENT : Expectation vs Reality

Shaoni Sanyal<sup>1</sup>, Ranjan Raychowdhury<sup>2</sup>

### Abstract :

**Background :** The undergraduate curriculum has recently been revised by the Medical Council of India after nearly two decades to lay more emphasis on competency-based training. We set out to survey the exposure graduates have had to ENT during their undergraduate training.

**Methods :** A questionnaire-based survey was conducted amongst the interns of our institute who had completed their ENT rotation by October 2019. Feed-back from the Departmental faculty was obtained to assess basic knowledge of ENT, examination skills and management of common ENT conditions.

**Results :** Thirty-one interns completed the questionnaire. The majority of the respondents (71%) belonged to private medical colleges of West Bengal and the rest were from foreign medical universities. Most respondents felt confident in being able to perform ENT examination. Nearly half the respondents however, had not observed common ENT operations and Emergency procedures. Despite the lacunae in their undergraduate training in terms of observing surgical and emergency procedures, 84% respondents were satisfied with their course structure.

**Conclusion :** There are great variations in the undergraduate training programmes in medical colleges, which has led to discrepancy in knowledge and skills of Interns. Competency based training implemented since August 2019 may be able to correct these deficiencies.

**Key words :** Universities, Curriculum, Surveys and Questionnaires, Faculty

### Introduction :

Disorders of the ear, nose and throat affect a large subset of patients in general and paediatric practice.<sup>[1]</sup> A three-year, retrospective, cross-sectional study carried out in West Bengal recorded that 9051 patients had attended the ENT emergency from January 2008 to December 2010 in one government medical college alone. The most common emergencies were earache, epistaxis, foreign body nose in children, tonsillitis and stridor.<sup>[2]</sup>

The medical undergraduate training programme as designed by the Medical Council of India (1997) is a five-and-a-half-year course. The average ENT rotation is for a period of 8 weeks, with a 2-week rotation during internship. The broad goal of teaching undergraduate Otorhinolaryngology is to impart adequate knowledge and skills for management of common disorders and emergencies.<sup>[3]</sup>

The undergraduate curriculum has recently been revised by the Medical Council of India (2018) after two decades to lay more emphasis on competency-based training.<sup>[4]</sup>

As a Post Graduate Institute, we have interns from all over the country. The aim of our study was to survey their exposure to ENT during their undergraduate training.

### Materials and Methods :

A questionnaire-based survey was conducted

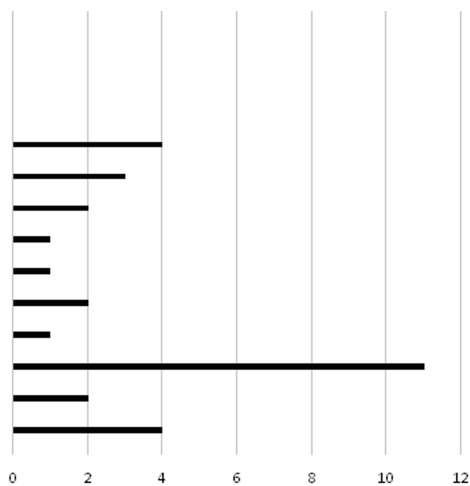
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amongst the interns of our institute who had completed their ENT rotation by October 2019. Feedback from the Departmental faculty was obtained to assess basic knowledge of ENT, examination skills and management of common ENT conditions. The results were tabulated using Microsoft Excel. As this was a voluntary questionnaire-based survey of opinions, no specific ethical clearance or informed consent was obtained.

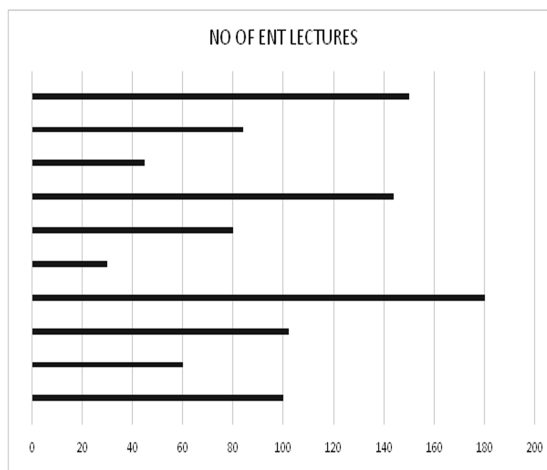
**Results and Discussion :**

Thirty-one interns completed the questionnaire. The majority of the respondents (71%) belonged to private medical colleges of West Bengal, and the rest were from foreign medical universities (Dali University and Jinan University in China; Tbilisi University Georgia) recognised by the Medical Council of India, as shown in Fig 1.



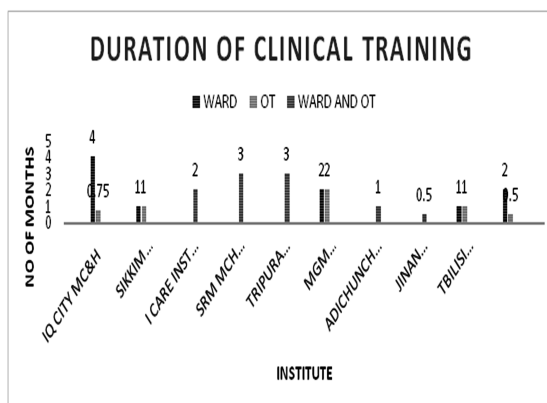
**Fig. 1 : Distribution of respondents according to institute**

Our results show a wide variation in the amount of formal teaching (didactic lectures) as well as clinical exposure to various common procedures. The average number of lectures held in an academic year was 97.5 as depicted in Fig 2.



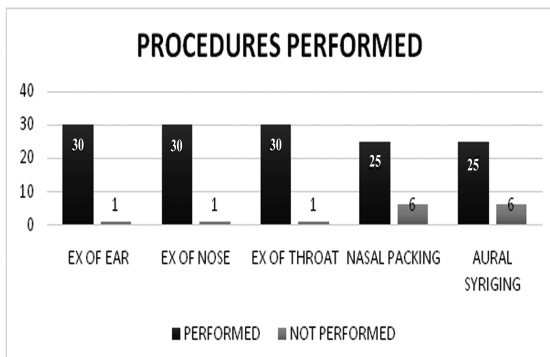
**Fig. 2 : Number of ENT lectures held in colleges**

On an average, clinical posting in ENT (ward as well as theatre) was 2.45 months. IQ City Medical College had the longest duration of ward postings. Jinan University (China) had the shortest duration of clinical posting - 2 weeks. Fig 3



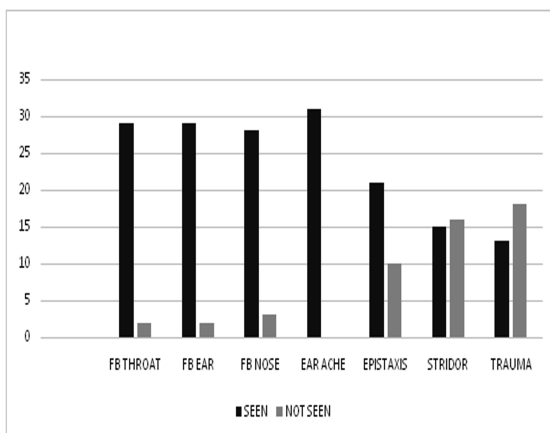
**Fig. 3 : Duration of Clinical Training**

Most respondents (30 out of 31) stated that they could perform ENT examination as shown in Fig 4.



**Fig. 4 : Procedures performed by respondents during ENT rotation**

Nearly half the respondents however, had not observed common ENT emergency procedures. Fig 5.

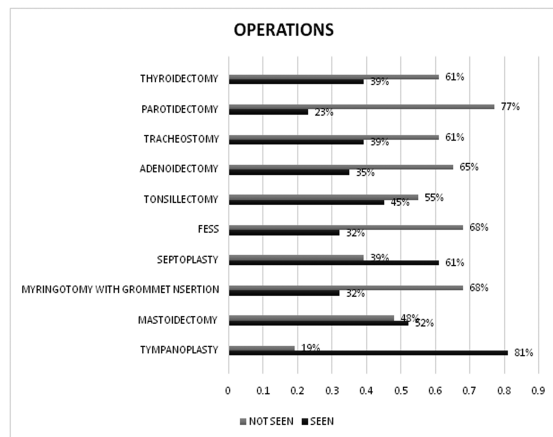


**Fig. 5 : Emergencies seen by respondents**

The common operations seen by the respondents were tympanoplasty (81%), septoplasty (61%) and mastoidectomy (52%). In contrast, emergency tracheostomy was seen by only 39% of the respondents. Interns, according to the Medical Council of India, are supposed to be trained to perform tracheostomies, but most had not observed the procedure.

Exposure to Head and Neck surgeries was also limited with only 23% and 39% of respondents

having observed parotidectomy and thyroidectomy respectively. Fig 6



**Fig. 6 : Operations seen by trainees**

Despite the lacunae in their undergraduate training in terms of observing surgical and emergency procedures, 84% of respondents were satisfied with their course structure. However, all faculty were in agreement that most interns had an average knowledge of ENT and showed unsatisfactory skills in examining patients and managing common ENT problems.

In order to impart a skill-set to undergraduate trainees in ENT and ensure competence to deal with common problems and emergencies we must assess where the lacunae lie. Only a few Indian studies have tried to highlight this problem.

A questionnaire-based study conducted in a medical college and teaching hospital in Pune by Mishra and Deshmukh (2013) surveyed 100 students who had completed their clinical posting in ENT. The respondents of the survey were third year students and interns. The majority of the respondents in this study were confident in diagnosing Acute Otitis Media and identifying the normal ear drum. Most of them were less confident about basic skills like identifying

perforations and clinical skills such as otoscopy and examination of nose. Participants were least confident about managing epistaxis and foreign bodies in the ear and nose. They were not confident about diagnosing cholesteatoma and Otitis Media with effusion.<sup>[1]</sup>

Our study, by comparison, only assessed the exposure to various emergency procedures and not the confidence of interns dealing with such cases. More than 50% of the respondents in our study had not even seen emergencies such as trauma or stridor. About 10% had not seen common emergency cases such as foreign bodies in the ear, nose or throat. All the respondents had seen patients with otalgia in outpatient clinics.

