(International Print/Online Journal)

SJIF IMPACT FACTOR: 5.565
PUBMED-National Library of Medicine ID-101739732

ISSN (Print): 2209-2870
ISSN (Online): 2209-2862

International Journal of Medical Science and Current Research (IJMSCR)
Available online at: www.ijmscr.com
Volume 4, Issue 2, Page No: 203-209
March-April 2021

Cleft surgeries in the time of COVID-19: Our experience with 205 patients in the pre-vaccination era

[1]Dr. Sarwpriya Sharma MDS, [2]Dr. Jaideep Singh Chauhan MDS, [3]Dr. Gargi Ghosh MD,[4]Dr. Shalini Khare MD

[1, 3]Consultant, [2,4]Consultant & Head,
1,2Department of Maxillofacial Surgery & 'Smile Train' Cleft Centre,
3Department of Molecular Biology, 4Department of Laboratory Medicine
CHL Hospitals A.B. Road, LIG Square Indore (M.P.)

Corresponding Author:
Dr. Sarwpriya Sharma MDS
Consultant, Department of Maxillofacial Surgery & 'Smile Train' Cleft Centre CHL Hospitals, AB Road, LIG Square, Indore (M.P.)

Type of Publication: Original Research Paper
Conflicts of Interest: Nil

ABSTRACT

Objective: To report our surgical strategy for the patients with cleft and the experience we had with these procedures in the times of corona, before the start of vaccination in our tertiary care center.

Material and Method: A total number of 205 patients were registered for the cleft surgeries from June 2020 to January 2021. All the patients underwent screening for corona. The newer protective methods were practiced by the staff and doctors. Preventive measures were followed by the patients/attendants. Teleconsultation was used for pre-operative evaluation and post-operative follow up.

Results: Out of 205, six patients came corona positive. They were treated accordingly. Five patients out of them received surgical care. All the patients recovered well from the surgery. None of the patient got infected in peri-operative and recovery phase.

Conclusion: Cleft procedures can be performed safely with following certain fixed protocols which must include proper screening of the patient, protective methods by team of doctors and preventive measures by the patient/ attendants.

Keywords: Cleft Lip Palate Surgery; Protocols; COVID-19; Teleconsultation

INTRODUCTION

Over the past 2 decades, coronaviruses have been associated with significant disease outbreaks in East Asia and the Middle East. The severe acute respiratory syndrome (SARS) and the Middle East respiratory syndrome (MERS) began to emerge in 2002 and 2012, respectively. Recently, a novel coronavirus designated as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged in late 2019. It has posed a global health threat by spreading coronavirus disease 2019 (COVID-19), an ongoing pandemic in many countries and territories [1]. Microbiologically, coronaviruses are positive-sense RNA (Ribonucleic acid) viruses having an extensive and promiscuous range of natural hosts and affect multiple organ systems [2,3]. Coronaviruses can cause mild to severe illness in humans that may extend from the common cold to more severe respiratory diseases like SARS and MERS [4].

The COVID-19 crisis has deeply affected the health care system. In light of ongoing COVID-19 pandemic, the American Society of Plastic Surgeons

(ASPS) has released a statement in March 2020, urging the suspension of all elective, non-essential procedures [5]. Hospitals around the world have had to suspend all the non-emergency procedures to deal with COVID-19 patients as well as comply with safety protocols. This created a lot of uncertainty and anxiety for the patients who were supposed to receive an elective procedure during that period. Similar concern was observed with parents who were waiting for the surgical procedure for their child affected with cleft lip and/or palate, especially if the child became eligible for the procedure. The outpatient department (OPD) and operation theatre (OT) in the hospital were closed for all the non-emergency services by the local administration from the last week of March 2020. All the pre-scheduled cleft surgeries were postponed. The lockdown affected post-operative patients also as they missed their follow-up visits. This made patients/parents anxious as no one had any clue that when the situation will be normalized and the cleft program at the hospital will be restored? To relieve their anxiety to some extent, we started teleconsultation. In teleconsultation, for pre-operative cases, we focused on counselling of the parents including advices on feeding and general care of the child, whereas for post-operative patients, we looked into wound care, lip massage and speech exercises. The OPD and OT for the cleft services at the hospital were restored after 3 months. We started cleft surgeries from the last week of June 2020 with following a revised surgical strategy to limit the spread of SARS-CoV-2 and also to provide safe surgical care. This surgical strategy was framed from the recommendations given by Al-Omar et al. [6] and Somashekhar et al. [7] and it was based on five P's; 1) Prioritizing cleft procedures, 2) Pre-operative screening of the patient, 3) Providing a clean and safe hospital environment to the patient and hospital personnel 4) Protective methods by hospital personnel and 5) Preventive measures by the attendants outside the hospital (Fig. 1). The aim of this paper is to share our surgical strategy, what we have followed and the experience what we had with the cleft procedures in this COVID era, before the start of vaccination programme. The vaccination for the health care workers was started from the last week of January 2021 at our center. Written consent from the patient/attendants and clearance from the ethical committee of the hospital were obtained.