Thirty-five percent of respondents in the study by Mishra and Deshmukh (2013) thought that clinics were the best learning experience; 18% of them felt operation theatre was good, 16% preferred lectures, and 12% tutorials and self-learning each. The remaining 7% learnt from the Internet, seniors' notes and social media. Our study did not explore the preferred learning methods of the respondents.<sup>[1]</sup>

Sixty-two percent of participants felt that 8 weeks was not enough to learn the subject and achieve confidence in skills; the remaining 38% were satisfied with 8 weeks of training. In contrast, 84% respondents in our study were satisfied with the duration of their ENT training.

A recent study by Qadri et al. (2019) conducted on 100 graduate medical students, observed that there was a lack of confidence in trainees in performing basic examination and handling emergencies. Most respondents felt confident in diagnosing nasal septal deviation, polyps and treating conditions like allergic rhinitis. They were less confident in managing patients with

cholesteatoma, otomycosis or laryngo-pharyngeal reflux disorders.<sup>[5]</sup>

The main issues with undergraduate training in ENT appear to be lack of a uniformity in the course and assessment, and the short duration of clinical exposure. These problems are by no means restricted to the Indian scenario.

Ear, nose and throat surgery is the fourth largest surgical specialty in the UK according to the Department of Health (2009). Within General Practice (GP) in the UK, ENT complaints make up approximately one in six adult consultations and up to half of paediatric consultations.<sup>[6,7]</sup>

A survey of undergraduate clinical teaching in otolaryngology in the UK was published by Mace and Narula (2004). Of the twenty-seven medical schools that took part in the survey, six did not have a compulsory ENT attachment. An optional ENT attachment was offered by three schools. The majority (58%) of all ENT attachments were combined with other specialities including dermatology, ophthalmology and neurology. The average length of time spent with the ENT department during medical school training was one and a half weeks.

Of the 27 medical schools, ten did not have a formal assessment of their clinical skills or knowledge at the end of such attachments. The findings of this survey suggest that otolaryngologists in teaching hospitals may have very limited time available to teach the fundamental clinical skills required for ENT examination to students.<sup>[8]</sup>

In 2011 an online questionnaire was e-mailed to 3544 newly qualified doctors from 30 UK medical schools. Undergraduate ENT exposure, confidence and educational value were measured

on a Likert scale. The response rate of the survey was 12.5%. The mean undergraduate ENT exposure was 3.4 days of pre-clinical teaching plus 5 days of ENT departmental experience. However, 15.8 per cent of respondents reported no formal departmental ENT experience. A 'student selected module' in ENT surgery was available to 66% of the respondents but, in spite of this, 65.8 % would have liked to have received further undergraduate ENT experience. Clinical and bedside teaching by consultants were thought to be the best teaching methods by most respondents. The trainees were less confident in history-taking, examination and management of common ENT conditions compared with cardiology.<sup>[9]</sup>

The need to train undergraduate medical students to perform with some measure of competence and confidence in a short span of time has made it important to review the structure of our syllabus and lay emphasis on its more relevant aspects.

A study conducted by Constable et al. (2017) aimed to find out which topics are rated as high priority by non-ENT practitioners. In order of priority, these were: clinical examination; when to refer; acute otitis media; common emergencies; tonsillitis and quinsy; stridor and stertor; otitis externa; and otitis media with effusion.<sup>[10]</sup>

In Canada, trainees undergo longitudinal integrated clerkship instead of rotating internship as is common in India and UK. The longitudinal integrated clerkship is a model of clinical education driven by tenets of social cognitive theory, situated learning, and workplace learning theories, and built on a foundation of continuity between students, patients, clinicians, and a system of care. An Otolaryngology and Head-Neck Surgery clerkship rotation is not required at most Canadian medical schools. Furthermore,

at institutions offering an Otolaryngology and Head-Neck Surgery rotation, less than 20% of students are able to complete a placement.<sup>[11]</sup>

During the longitudinal integrated clerkship at the Northern Ontario School of Medicine (NOSM), students were assigned to one of 14 sites. Not all had access to an otolaryngologist. The study conducted by Scott et al (2017) aimed to quantify the level of exposure students received in Otolaryngology and Head-Neck Surgery at NOSM and to assess their comfort level with diagnosing and treating common otolaryngologic conditions. A majority (67.9%) of medical students surveyed had not observed an otolaryngologist. Furthermore, most students (90.6%) reported receiving very little classroom based and clinical instruction during medical school.<sup>[11]</sup>

The Regulations on Graduate Medical Education of the Medical Council of India (1997) laid the basic framework and defined the objectives and goals of undergraduate medical teaching in ENT.<sup>[3]</sup> These guidelines were however broad outlines and not clearly structured. All medical colleges therefore have had to structure their own curriculum and methods of assessment. There was a lack of uniformity both in the teaching and assessment methodology. The recent Competency Based training which has been implemented since August 2019 may be able to correct the deficiencies in the current undergraduate training curriculum in ENT.<sup>[4]</sup>

The undergraduate trainee is now supposed to acquire a total of 77 competencies in ENT in order to qualify. Emphasis has shifted from didactic lectures to small group teaching and bed side clinics. According to our study an average of 97.5 lectures are held during an academic year. A questionnaire-based study

conducted by Stuart and Rutherford (1978) in Queen Elizabeth Hospital, Birmingham concluded that the attention span of a student rose to a peak 10-15 minutes into a lecture and fell sharply thereafter. They recommended that the duration of lectures should be reduced to half an hour.<sup>[12]</sup> A more recent study conducted at Armed Forces Medical College found that students taught by interactive methods were likely to score 8% to 10% higher in the immediate post class evaluation, and 15% to 18% higher after 8 to 12 weeks.<sup>[13]</sup>

The new curriculum clearly defines the competencies to be achieved, indicates the best teaching methodology for teaching and suggests appropriate assessment methods.

#### **Conclusion :**

The current methods of teaching and assessment

appear to lead to a wide variation of ENT knowledge and skills amongst freshly qualified medical graduates. The stated goals of the undergraduate curriculum - imparting adequate knowledge and skills in ENT are apparently not being achieved. We recognise that our sample size is small and a generalised extrapolation may not be accurate. The new competency-based training will hopefully improve matters.

**Grant :** None

**Conflict of Interest :** None

**Statement of Human and Animal Rights :** As this was a voluntary questionnaire-based survey of opinions, no specific ethical clearance was obtained.

**Informed Consent :** As this was an anonymous voluntary questionnaire-based survey of opinions, no separate informed consent was obtained.

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**Annexure I**

**UNDERGRADUATE ENT PROGRAMME QUESTIONNAIRE**

1. Name of Institution where graduation was done
2. Number of ENT lecture classes held in academic year
3. Duration of ward posting
4. Duration of OT posting in ENT (if separate)
5. Procedures observed during of posting

<b>Procedure</b>	<b>Yes/no</b>
Myringotomy and grommet insertion	
Tympanoplasty	
Mastoidectomy	
Septoplasty/SMR	
Fess	
Tonsillectomy	
Adenoidectomy	
Thyroidectomy	
Parotidectomy	
Trachesostomy	

6. ENT emergencies observed

<b>Emergencies observed</b>	<b>Yes/no</b>
Forign body removal from ear	
Forign body removal from nose	
Ear ache	
Epistaxis	
Stridor	
Trauma (head & neck)	
Foreign body in throat/esophagus	

7. Were you able to perform the following before your internship

<b>Procedure</b>	<b>Yes/no</b>
Examination of ear	
Examination of nose	
Examination of throat	
Nasal packing	
Aural syringing	

8. Comments regarding ability to manage ENT cases post internship

## A Critical Analysis of Medical Negligence in India And Its Defences

Bodhisattya Haldar

### Introduction :

The introduction of high compensation awards for medical negligence claims in India by the Supreme Court has resulted in apprehensive conjecture regarding the impact that such awards may have on the doctors and patients in India. On one hand some scholars predict a consequent rise in false and frivolous litigation against the doctors and medical institutions, others posit the argument that the health sector in India needs to be regulated more stringently and the fear of huge compensation awards will ensure that doctors and medical institutions are not negligent. In light of the recent judgments passed by the Supreme Court and National Consumer Disputes Redressal Commission offering large compensation awards it is pertinent to examine if this signals the beginning of increasing medical negligence litigation and if there is a consequent need to modify the manner in which medical negligence is currently addressed in India.

### Definition of Medical Negligence :

There are no specific definitions available under the Consumer Protection Act 1986 or its amended version 2019 for the term medical negligence although we have seen that in the recent years most of the medical negligence cases are being filed under this act.

“Medical Negligence” can be defined as the improper, unskilled or negligent treatment of a patient by a medical practitioner which includes negligence in taking care from a physician, surgeon, nurse, pharmacist, or any other medical practitioner. Medical negligence leads to medical

malpractices where the victims suffer some sort of injury from the treatment given by a doctor or any other medical practitioner or health care professional.

### Examples of Medical Negligence Instances.

- ❖ improper administration of medicines.
- ❖ performing the wrong or inappropriate type of surgery.
- ❖ not giving proper medical advice.
- ❖ leaving any foreign object in the body of the patient such as a sponge or bandage, etc. after the surgery.

### Types of Medical Negligence :

The instance of medical negligence can occur in different ways. Let’s discuss hereunder about some of the common categories of medical negligence.

#### 1. Wrong Diagnosis or Delayed Diagnosis –

When a patient visits a hospital or clinic the first step is the diagnosis. Diagnosing symptoms correctly is critical and important to provide proper medical care to any patient. If a patient is not treated properly due to any mistake in diagnosis, the doctor can be made liable by the said for any further injury or damages caused as a result of the wrong diagnosis.

A delayed diagnosis will also be treated as medical negligence if another doctor would have reasonably diagnosed the same condition in a timely fashion. A delay in diagnosis can cause injury to the patient if the illness or injury is left to worsen with time rather than being treated.

#### 2. Surgical error – Surgical operations should

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be done with due care and caution and according to standard medical practise and protocol because even the slightest mistakes can be highly detrimental to the patient. The wrong-site surgery, lacerations of any internal organ, severe blood loss, or a foreign object being left in the body of the patients etc. are the examples of gross Surgical error.

**3. Errors in The Administration of Anaesthesia** – Anaesthesia is a risky part of any major medical operation and requires a specialist (anaesthesiologist) to administer and monitor its effect on the patient. Prior to any medical procedure requiring anaesthesia, the anaesthesiologist has to review the patient's condition, history, medications, etc. The anaesthesiologist can be made liable by the patient for injury or damages caused as a result of the wrong diagnosis and administration of wrong medicines.

**4. Childbirth and Labour Malpractice** – Childbirth is a difficult event for a woman and can be further complicated if not handled properly by the doctors and nurses. There are several instances of medical negligence in India during childbirth.

**5. Long-Term Negligent Treatment** – Medical negligence can also occur when there is an instance of long-term negligent treatment which ultimately results in serious complications or development of a serious disease which could have been prevented if treated properly at the early stage.

**Some Basic Principles to decide “Medical Negligence”**

❖ **Standard of care**

According to the eminent scholars of medicine a standard of care specifies the appropriate treatment, medication and procedure as per the

requirements that should be taken into account by a doctor while providing the treatment to his patients. The care should not be of the highest degree nor the lowest. Here, the degree means the level of care an ordinary doctor, with the same training and experience, would render in similar circumstances in the same community. This is the critical question in medical negligence cases and if the answer is “no,” and the patient suffered injury as a result of the poor treatment, then the doctor can be made liable for medical negligence.

❖ **The doctrine of “Res ipsa loquitur”**

An Important Latin maxim in case of medical negligence “res ipsa loquitur” means that “the thing speaks for itself.”

In terms of medical negligence, it refers to the cases where the treatment of the doctor was far below the set standards of care under that negligence is assumed.

Some common examples: -

- i. Negligently leaving any object inside the body of the patient after surgery.
- ii. Surgery done on a wrong patient.
- iii. Surgery done on a wrong body part or organ of a patient.

❖ **Expert opinion**

Expert Opinion is one of the important factors to prove the medical negligence cases because except in case of “res ipsa loquitur” it is not possible for the judiciary to determine whether it is a medical negligence or not, hence the judiciary test the validity of the claim under the light of the opinion given by Expert doctors and the Board of Expert Medial practitioners.

**Burden of Proof under Medical Negligence case.**

According to the Indian judicial system the

burden of proof of negligence generally lies with the complainant. The judiciary requires a higher standard of evidence to support an allegation of negligence against any medical practitioner.

### **What is The Necessary Test to Determine Medical Negligence?**

The necessary test to determine medical negligence is “Custom Test”. In the Customs Test, it must be proven that there was regular practice being done and it should be proved that the doctor or the hospital has not done the practice correctly as they were supposed to.

### **What type of cases and Judicial Proceedings a Doctor might face under Medical Negligence?**

#### **Criminal Cases**

Doctors, medical staffs and hospitals can be charged with Penal provisions defined under Indian penal Code 1860 if, anyone suffers and injury or develop a disease during the course of treatment under the supervision of the doctor and if it proves that it had occurred due to careless and negligent act of the doctor or the hospital. It is pertinent to mention that in a criminal complaint the motive or intention of the accused person and the extend of the offence need to be proved beyond any reasonable doubt.

### **Penal provisions available under Indian Penal Code 1860 under which a doctor can be prosecuted are as follows: -**

- ❖ **Section 304A** : “Causing death by negligence — Whoever causes the death of any person by doing any rash or negligent act not amounting to culpable homicide, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both”.
- ❖ **Section 337** : “Causing hurt by act endangering life or personal safety of others

— Whoever causes hurt to any person by doing any act so rashly or negligently as to endanger human life, or the personal safety of others, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to five hundred rupees, or with both.”

- ❖ **Section 338** : “Causing grievous hurt by act endangering life or personal safety of others:- Whoever causes grievous hurt to any person by doing any act so rashly or negligently as to endanger human life, or the personal safety of others, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine which may extend to one thousand rupees, or with both.”

### **Defences under Indian Penal Code 1860 available for the Doctors :-**

- ❖ **Section 80** : “Accident in doing a lawful act:- Nothing is an offence which is done by accident or misfortune, and without any criminal intention or knowledge in the doing of a lawful act in a lawful manner by lawful means and with proper care and caution. Illustration A is at work with a hatchet; the head flies off and kills a man who is standing by. Here, if there was no want of proper caution on the part of A, his act is excusable and not an offence.”
- ❖ **Section 81** : “Act likely to cause harm, but done without criminal intent, and to prevent other harm :- Nothing is an offence merely by reason of its being done with the knowledge that it is likely to cause harm, if it be done without any criminal intention to cause harm, and in good faith for the purpose of preventing or avoiding other harm to person or property.”

❖ **Section 88** : “Act not intended to cause death, done by consent in good faith for person’s benefit:- Nothing which is not intended to cause death, is an offence by reason of any harm which it may cause, or be intended by the doer to cause, or be known by the doer to be likely to cause, to any person for whose benefit it is done in good faith, and who has given a consent, whether express or implied, to suffer that harm, or to take the risk of that harm.”

**Medical Negligence Complaint in Civil Cases**

In cases where treatment or services provided by doctors or hospitals doesn’t fall within the term of “services” defined under Consumer Protection Act then the patient can claim compensation under the civil law more specifically tort law.

**Vicarious Liability** : It simply means when one person will be held liable due to the wrongful or negligent act of any other person. For Example: If any employee of a hospital causes harm to a patient by acting negligently then in preview of the law of tort the hospital will be held responsible and liable to pay compensation to the patient.

**Medical Negligence cases before the Consumer Courts**

A revolutionary change in the medical negligence cases has occurred after the famous judgment of the Supreme Court in Indian Medical Association vs. V.P. Shanthawhere. The Supreme Court had brought all medical services and medical

profession under the purview of the Act. In this case, the Supreme court had laid down the following points:

1. Medical Services should be treated as the “services” under Section 2(1) (o) of the Consumer Protection Act, 1986.
2. Medical Services which are free of charge are not considered under the purview of Section 2(1) (o) of the Act.
3. Medical Services which are rendered by independent doctors and are free of charge are under the jurisdiction of Section 2(1)(o) of the Act.
4. Medical Services rendered against payment of consideration are also within the scope of the Act.
5. The payment of consideration of a medical service is paid by some third party and is treated under the ambit of this Act.
6. Hospitals in which some persons are exempted from charging because of their inability to afford or any other financial problems will be treated as a consumer.

**When a Patient can file Consumer Complaint before the Consumer Court.**

When the patient has suffered an injury due to the doctor’s reckless or negligent conduct and it was not appropriate according to the set standards of the medical principles then the patient has the right to file consumer complaint before the District Forum or State Commission or National Commission in accordance with the amount of compensation.

The Pecuniary Jurisdiction is described here under :-

<b>Consumer Court</b>	<b>Pecuniary Jurisdiction (Based on total compensation amount)</b>
The District Forum	0 to 1 Crore Rupees.
The State Commission.	More that 1 Crore but less than 10 Crore
The National Commission	More than 10 Crore Rupees.

### **Defence available for Doctors and Medical Practitioner in India under Medical Negligence Case: -**

The Hon'ble Supreme Court of India has provided most of the defences for the doctors and medical practitioners through different Landmark Judgments. Let's discuss the defence mechanisms of medical negligence in the light of few Landmark Judgments.

- 1. Law only expects a reasonable degree of care from a doctor :** In Jacob Mathew Petitioner v. State of Punjab and Anr., (hereinafter mentioned as Jacob Mathew case) the Hon'ble Supreme Court observed that: "The degree of skill and care required by a medical practitioner is so stated in Halsbury's Laws of England (Fourth Edition, Vol. 30 Para 35) : The practitioner must bring to his task a reasonable degree of skill and knowledge, and must exercise a reasonable degree of care. Neither the very highest nor a very low degree of care and competence, judged in the light of the particular circumstances of each case, is what the law requires"
- 2. The doctor must prove that he has treated the patient as per general and approved practice :** The Hon'ble Supreme Court, in Jacob Mathew case held that "The fact that a defendant charged with negligence acted in accord with the general and approved practice is enough to clear him of the charge"
- 3. The Doctor had taken all the care that was expected from any reasonable prudent medical practitioner and therefore there cannot be any element of negligence or rashness in the services rendered by him:** In Martin F.D'Souza v. Mohd. Ishfaq (hereinafter mentioned as Martin's case, the

Apex Court laid down the precautions which doctors/hospitals, etc., should have taken: Current practices, infrastructure, paramedical and other staff, hygiene and sterility should be observed strictly. No prescription should ordinarily be given without actual examination. The tendency to give prescription over the telephone, except in an acute emergency, should be avoided. A doctor should not merely go by the version of the patient regarding his symptoms, but should also make his own analysis including tests and investigations where necessary. A doctor should not experiment unless necessary and even then, he should ordinarily get a written consent from the patient. An expert should be consulted in case of any doubt. Full record of the diagnosis, treatment, etc., should be maintained."

- 4. Difference in opinion :** A difference of opinion is not negligence. If there are two accepted schools of thought and a doctor has adopted any one method, he is not liable. In Jacob Mathew case the Supreme Court stated that "The degree of skill and care required by a medical practitioner is so stated in Halsbury's Laws of England (Fourth Edition, Vol. 30 Para 35): "...and a person is not liable in negligence because someone else of greater skill and knowledge would have prescribed different treatment or operated in a different way; nor is he guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art, even though a body of adverse opinion also existed among medical men" In the same judgment, the Court further observed: "Differences of opinion and practice exist, and will always

exist, in the medical as in other professions. There is seldom any one answer exclusive of all others to problems of professional judgment. A court may prefer one body of opinion to the other, but that is no basis for a conclusion of negligence. A judge's 'preference' for one body of distinguished professional opinion to another also professionally distinguished is not sufficient to establish negligence in a practitioner whose actions have received the seal of approval of those whose opinions, truthfully expressed, honestly held, were not preferred”

5. **Error of Judgment is not always a case of medical negligence :** The standards expected from any medical practitioner in an emergency are always lower than the standards expected from him in an ideal setting. The Hon'ble Supreme Court Jacob Mathew case has stated: “A mere deviation from normal professional practice is not necessarily evidence of negligence. Let it also be noted that a mere accident is not evidence of negligence. So also an error of judgment on the part of a professional is not negligence per se Higher the acuteness in emergency and higher the complication, more are the chances of error of judgment. ...A medical practitioner faced with an emergency ordinarily tries his best to redeem the patient out of his suffering. He does not gain anything by acting with negligence or by omitting to do an act. Obviously, therefore, it will be for the complainant to clearly make out a case of negligence before a medical practitioner is charged with or proceeded against criminally.”
6. **Mere Death of a patient is not the incident of medical negligence :** In Martin case it has been submitted “It must be remembered that

sometimes despite their best efforts the treatment of a doctor fails. For instance, sometimes despite the best effort of a surgeon, the patient dies. That does not mean that the doctor or the surgeon must be held to be guilty of medical negligence, unless there is some strong evidence to suggest that he is”