Materials and Method

The surgical strategy for performing cleft surgeries at our center during COVID-19 included:

1. Prioritizing cleft procedures

We started cleft surgeries with primary procedures only. Secondary procedures were strictly kept on hold in the initial phase. Once all the protocols related with COVID-19 prevention were streamlined in the hospital, we started with age bound essential secondary surgeries which included palatal fistula closure, alveolar bone grafting (ABG) and correction of velo-pharyngeal dysfunction (VPD). Procedures like secondary lip/nose correction, osteotomies and rhinoplasties were strictly denied. From June 2020 to January 2021, a total number of 205 patients were registered in the hospital for the cleft procedures, 183 for the primary and 22 for the secondary procedures (Table 1).

2. Pre-operative screening of the patient

For every patient, we collected prior information related to their age, weight, haemoglobin and blood counts other than the clinical picture of the deformity through the teleconsultation. They were advised to get a general check-up, if possible, from any nearby paediatrician/physician. After they reached the hospital, they followed a protocol for the admission (Fig. 2). The patients and attendants were screened in an isolated zone, which was made outside the building but, inside the premises of hospital. The patient underwent chest radiography and sampling for the COVID test in the screening zone. We preferred real-time reverse transcription polymerase chain reaction (rRT- PCR) as the COVID test. If the patient was found negative, only then he/she was given admission in the cleft ward and the surgery was planned. If the patient was found COVID positive, then surgery was deferred and the patient was referred to a specialist to manage the COVID.

3. Providing a clean and safe hospital environment to the patient and hospital personnel

Standard institutional infection control measures as advised by the Ministry of Health and Family Welfare, Government of India (2020) were taken [8]. This included regular cleaning and disinfection of

Volume 4, Issue 2; March-April 2021; Page No 203-209

OPD, ward and OT, minimizing the numbers of visitors inside the hospital premises and restricted movements of the attendants within the hospital.

4. Protective methods by the hospital personnel

In the ward and OT, all the necessary protective measures were taken by the staff and doctors as suggested by Somashekhar et al. [7], which included judicious use of N95 respirators, face shield, surgical gloves and personal protective equipment (PPE) kit. High efficiency particulate air (HEPA) filter was made mandatory for the OT.

5. Preventive measures by the attendants outside the hospital

We provided all the necessary instructions to the parents/attendants which they need to follow before admission and after discharge from the hospital to minimise the chances of infection (Fig. 3). All the operated patients were followed till one month of the surgery.

Results

Out of 205 patients which were registered for the surgical care, six patients came COVID positive during their first visit to the hospital. All the six patients including their attendants were asymptomatic. No abnormality was evident on their chest radiograph, lungs were completely clear bilaterally. Their cycle threshold (CT) values including E-gene, Orf1A were noted (Table 2, Fig.4). They were referred to the concerned authority for the management of COVID. These patients and their families were followed by the local administration and government health department. After they received clearance regarding their COVID status from these authorities, we made them to wait for another 6 weeks for the surgery. After 6 weeks, same protocol for the admission was followed. Out of 6, five patients received the surgical care and their post-operative period were completely uneventful. The sixth patient has recovered from the COVID and waiting for 6 weeks to receive the surgery. Rest 199 patients, who came COVID negative during their first visit to hospital, also recovered well from the surgery. None of the post-operative patient got infected with COVID during their recovery phase.

Discussion

COVID has affected our health care system specially the elective procedures throughout the globe. We have been providing cleft care in our tertiary care hospital since 2006 and in last 15 years we have delivered almost 9000 cleft surgeries, including both primary as well as secondary. We halted all sorts of cleft procedures including OPD for about 3 months. This resulted in significant increase in numbers of pending procedures. Meredith et al. [9] stated that elective procedures are essential contributors to the patient health and well-being of communities. Al-Omar et al. [6] commented that in some instances the consequences resulting from a delay in delivering surgical care may outweigh those of viral infection itself. We completely agreed with these authors and started our cleft work from the last week of June 2020. Although parents/patients were waiting eagerly for us to start the cleft surgeries but, when they were given an appointment for the same, most of them showed an apprehension to come to the hospital because of chances of exposure to SARS-CoV-2. To reduce their anxiety and gain their confidence, we focused on a surgical strategy which ensured safety of the patients, attendants and hospital personnel.

First of all, we categorized cleft procedures as ‘essential’ and ‘non-essential’. Essential procedures included primary cleft lip and palate repair, palatal fistula closure, ABG and correction of VPD, whereas secondary lip/nose correction, osteotomies and rhinoplasties were categorized as non-essential in the current situation. Ancillary treatments like speech therapy and orthodontic treatments were started very recently, that too for very selective patients. Speech therapy services for most of the patients were given via teleconsultation. We followed a strict protocol for the screening of the patient and attendants, which included history taking and vitals measurement (body temperature and oxygen saturation). Chest radiography and rRT-PCR were mandatorily performed for the patient. Initially, we used to get chest radiograph of the attendants also, but it increased the burden on the patient’s hospital bill therefore, it was soon discontinued. The hospital authority took all the necessary measures to provide a clean and safe environment inside the campus which included setting up the screening zone outside the hospital building, frequent cleaning of all the surfaces which may be contaminated, installation of hand sanitizer units at all the required places and limiting

Volume 4, Issue 2; March-April 2021; Page No 203-209

the numbers of visitors. Surgical training programs in all the departments were completely put-on hold. The movements of the attendants were also restricted inside the hospital premises. The universal instructions for the COVID-19 prevention (use of facemask, frequent hand washing and social distancing) were displaced at every noticeable place of the hospital. The consent for the admission and procedure were revised in accordance to COVID-19. The newer protective methods were adopted by the hospital personnel like use of N95 respirators, face shield and PPE kit. The operated patients, on their discharge were given necessary instructions related to COVID-19 prevention in the recovery phase (Fig.3), and asked them to follow it strictly. For follow up, teleconsultation was preferred unless the physical presence of the patient was required. Teleconsultation is a safe and effective way to assess the clinical condition of the patient without having risk of disease transmission. Telepresence can be used to provide telecare, surgery-based information, follow-up, and also the discussion among the cleft care team as advised by Pan American Health Organization (PAHO) and World Health Organization (WHO) [10].

Following all the above protocols for our cleft program, we could identify the COVID positive patients in the screening zone itself. This reduced the chances of cross infection within the hospital. Similarly, precautions taken by the attendants during recovery phase prevented the patient from getting infected during healing phase. This revised strategy for performing cleft procedures in the hospital increased the cost of surgery per patient by almost 20%, which included the expenses against COVID testing, frequent cleaning of the hospital and the newer protective methods adopted by staff and doctors.

Out of 205 patients who were registered for the cleft procedures in the hospital, only six patients (2.93%) came COVID positive, whereas the test positivity rate in our state stands 4.5% as dictated by the government official site (covid19india.org) [11]. The lesser percentage of infection in our study can be attributed to the presence of larger population of paediatric patients. Many authors reported that the paediatric age group shows less effect of COVID [3,12]. Yu et al. stated that in paediatric patients, less effect of COVID is not due to the vaccines, but due to no significant cross reactivity against SARS-CoV-2 [13]. According to Rehman, thymus gland plays a key role in this regard which is more active in the childhood. This gland has a major role with its resident plasma cells secreting functional antibodies fixing complements, which promotes the immunity in early childhood [14].

Conclusion

Cleft surgeries, especially essential ones, can be carried out safely in times of corona after a thorough screening of the patient, taking proper protective and preventive measures at the hospital and home. Teleconsultation is of great help for the doctors and patients during this pandemic.