7. **Things have gone wrong doesn't mean that its an act of negligence :** A doctor is not liable if a treatment, which in ordinary circumstances would be sound, has unexpected results: In Jacob Mathew case the Apex Court held “For a medical accident or failure, the responsibility may lie with the medical practitioner and equally it may not. The inadequacies of the system, the specific circumstances of the case, the nature of human psychology itself, and sheer chance may have combined to produce a result in which the doctor's contribution is either relatively or completely blameless.”
8. **Fraudulent Concealment by the patient :** When a petitioner comes to the Court and deliberately does not disclose relevant information and resorts to falsehood with intentions of obtaining fraudulently a favourable Order, then the complaint should be dismissed with costs. In the case of S.P. Chengalvaraya Naidu (dead) by LRs v. Jagannath (dead) by LRs and Ors. it was held by the Supreme Court that “The courts of law are meant for imparting justice between the parties. One who comes to the court, must come with clean hands. We are constrained to say that more often than not, process of the court is being abused. Property grabbers, tax evaders, bank loan dodgers and other unscrupulous persons from all walks of life find the court-process a convenient lever to

retain the illegal-gains indefinitely. We have no hesitation to say that a person, who's case is based on falsehood, has no right to approach the court. He can be summarily thrown out at any stage of litigation.”

**9. Defence in case of Vicarious liability :** A doctor can be held liable for the acts of a junior doctor, who is a part of his team. Henceforth it is the duty of a senior doctor to give appropriate advice to his junior doctor. In *Malay Kumar Ganguly v. Sukumar Mukherjee and Ors.* the Apex Court stated: “Even delegation of responsibility to another may amount to negligence in certain circumstances. A consultant could be negligent where he delegates the responsibility to his junior with the knowledge that the junior was incapable of performing his duties properly.”

**10. Consent of the Patient :** The doctor must inform the patient or his relatives about the risk of every step and must take written consent which needs to be properly documented. In the famous case of *Malay Kumar Ganguly v. Sukumar Mukherjee and Ors.* on August 7, 2009 Criminal Appeal Nos. 1191–1194 of 2005; Civil Appeal No. 1727 of 2007 it was held that “The patients by and large are ignorant about the disease or side

or adverse effect of a medicine. Ordinarily the patients are to be informed about the admitted risk, if any. If some medicine has some adverse effect or some reaction is anticipated, he should be informed thereabout...”

#### **Conclusion :**

We all know that in South East Asia India is one of the most medically advanced countries, and not only the citizens of India but also patients from different neighbouring countries depend on the Indian doctors and its medical system. It is very unfortunate that nowadays people are losing faith in the medical profession due to some serious medical negligence cases and the number of medical negligence cases in the country is increasing at rapid pace. In this scenario, the Indian judiciary has to take a major role in adjudicating each and every case of medical negligence with minute detail and perfection so that doctors do not feel insecure. As in one of its famous cases the Apex Court of the Country rightly said “A surgeon with shaky hands under fear of legal action cannot perform a successful operation and a quivering physician cannot administer the end-dose of medicine to his patient.”

#### **Further Reading :**

- <https://indiankanoon.org/>
- Indian Penal Code 1860
- Consumer Protection Act 1956
- Consumer Protection Act 2019
- Civil Procedure Code 1908
- *Malay Kumar Ganguly v. Sukumar Mukherjee and Ors.* on August 7, 2009 Criminal Appeal Nos. 1191–1194 of 2005; Civil Appeal No. 1727 of 2007
- *S.P. Chengalvaraya Naidu (dead) by LRs v. Jagannath (dead) by LRs and Ors.* AIR 1994, 853
- *Martin F. D'Souza v. Mohd. Ishfaq*, (2009) 3 SCC 1
- *Jacob Mathew Petitioner v. State of Punjab and Anr.*, 2005 (3) CPR 70 (SC)
- *Indian Medical Association vs. V.P. Shantha* 1996 AIR 550, 1995 SCC (6) 651

# Pseudoaneurysm in An Anomalous Common Hepatic Artery : A Case Report

Debjani Sinha Ray<sup>1</sup>, Suprotik Basu<sup>2</sup>

### Abstract :

**Aim :** To report a case of pseudoaneurysm developing as a complication of pancreatitis in an anomalous common hepatic artery originating from superior mesenteric artery.

**Method :** The initial assessment was done with ultrasonography using B-mode, colour and pulse wave doppler and subsequent confirmation was achieved using contrast enhanced MDCT.

**Discussion :** Importance of variations in hepatic arterial anatomy are felt to greatly influence the surgical and interventional radiological procedures.

**Keywords :** Pseudoaneurysm, Anomalous Common Hepatic Artery, Pancreatitis, Celiac trunk, MDCT, Colour Doppler Ultrasound

### Introduction :

Pseudoaneurysm formation can occur in as many as 10% cases of pancreatitis with an interval ranging from days to years after the acute episode. Splenic and gastroduodenal arteries being most commonly affected and common hepatic artery being uncommon.<sup>[1]</sup>

Anomalies of hepatic arteries are frequent, seen in 40-50%. A large number of studies have been undertaken on variant patterns of aberrant hepatic arteries because of its high surgical relevance.<sup>[2,3]</sup> The most common variants include a replaced right hepatic artery arising from the SMA, seen in about 11% of patients, and a replaced left hepatic artery arising from the left gastric artery,

seen in approximately 10% of patients.<sup>[4]</sup>

A comprehensive understanding of common and uncommon variations in hepatic arterial system is very much essential for the surgeons and Interventional radiologists to avoid any potentially disastrous complication.

### Methods :

Initial imaging evaluation of the patient was done using ultrasonography at an outside centre and subsequently referred to a higher centre for further work-up. A targeted upper abdominal ultrasonography was done using B-mode, colour and pulse wave doppler for evaluation of the lesion following which a contrast enhanced computed tomography with multiplanar reconstruction with thick and thin slices was done and used as confirmation.<sup>[5]</sup> Angiography was refused by patient.

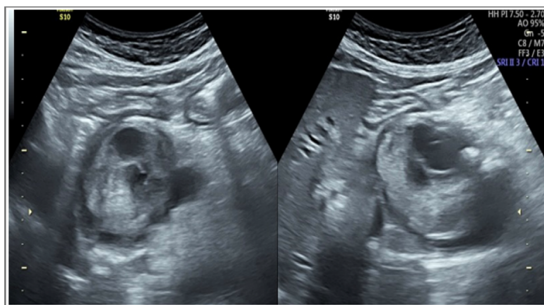
### Case Report :

A 41 year old gentleman with a complaint of a dull aching pain over the epigastrium for a long duration was referred to our hospital for evaluation of a space occupying lesion in the epigastrium previously characterised as an abscess (on ultrasonography). He had no significant past medical history. No surgical history was present. The patient gave a history of alcohol intake of about 36 units per week for the past 18 years. The patient denied ever having severe upper abdominal pain or ever having being hospitalised. Physical examination revealed

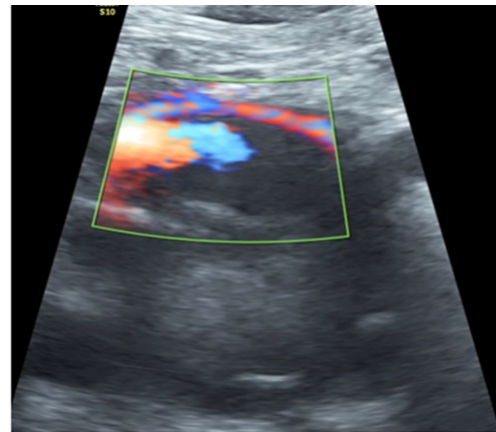
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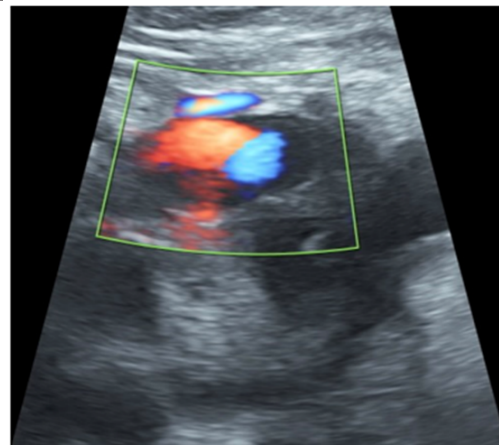
a lump (7x7cm) in the epigastrium without tenderness or guarding. His laboratory studies were unremarkable. On Ultrasonography [Fig.1] a large well defined heteroechoic SOL caudal to the liver edge and abutting the pancreatic body was noted (6.8x6.0x5.5cm) with an eccentric elongated hypo to an echoic area (3.7x2.8cm) showing slow flows wirling motion. Upon interrogation with colour doppler the characteristic Yin-yang sign of a pseudoaneurysm was seen showing to and fro spectrum on pulse wave doppler. An artery could be observed adjacent to the SOL in a curvilinear fashion through which the pseudoaneurysm originates, however the origin of the artery could not be traced. The portal vein and c-loop of the duodenum were abutted. Main pancreatic duct and common bile duct were not dilated. On CECT a heterogeneously hypodense mass was noted with no contrast enhancement and an eccentric avidly enhancing area.<sup>[6]</sup> On Multi Planar Reconstruction with thick sections [Fig.2-Fig.3] the pseudoaneurysm was seen to be originating from the common hepatic artery which in turn originated from the superior mesenteric artery. There was no proper celiac trunk, the left gastric artery and splenic artery originated directly from the abdominal aorta at the level of T12.



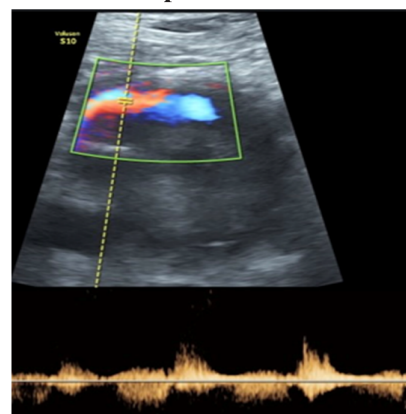
**Fig. 1a : B-mode showing the thrombosed Pseudoaneurysm with eccentric lumen**



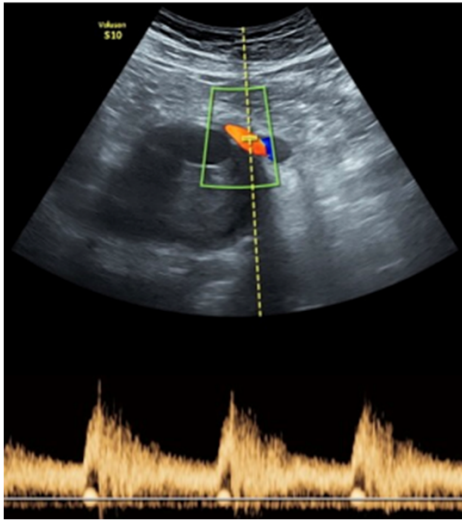
**Fig. 1b : Artery with a rent in the wall showing spurt of blood into the lumen**



**Fig. 1c : Arterial spectral flow observed**



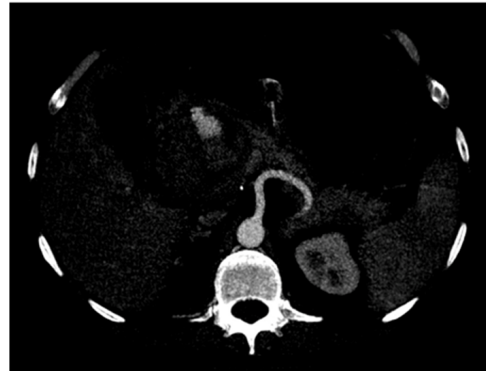
**Fig. 1d : Pulse wave at the neck of Pseudoaneurysm showing to-and-fro pattern**



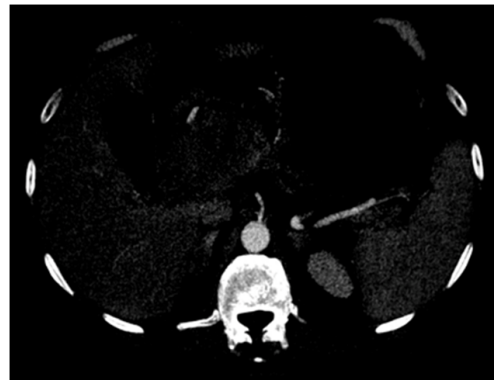
**Fig.1e : Classic Yin-yang sign of Pseudoaneurysm**



**Fig. 2a : Sagittal thick section CECT showing the origins of left gastric artery, splenic artery and superior mesenteric artery in a craniocaudal orientation**



**Fig. 2b : Axial CECT thick sections showing the origin of left gastric artery**



**Fig. 2c : Axial CECT thick sections showing the origin of splenic artery directly from the abdominal aorta.**



**Fig. 3a : Para-sagittal thick section CECT showing the common hepatic artery origin and course with the pseudoaneurysm**



**Fig. 3b : The 3D volume rendered image**

#### **Discussion :**

The classic hepatic artery arises from the celiac axis, gives off right gastric artery and becomes proper hepatic artery after giving rise to the gastroduodenal artery. Normally proper hepatic artery runs in the free margin of lesser omentum on the left side of bile duct and terminates near the porta hepatis by dividing into right and left hepatic arteries. In our case the replaced common

hepatic artery originates from the superior mesenteric artery and courses anteriorly, laterally and superiorly with respect to the SOL to the porta and divides into its branches. Distal to the pseudoaneurysm the common hepatic artery gave origin to the gastroduodenal artery and the right gastric artery.

Hepatic artery pseudoaneurysms are a rare complication and pseudoaneurysm from an anomalous origin of common hepatic artery from the superior mesenteric artery is even more so. However, rupture is common in a pseudoaneurysm and with high mortality. Pseudoaneurysm formation in pancreatitis is thought to occur because of autodigestion by pancreatic enzymes, especially elastase, liberated due to pancreatitis. Although angiography remains the gold standard for detection of pancreatitis related vascular complications, USG and CECT scan are often diagnostic and may provide an early mechanism for identifying patients with pseudoaneurysms following pancreatitis.

Otherwise, diagnosis is usually made late in the course of disease when severe or even fatal haemorrhage has occurred.

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## Epigenetic Events in Cancer

Argha Nath<sup>1</sup>, Shubhadeep Bhattacharya<sup>2</sup>

### Abstract :

Cancer is a disease in which abnormal cells divide uncontrollably and destroy body tissue. This disease arising from both genetic and epigenetic modifications of DNA that contribute to changes in gene expression in the cell. Genetic modifications include loss or amplification of DNA, loss of heterozygosity (LOH) as well as gene mutations. The field of cancer epigenetics is evolving rapidly on several fronts. Epigenetics has classically been defined as heritable changes in gene expression that are not due to any alteration in the DNA sequence. Epigenetic changes in cancer are generally thought to be brought about by alterations in DNA and histone modifications that lead to the silencing of tumour suppressor genes and the activation of oncogenic genes. Other consequences that result from epigenetic changes, such as inappropriate expression or repression of some genes in the wrong cellular context, can also result in the alteration of control and physiological systems such that a normal cell becomes tumorigenic. DNA methylation, histone modification, nucleosome remodelling, and RNA-mediated targeting regulate many biological processes that are fundamental to the genesis of cancer. Epigenetic mechanisms act to change the accessibility of chromatin to transcriptional regulation locally and globally via modifications of the DNA and by modification or rearrangement of nucleosomes. Epigenetic gene regulation collaborates with genetic alterations in cancer

development. This is evident from every aspect of tumour biology including cell growth and differentiation, cell cycle control, DNA repair, angiogenesis, migration, and evasion of host immune-surveillance. In this review, we discuss the current understanding of alterations in the epigenetic events that occur in cancer and a better and thorough understanding of these aspects may significantly contribute to one of mankind's greatest challenges – treatment of different forms of cancer.

**Keywords :** Epigenetics, Cancer, Mutation, Gene expression, Remodelling.

### Introduction :

Epigenetics refers to alternate phenotypic states which are not based on differences in genotype, and are potentially reversible. These are generally well-balanced during cell division.<sup>[1,2]</sup> The interpretation of epigenetics is that of stable differential states of gene expression. Cancer initiation and progression have been recognized for many years to be the result of accumulation of genetic mutations which lead to changes in cellular function. While inherited or sporadic mutations may result in the activation of oncogenes or the inactivation of tumour suppressor genes, changes in modification of both DNA and histones (collectively the epigenome) can also contribute to the initiation and the progression of cancer.<sup>[3]</sup> It should be noted that epigenetic markers are dynamic and can respond to changes in physiological

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conditions and hence, in addition to gene mutations, can be drivers of the development of the cancer<sup>[4]</sup> (Figure 1). The earliest indications of an epigenetic link to cancer were derived from gene expression and DNA methylation studies. Although many of these initial studies were purely correlative, they did highlight a potential connection between epigenetic pathways and cancer. These early observations have been significantly strengthened by recent results from the International Cancer Genome Consortium (ICGC).<sup>[5]</sup> Whole genome sequencing in a vast array of cancers has provided a catalogue of recurrent somatic mutations in numerous

epigenetic regulators.<sup>[5,6]</sup>

Epigenetic Silencing refers to the molecular events that occur at CpG-rich promoters in cancer cells. The open chromatin structure of a transcriptionally active gene with loosely spaced nucleosomes is shown at the top in and the transcriptionally silenced state with more tightly packed nucleosomes is shown at the bottom in Figure 2. Proteins involved in transcriptional silencing are DNMT (DNA methyl transferase); MBD (methyl-binding domain protein); CO-REP (co-repressor); HP1, (heterochromatin protein1) and CAF-1 (chromatin assembly factor-1).<sup>[6]</sup>