Abbreviations

SARS – Severe Acute Respiratory Syndrome

MERS – Middle East Respiratory Syndrome

SARS- CoV- 2 – Severe Acute Respiratory Syndrome Coronavirus 2

COVID-19 – Coronavirus Disease 19

RNA – Ribonucleic Acid

ASPS – American Society of Plastic Surgeons

OPD – Out Patient Department

OT – Operation Theatre

ABG – Alveolar Bone Grafting

VPD – Velo-pharyngeal Dysfunction

rRT-PCR - Real time Reverse Transcription Polymerase Chain Reaction

PPE – Personal Protective Equipment

HEPA – High Efficiency Particulate Air

CT – Cycle Threshold

PAHO – Pan American Health Organization

WHO – World Health Organization

References

1. Dhama K, Khan S, Tiwari R, Sircar S, Bhat S, Malik YS, Singh KP, Chaicumpa W, Bonilla-Aldana DK, Rodriguez-Morales AJ. 2020. Coronavirus disease 2019 –COVID-19. Clin Microbiol Rev 33:e 00028-20. https://doi.org/10 .1128/CMR.00028-20.

Volume 4, Issue 2; March-April 2021; Page No 203-209

2. Weiss SR, Leibowitz JL. 2011. Coronavirus pathogenesis. Adv Virus Res 81:85–164. https://doi.org/10.1016/B978-0-12-385885-6.00009-2.
3. Wang, X.F., Yuan, J., Zheng, Y.J., Chen, J., Bao, Y.M., Wang, Y.R., Wang, L.F., Li, H., Zeng, J.X., Zhang, Y.H., 2020b. 'Clinical and epidemiological characteristics of 34 children with 2019 novel coronavirus infection in Shenzhen', Zhonghua er ke za zhi. Chin. J. Pediatrics 58, E008.
4. Lu R, Zhao X et al Genomic characterization and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding. Lancet 395:565–574. https://doi.org/10.1016/S0140-6736(20)30251-8.
5. American Society of Plastic Surgery website. ASPS guidance regarding elective and non-essential non- essential patient care. https://www.plasticsurgery.org/for-medical-professionals/ covid19-member-resources#statement. [Accessibility verified March 19, 2020])
6. Al-Omar K, Bakkar S, Khasawneh L, Donatini G, Miccoli P. Resuming elective surgery in the time of COVID-19: a safe and comprehensive strategy. *Updates Surg*. 2020;72(2):291-295. doi:10.1007/s13304-020-00822-6
7. Somashekhar SP, Shivaram HV, Abhaham SJ, et al. ASI's Consensus Guidelines: ABCs of What to Do and What Not During the COVID-19 Pandemic [published online ahead of print, 2020 Jun 9]. *Indian J Surg*. 2020;1-11. doi:10.1007/s12262-020-02452-z
8. Ministry of Health and Family Welfare, Government of India. Clinical management protocol for COVID 19. https://www.mohfw.gov.in/pdf/Clinical Management Protocol for COVID19 dated 27.06.2020
9. Meredith JW, High KP, Freischlag JA. Preserving Elective Surgeries in the COVID-19 Pandemic and the Future. *JAMA*. 2020;324(17):1725–1726. doi:10.1001/jama.2020.19594
10. Teleconsultations during a pandemic – Factsheet – PAHO and WHO 2020
11. Madhya Pradesh (India) District wise data base. Available at: https://covid19india.org/state/MP. Accessed March 5, 2021
12. Wei, Min, Jingping Yuan, Yu, Liu, Tao Fu, Xue, Yu, Zhang, Zhi-Jiang, 2020. Novel coronavirus infection in hospitalized infants under 1 year of age in China. JAMA.
13. Yu Y, Jin H, Chen Z, Yu QL, Ma YJ, Sun XL, Wang B. Children's vaccines do not induce cross reactivity against SARS-CoV. J Clin Pathol. 2007 Feb;60(2):208-11. doi: 10.1136/jcp.2006.038893. PMID: 17264247; PMCID: PMC1860633.
14. Rehman S, Majeed T, Ansari MA, Ali U, Sabit H, Ebtesam A. Al-Suhaimi, Current scenario of COVID-19 in pediatric age group and physiology of immune and thymus response. Saudi Journal of Biological Sciences 27 (2020) 2567–2573

Volume 4, Issue 2; March-April 2021; Page No 203-209

Tables

Type of procedures	Numbers of patients	Mean age in months
Cleft lip repair	116	8.3
Cleft palate repair	66	20.2
Fistula closure	14	26.7
Alveolar bone grafting	3	126
VPD Correction	5	120
Un-operated cleft lip	1	8

Table 1: Types of procedures and mean age of the patients

S.N.	E-GENE	Orf1A	Control
Case 1	16	17.33	23.2
Case 2	15.4	16.81	23
Case 3	18.1	20.11	24.5
Case 4	21.6	21.2	24
Case 5	20.9	19.1	23.3
Case 6	17.2	18.1	22.3