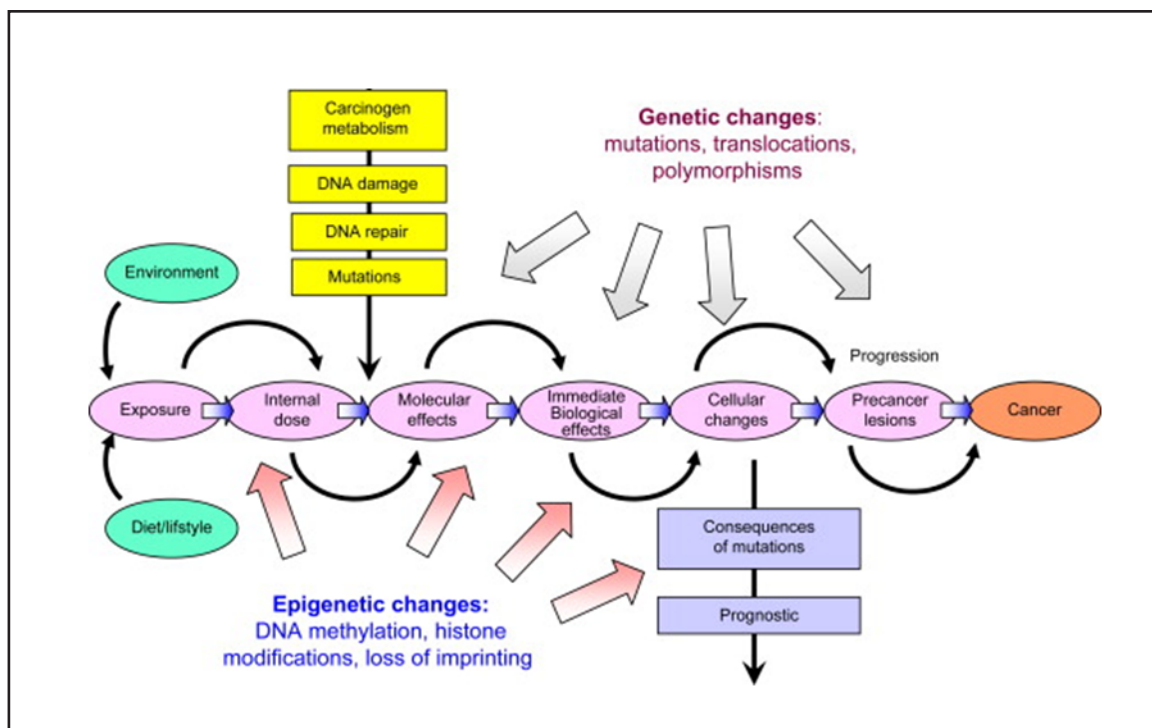


Fig. 1 : Epigenetic changes that can cause cancer

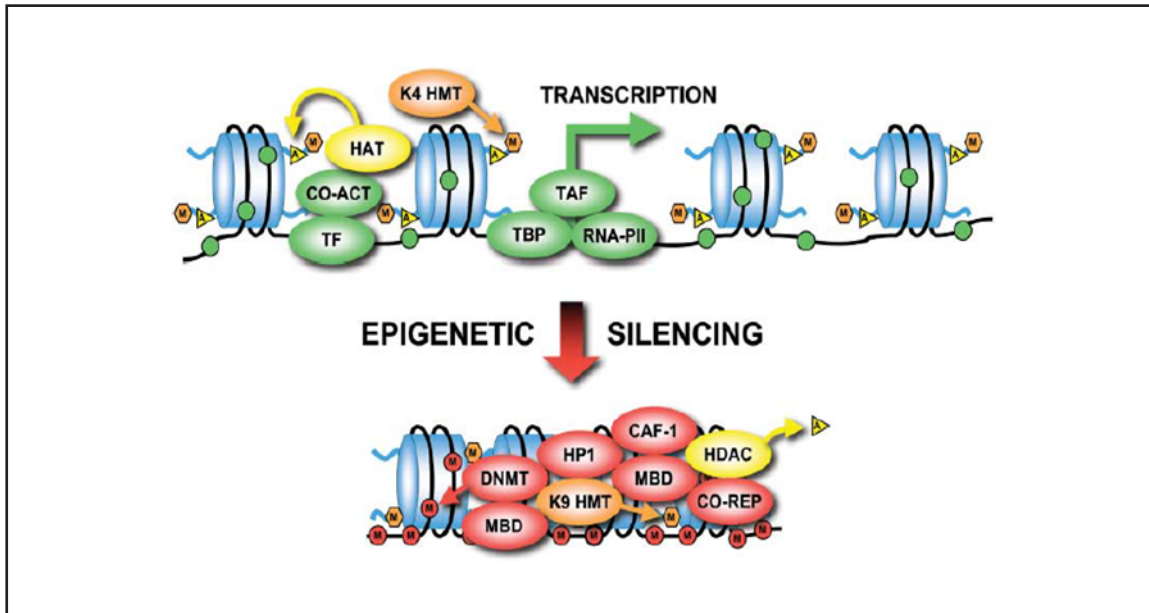


Fig. 2 : Epigenetic silencing in DNA

### Types of Epigenetic Changes & Effect :

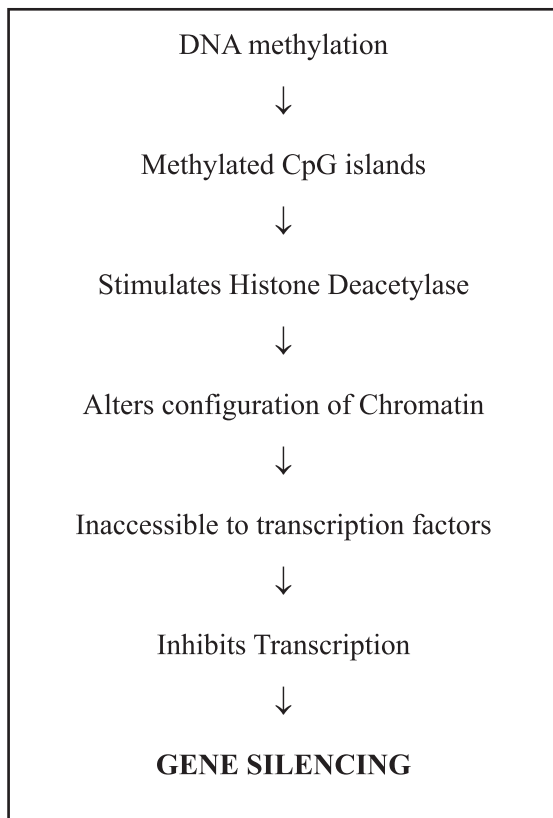
#### Histone Modifications :

In 1964, Vincent Allfrey prophetically surmised that histone modifications might have a functional influence on the regulation of transcription.<sup>[7]</sup> Nearly half a century later, the field is still grappling with the task of unravelling the mechanisms underlying his enlightened statement. The great diversity in histone modifications introduces a remarkable complexity that is slowly beginning to be elucidated. Histone modifications occur in different histone proteins, histone variants (e.g., H3.3), and histone residues such as lysine, arginine, and serine. These modifications also involve different chemical groups (e.g., methyl, acetyl, and phosphate) and have different degrees of methylation (e.g., mono-, di- and trimethylation). Acetylation and methylation of histones have direct effects on a variety of nuclear

processes, including gene transcription, DNA repair, DNA replication, and the organization of chromosomes.<sup>[6]</sup>

#### DNA Methylation :

DNA methylation has critical roles in the control of gene activity and the architecture of the nucleus of the cell: it is the addition of a methyl group to DNA at the 5-carbon of the cytosine ring that precedes a guanine (CpG). As a generalization, promoters with methylated DNA tend not to be expressed. Clusters of CpGs (the predominant target for DNA methylation) are known as CpG islands and are located at the 5'ends of many human genes. In tissues, most CpG islands are unmethylated, even when the associated genes are not expressed.<sup>[7]</sup> However, in cancer, DNA hypermethylation occurs at many CpG islands. The result of such DNA methylation is shown in Figure 3.



**Fig. 3 : Flow chart showing sequence events of DNA methylation on chromatin structure**

#### **DNA Demethylation :**

DNA demethylation has also been postulated to contribute to cancer development.<sup>[8]</sup> Despite evidence for regional hypermethylation, global levels of 5-methylcytosine have actually been found to be 5-10% less in tumours compared to normal cells.<sup>[9,10]</sup> The methylation changes have been suggested to occur specifically between the stages of hyperplasia and benign neoplasia as DNA was found to be significantly hypomethylated in both benign polyps and malignant tissues when compared to normal

tissue.<sup>[11]</sup> Methylation patterns were therefore altered before the lesions became malignant, suggesting that they could be a key event in tumour evolution. The cause of global hypomethylation in cancer is unknown but the outcome, in due course, may be that oncogene expression is increased or other genes important for growth control are deregulated.

#### **Acetylation :**

Acetylation is highly dynamic and is regulated by the competing activities of two enzymatic families, the histone lysine acetyl transferases (KATs) and the histone deacetylases (HDACs). There are two major classes of KATs: (1) type-B, which are predominantly cytoplasmic and modify free histones, and (2) type-A, which are primarily nuclear and can be broadly classified into the GNAT, MYST, and CBP/p300 families. Acetylation is a post-translational chemical modification of histones, tubulins, and the tumour suppressor p53.<sup>[11]</sup>

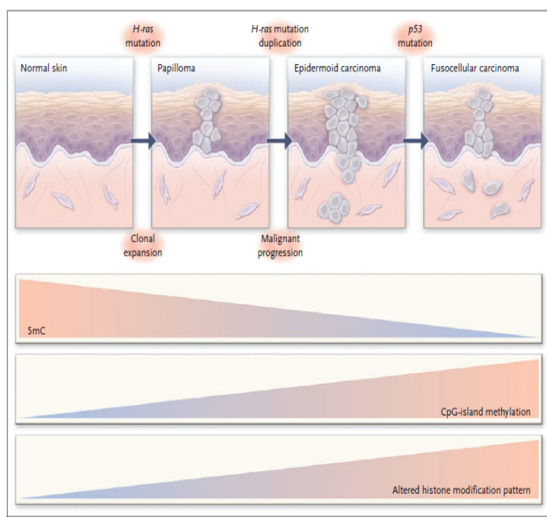
#### **Inactivation of Tumour-suppressor Genes :**

In a normal cell, expression of the mRNA of a tumour-suppressor gene occurs in the context of an unmethylated promoter CpG island and histone modification, such as hyperacetylation and methylation of lysine 4 of histone H3. A combination of selection and targeted disruption of the DNA methylation and histone-modifier proteins disrupts the epigenetic circumstances in the cancer cell. Epigenetic inactivation of tumour-suppressor genes is associated with dense CpG-island promoter hypermethylation and the appearance of repressive histone markers such as methylation of lysines 9 and 27 of histone H3.<sup>[12]</sup>

### Epigenetic Disruption in Various Types of Cancer :

Type of Cancer	Epigenetic Disruption
Colon cancer	CpG-island hypermethylation (hMLH1, p16INK4a, p14ARF, RARB2, SFRP1, and WRN), hypermethylation of miRNAs (miR-124a), global genomic hypomethylation, loss of imprinting of IGF2, mutations of histone modifiers (EP300 and HDAC2), diminished monoacetylated and trimethylated forms of histone H4
Breast cancer	CpG-island hypermethylation (BRCA1, E-cadherin, TMS1, and estrogen receptor), global genomic hypomethylation
Lung cancer	CpG-island hypermethylation (p16INK4a, DAPK, and RASSF1A), global genomic hypomethylation, genomic deletions of CBP and the chromatin-remodelling factor BRG1
Glioma	CpG-island hypermethylation (DNA-repair enzyme MGMT, EMP3, and THBS1)
Leukaemia	CpG-island hypermethylation (p15INK4b, EXT1, and ID4), translocations of histone modifiers (CBP, MOZ, MORF, MLL1, MLL3, and NSD1)
Lymphoma	CpG-island hypermethylation (p16INK4a, p73, and DNA-repair enzyme MGMT), diminished monoacetylated and trimethylated forms of histone H4
Bladder cancer	CpG-island hypermethylation (p16INK4a and TPEF/HPP1), hypermethylation of miRNAs (miR-127), global genomic hypomethylation
Kidney cancer	CpG-island hypermethylation (VHL), loss of imprinting of IGF2, global genomic hypomethylation
Prostate cancer	Prostate cancer CpG-island hypermethylation (GSTP1), gene amplification of polycomb histone methyltransferase EZH2, aberrant modification pattern of histones H3 and H4
Oesophageal cancer	CpG-island hypermethylation (p16INK4b and p14ARF), gene amplification of histone demethylase JMJD2C/GASC1
Stomach cancer	CpG-island hypermethylation (hMLH1 and p14ARF)
Liver cancer	CpG-island hypermethylation (SOCS1 and GSTP1), global genomic hypomethylation
Ovarian cancer	CpG-island hypermethylation (BRCA1)

A proposed model of multistage epigenetic alterations leading to dermal carcinogenesis is shown in Figure 4.