Table 2: Cycle threshold values; E-gene, Orf1A and Control (RT-PCR by MolBio TruNAT)

Figures

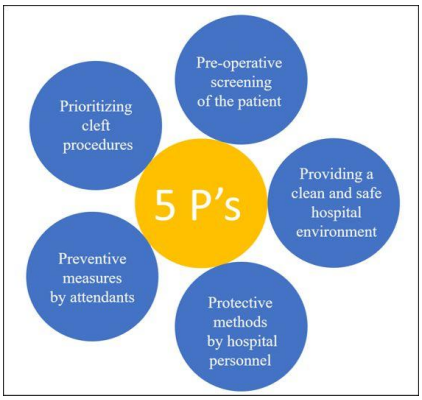

Fig.1 Five P's of surgical strategy during COVID-19

Volume 4, Issue 2; March-April 2021; Page No 203-209

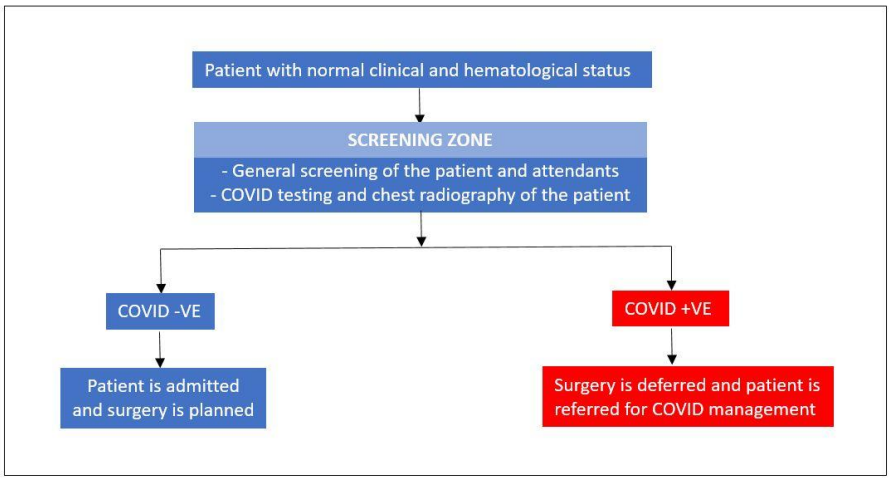

Fig.2 Protocol for admission

Pre-operative instructions
1. Home quarantine should be followed for 2 weeks by the patient and attendants before surgery. 2. Number of attendants permissible – 2 (for patients ≤ 15 years of age) and 1 (for patients >15 years of age). 3. Personal transportation should be preferred rather than public transportation. 4. Universal precautions for COVID-19 (wearing a mask, frequent hand washing and social distancing) should be followed by the attendants inside hospital premises.
Post-operative instructions
1. Personal transportation should be preferred rather than public transportation. 2. Home quarantine should be followed for 2 weeks by the patient and caretaker after the surgery. 3. Universal precautions should be followed by all the family members inside home.

Fig.3 Pre-operative and post-operative instructions

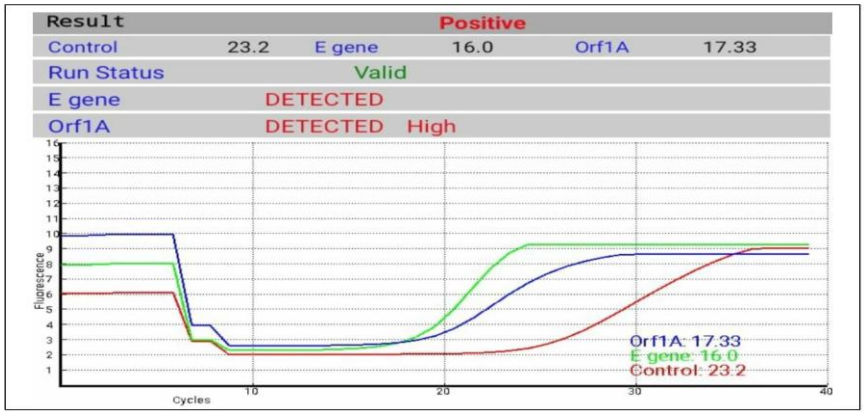

Fig.4 Positive SARS-Cov-2 genes (RT-PCR by MolBio TruNAT)

Volume 4, Issue 2; March-April 2021; Page No 203-209