**Fig. 4 : Epigenetic Alterations in Tumour Progression**

## Conclusion :

Epigenetic changes occur frequently during tumour development. The major changes are aberrant DNA methylation and histone modification in chromatin. Both these epigenetic events act in concert to silence the expression of genes that suppress tumorigenesis. The aberrant DNA methylation of some of these target genes can be used for early diagnosis of cancer using MSP. In addition, these epigenetic changes are potential targets for therapeutic intervention using inhibitors of DNA methylation and histone deacetylation. The synergistic activation of tumour suppressor genes and the synergistic *in vitro* antineoplastic activity by the combination of these epigenetic agents suggest that they have interesting potential for the chemotherapy of cancer.

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## Covid 19 Associated Mucormycosis — A Review and Illustrative Case Report

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### Abstract :

The second wave of COVID 19 in India has seen a rise in cases of Mucormycosis. According to an Indian Registry, in May 2021, India alone contributed to the majority of patients receiving care for Mucormycosis. The Mucormycosis epidemic in India has brought into sharp focus the seriousness of fungal infections and the relatively poor state of the science of their prevention, diagnosis, and management. We conducted a systematic review of the literature and also report an illustrative case with management.

**Keywords :** Mucormycosis, Rhino-cerebral, Corticosteroids, Amphoterecin B liposomal, Rhino orbital.

### Introduction :

With the upsurge of Covid 19 cases in India in 2021, there has been a rise in bacterial and fungal opportunistic infections.<sup>[1]</sup> The second wave of COVID-19 affected India significantly, with the highest number of daily reported cases being slightly more than 0.4 million in May 2021. With the decline in cases, India still contributed to approximately 45% of the new cases detected globally and nearly 34% of the deaths globally during the third week of May 2021.<sup>[2]</sup> Globally, prior to the COVID pandemic, the prevalence of Mucormycosis varied from 0.005 to 1.7 per million population, while its prevalence was nearly 80 times higher (0.14 per 1000) in India compared to developed countries.<sup>[3]</sup> Though

mucor is an ubiquitous microorganism, its multiplication inside the human body depends upon various predisposing factors in active and post-COVID cases. The major factors attributable to mucor infection in COVID 19 cases are hypoxia, hyperglycaemia (in the form of diabetes, new onset hyperglycaemia or steroid induced hyperglycaemia), high ferritin levels, metabolic acidosis or diabetic ketoacidosis. Altered immune mechanisms (primarily reduced phagocytic activity of the leucocytes), use of industrial oxygen and repeated use of suction catheters and cannulae which remain moist over a period of time, and other factors like prolonged hospital stay, prolonged intubation with mechanical ventilators may also contribute to the mucor infection.<sup>[4 5]</sup>

Mucormycosis warrants early diagnosis as it is extremely difficult to treat this infection. It is almost always 100 percent fatal if left untreated especially with intracranial involvement.<sup>[6]</sup> This prompted us to conduct a systematic review of published case reports/series of Mucormycosis associated with COVID-19, to ascertain its temporal associations in relation to comorbidities, association with drugs being used in COVID-19 and overall characteristics of patients, with outcomes. We additionally have discussed a case which was managed at our institution.

### Case Report :

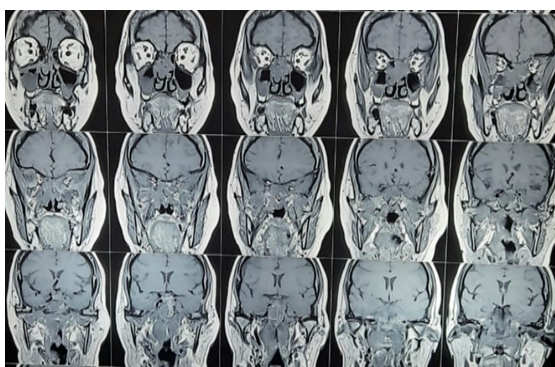
A 62 year old female patient, with recently diagnosed Type 2 Diabetes Mellitus, presented to our OPD clinic with a nine day history of

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numbness of the left lower face associated with heaviness of the left upper eyelid. She had tested positive for COVID 19 and was hospitalised in Nagpur for 20 days. During the course of this hospital stay she received systemic corticosteroids in a dose of 1 mg/kg/day for 10 days. She developed the presenting symptoms a month after discharge.

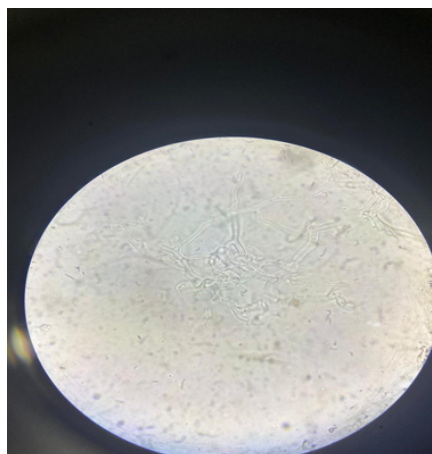
Clinically, on examination, there was mild proptosis of the left eye. Cranial nerve examination revealed hypoaesthesia in the distribution of the Maxillary division of the Left Trigeminal nerve. Second and seventh cranial nerve function was normal. There was a mild left ophthalmoplegia on left lateral gaze, indicating left lateral rectus paresis. Anterior rhinoscopy appeared normal.

A magnetic resonance imaging (MRI) scan of the nose, paranasal sinuses and orbits was obtained, which revealed fluid collection in both maxillary sinuses, areas of devascularisation in the left pterygoid fossa, thrombosis of the left internal carotid artery and the left cavernous sinus. Bilateral lamina papyracea were intact. There were no signs of meningeal involvement (Fig 1)



**Fig 1: MRI (T1 weighted image) of nose and paranasal sinuses showing thrombosis of left internal carotid artery**

Urgent diagnostic nasal endoscopic (DNE) biopsy and limited Functional Endoscopic Sinus Surgery (FESS) was performed to obtain a specimen for tissue diagnosis. DNE revealed devascularised areas in the posterior part of the right septum and the right middle turbinate. The sphenoid sinus was found to be filled with fungal debris. The left anterior and posterior ethmoidal air cells were filled with fungal debris and lined by devitalised tissue. The posterior end of septum was partly necrosed. Tissue specimens from the left nasal cavity and maxillary sinus were sent for KOH mount examination and frozen section. Both KOH mount and frozen section revealed aseptate acutely branching hyphae confirming the presence of mucor species (Fig 2).



**Fig 2 : Wide aseptate hyaline fungal hyphae with right angled branching suggesting mucor on KOH mount**

A complete debridement was planned after initial treatment with systemic Amphotericin B. This was started at a dosage of 5mg/kg body weight in two divided doses and a trans nasal endoscopic surgical debridement of the Sino nasal Mucor mycosis was performed. An endoscopic left medial maxillectomy was performed by a

modified Denker's approach, with the nasolacrimal duct cut flush with the floor of the orbit. The posterior wall of the left maxilla was removed to expose the pterygopalatine fossa as far laterally as the left infratemporal fossa. The left Greater Palatine artery was found to be normal, although the left sphenopalatine artery was thrombosed. A wide Sphenoidotomy with Posterior Septectomy was performed. The pterygoid wedge was drilled out to remove necrosed bone. The patient improved symptomatically following the procedure, with reduction of lateral rectus paresis and proptosis by the second post-operative day. The patient was discharged on oral Posaconazole once daily for a month (Fig 3).



**Fig 3 : Patient on 7th post operative day with resolution of lateral rectus palsy and reduction in proptosis.**

#### **Literature Search Methodology :**

We searched the electronic database of PubMed and Google Scholar from the onset of pandemic

until May 13, 2021 using keywords "COVID-19", "SARS CoV-2", AND "Mucormycosis", "Zygomycosis", "Phycomycosis, "Mucorales", "Mucor", "Rhizopus", "Rhizomucor", "Cunninghamella", and "Absidia,"Black fungus". We retrieved all the details of case reports/series of patients with mucormycosis and COVID-19 reported world-wide. Subsequently we analysed the patient characteristics, associated comorbidities, location of mucormycosis, use of steroids and outcomes.

#### **Results :**

Overall, 18,590 cases of Mucormycosis in people with COVID-19 were reported in the literature up to May 13<sup>th</sup> 2021, of which 14872 cases were from India and 3718 from the rest of the world. Mucormycosis was predominantly seen in males (78.9%), and in people who were active (59.4%) or recovered (40.6%) from COVID-19. The median time interval between COVID-19 diagnosis and the first evidence of Mucormycosis infection was 15 days. Pre-existing diabetes mellitus (DM) was present in 80% of cases, while concomitant diabetic ketoacidosis (DKA) was present in 14.9%. Corticosteroid intake for the treatment of COVID-19 was recorded in 76.3% of cases . Glucocorticoid use was reported in 85% of cases. Rhino-orbital mucormycosis (ROM) was most common 42%, followed by rhino-orbito-cerebral mucormycosis (ROCM) 24%. Pulmonary mucormycosis was observed in 10% patients. The mortality rate was 34%; the use of adjunct surgery, which was undertaken in 81% of patients, was associated with better clinical outcomes.

#### **Review of Literature :**

In this review, we discuss the factors explaining the substantial rise in cases of covid associated

mucormycosis (CAM). The etiologic agent responsible for Mucormycosis is a group of thermotolerant eukaryotic fungi of the order Mucorales. The larger spores (e.g., *Rhizopus arrhizus*) commonly settle in the upper respiratory tract, while the smaller spores (for instance, *Cunninghamella*) reach the lower respiratory tract.<sup>[6]</sup>

Innate immunity is primarily responsible for clearing the spores from mucosal surfaces in healthy individuals. Neutrophilic disorders (qualitative or quantitative) are the main risk factors for Mucormycosis<sup>[7]</sup> while lymphocytic disorders have rarely been implicated as a predisposing factor for Mucormycosis.<sup>[8]</sup> The conventional risk factors for invasive mould infections include neutropenia, haematological malignancies, solid organ transplantation, haematopoietic stem cell transplant, immunosuppressive therapies targeting T-cells (calcineurin inhibitors, tumour necrosis factor inhibitors, lymphocyte-specific monoclonal antibodies, prolonged use of corticosteroids at a dose of 0.3 mg/kg for 3 weeks in the past two months), and certain inherited immunodeficiency diseases.<sup>[9]</sup>

Diabetes mellitus is a risk factor for severe COVID-19 and is associated with increased mortality due to COVID-19.<sup>[1,10,11]</sup> Diabetes hinders innate immune function by impairing phagocytic function, which significantly improves following glycaemic control. Further, impaired dendritic cell responses delay the timely activation of adaptive immune responses.<sup>[11]</sup> Conversely, COVID-19 can lead to the onset of diabetes, and diabetic ketoacidosis (DKA) has been precipitated in newly diagnosed diabetes following COVID-19. Angiotensin-converting enzyme 2 (ACE2) receptors found in the lung

and pancreas serves as the entry point for COVID-19. The ACE2 receptor protein allows entry of SARS-CoV-2 into pancreatic islet cells and may injure the beta cells.<sup>[11,12]</sup>

Corticosteroids are an important predisposing factor for CAM. They are potent immunosuppressants with a wide range of effects on various aspects of adaptive and innate immunity. Corticosteroids impair the ability of phagocytes to clear the fungi.<sup>[12]</sup>

Hyperferritinemia, due to the profound inflammation, is a characteristic feature of COVID-19 and is associated with increased mortality.<sup>[13]</sup> Notably, ferritin-associated iron induces defects in innate (neutrophils) and adaptive immunity (T-lymphocytes) in mice models.<sup>[14]</sup> In patients with DKA, acidosis temporarily dislocates iron bound to transferrin.<sup>[13,14]</sup> The ketoacid,  $\beta$ -hydroxybutyrate, indirectly compromises the ability of transferrin to chelate iron.<sup>[15]</sup> The increased iron can permit the growth of *Mucor* species.

COVID-19 is associated with endothelial dysfunction. Autopsy studies have found severe endothelial injury associated with the presence of intracellular virus and disrupted cell membranes in patients with severe COVID-19.<sup>[16,17]</sup>

#### **Discussion :**

Mucor mycosis is characterised by an acute fulminant pattern and carries a very high mortality. It is an opportunistic infection which is caused by a broad, aseptate, saprophytic, ubiquitous fungus found in soil, air, bread mould, rotten fruit and vegetables.

The predisposing factors are immunocompromised states like diabetes mellitus, chronic renal failure, anti-cancer chemotherapeutic agents,

iron overload for haematological disorders, subjects receiving deferoxamin (an iron chelating agent), protein calorie malnutrition, organ and bone marrow transplantation, vascular disorders like sarcoidosis, polyarteritis nodosa and in Human immunodeficiency virus (HIV) infection.<sup>[16]</sup>

Mucormycosis can involve the nose, sinuses, orbit, central nervous system (CNS), lung (pulmonary), gastrointestinal tract (GIT), skin, jaw bones, joints, heart, kidney, and mediastinum (invasive type), but ROCM is the commonest variety seen in clinical practice world-wide.<sup>[14,15]</sup> ROCM refers to the entire spectrum ranging from limited sino-nasal disease (sino-nasal tissue invasion), limited rhino-orbital disease (progression to orbits) to rhino-orbital-cerebral disease (CNS involvement).<sup>[16]</sup> ROCM is frequently observed in association with uncontrolled diabetes and DKA, whereas pulmonary involvement is often observed in patients having neutropenia, bone marrow or organ transplant, and haematological malignancies, while GIT is more involved in malnourished individuals.<sup>[18]</sup>

Prakash et al in a multicentric study of 338 patients of mucormycosis found that 18% had DKA and 57% of patients had uncontrolled DM.<sup>[19]</sup> The commonest presentation in mucormycosis is rhino orbital.

After inhalation into the nasal cavity and paranasal sinuses, the fungi infect the host by causing necrotizing vasculitis of the nose and sinuses, and rapidly extend into the orbits, deep face, meninges, and cranial cavity.<sup>[20]</sup> This results from perivascular, perineural, or direct soft-tissue invasion by the fungi, causing suppurative arteritis, vascular thrombosis, and infarction of

the surrounding tissues.

Fungal hyphae have a marked predilection for vascular invasion. They directly invade the walls of large and small arteries and sometimes veins, causing thrombosis. This contributes to the necrotic ischemic appearance characteristic of advanced disease. Inflammatory tissue reaction is variable and reflects the host's immunologic status. Acidotic environments enhance the fungal growth and ischemia limits activity of phagocytes. In its invasive form, the fungal infection typically spreads by osseous erosion or vascular invasion, with perineural extension being an unusual mode of spread.<sup>[20]</sup>

#### **Diagnosis :**

The diagnosis of mucormycosis is challenging and treatment should start as early as possible in order to decrease mortality. No circulating antigen detection test is available for diagnosis.

So far, no standardized blood polymerase chain reaction (PCR) test is available. Therefore, analysis of biological specimens from clinically involved sites is mandatory for diagnosis. Every effort should be made to obtain tissue biopsies for histopathology and culture.

The material taken for biopsy should be carefully handled as rough handling may cause damage to the fragile mucor, and culture may not show any growth. Usually culture growth is rapid and occurs during incubation for 24 h at 25-37°C.

Demonstration of hyphae in clinical samples by direct microscopy is important because it can be done rapidly and is highly suggestive of the disease. Specimens can be observed after treatment with potassium hydroxide (KOH), staining with an optical brightener (calcofluor white), or with Gomori methamine-silver.

When cultures are negative and clinical suspicion is strong, molecular identification from tissue samples can confirm the histological diagnosis. Molecular identification of the causative agent of mucormycosis can help to confirm the diagnosis and identify the fungus to the genus and species level. Different techniques have been reported: DNA probes targeting 18S subunit, ITS 1 sequencing after PCR with pan-fungal primers, 18S-targeted semi-nested PCR and real-time PCR targeting cytochrome b gene.<sup>[21]</sup>

Preoperative contrast-enhanced (CT) is useful in defining the extent of the disease. Scans show the oedematous, fluid filling the, and destruction of periorbital tissues and bony margins. Although sinus CT is the preferred imaging modality, bony destruction is often seen only late in the course of the disease after soft-tissue has already occurred.<sup>[22]</sup>

MRI is useful in identifying the intradural and intracranial extent of the disease, cavernous sinus thrombosis, or thrombosis of the cavernous portion of the internal carotid artery. Perineural spread of the disease can also be demonstrated with contrast-enhanced scans.

Although evidence of infection of the soft tissues of the orbit may sometimes be seen by CT Scan, MRI is more sensitive when soft tissue lesions are depicted. However, patients with early ROCM may have normal MRI and CT scans and surgical exploration with biopsy of the areas of suspected infection should always be performed in high-risk patient.

Treatment of Mucor mycosis includes immediate use of systemic antifungals and surgical debridement, preferably endoscopic procedures. Blood vessel thrombosis and resulting tissue

fungal agents, thus the timing and extent of surgical debridement contributes critically to the outcome of disease. Xiao et al found that there is no significant reduction in the mortality outcomes with endoscopic techniques when compared to external procedures.<sup>[23]</sup>

Systemic polyenes such as Amphotericin B, are the drugs of choice. Lipid formulations of Amphotericin B (LFABs) are significantly less nephrotoxic and hence are the preferred option. Initiation of polyene therapy within 5 days of the diagnosis of mucormycosis was associated with improvement in survival, compared with initiation more than 6 days after diagnosis (83% vs. 49% survival).<sup>[23]</sup> In the absence of comparative data, the total dosage and duration of therapy for mucormycosis should be individualized for each patient. A dosage of 5 – 7.5 mg/kg/d of lipid polyenes is reasonable in most cases of mucormycosis.<sup>[23]</sup> A recent randomized study of 339 patients with various mould infections found no clinical benefit of Liposomal Amphotericin B (LAmB) dosed at 10 mg/kg/d versus 3 mg/kg/d.<sup>[22,23]</sup> Given the low CNS penetration of polyenes, some experts prefer dose escalation to 10 mg/kg/d of LAmB for CNS mucormycosis. Higher doses of LAmB do not result in pharmacokinetic advantage compared to 10 mg/kg/d.<sup>[18]</sup> Liposomal amphotericin B achieves high MIC at the recommended dose 3-7.5mg/kg/day.<sup>[23]</sup>

Greenberg et al in a controlled clinical trial (2006) concluded that posaconazole is only suitable for salvage therapy, as the oral preparation, which is only available at present, is erratically absorbed from the gut. Fluconazole, voriconazole, and itraconazole do not have reliable activity against Mucormycosis.<sup>[24]</sup> The reported in vitro MIC for 90% of organisms

(MIC<sub>90</sub>) of posaconazole against the Mucormycotina has ranged from 1 µg/mL to ≥4 µg/mL.<sup>[23,24]</sup> However, in patients with febrile neutropenia or invasive fungal infections, posaconazole dosed at 400 mg twice daily resulted in serum levels less than 1 µg/mL, with considerable variability.<sup>[22]</sup> These data raise concerns about the reliability of achieving adequate in vivo levels of posaconazole to treat mucormycosis. The efficacy of posaconazole as an option is further into question by reports of mucormycosis developing as a breakthrough infection while on posaconazole prophylaxis.<sup>[24]</sup> Thus, posaconazole cannot be recommended as a first-line treatment for mucormycosis. Adjuvant therapy with granulocyte-macrophage colony-stimulating factor, interferon, granulocyte colony-stimulating factor, and/or hyperbaric oxygen therapy has been used successfully in some patients.<sup>[12]</sup>

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In general, antifungal therapy for mucormycosis should be continued until all of the following objectives are attained : (1) there is resolution of clinical signs and symptoms of infection (2) there is resolution or stabilization of residual radiographic signs of disease on serial imaging and (3) there is resolution of underlying immunosuppression.

#### Conclusion :

A combination of diabetes and the rampant use of corticosteroids on a background of COVID-19 appears to increase the risk of Mucormycosis. All efforts should be made to maintain optimal glycaemic control, with judicious use of corticosteroids in patients with COVID-19. It is important to develop a risk-based approach for patients based on early diagnosis, quick referral and timely intervention to reduce the mortality.

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