

Legal Aspects & Problems of Rhinoplasty During COVID-19

Rhinoplasty Society Europe Task Force

Haldun Kamburoğlu

MD, PhD, FEBOPRAS, Assoc.Prof.

Plastic, Reconstructive and Aesthetic Surgeon (European Board Certified)

Oral and Maxillofacial Surgeon

Doctor of Philosophy in Aesthetic Surgery

Koc Ikiz Kuleleri A Blok No:57 Sogutozu Mah. 06520 Cankaya / Ankara / Turkey

Level of Evidence: 5

Q1: Does COVID-19 influence the rate of problems during surgery?

(Does COVID-19 increase complication rate? Yes)

A1:

According to a report from Wuhan 34 patients who underwent elective surgery during the incubation period of COVID-19, had 44.1% ICU (15 patient) need and 20.5% mortality (7 patient)¹. When the surgical difficulty increased, the need of ICU was increased as well. Also, the patients in ICU had longer operative times. All 34 patients had developed pneumonia and had demonstrated bilateral distribution of patchy shadows or ground glass opacity on CT scan. Died patients had underwent surgeries with the difficulty level 3 over 4.

Although there was no control group, they were able to compare their findings with the general literature about COVID-19. They found higher rate of ICU need (44.1%) than the reported ICU need for hospitalized COVID-19 patients (26.1%)². Although the hospitalized COVID-19 ICU need number is quite high³ than the literature, it may be comparable. They found most patients in ICU were older, had more comorbidities, longer surgical time and more difficult surgery.

Authors stated that the mortality rate was higher than the reported overall case-fatality rate of 2.3% in COVID-19 patients⁴ and reported overall case-fatality rate 7.9% in non-cardiac surgical patients admitted to ICU without COVID-19⁵. But the major problem of the paper is, they should compare their findings with the mortality rate of the COVID-19 patients who had similar comorbidities in ICU. The most prevalent comorbidities with COVID-19 are hypertension and diabetes which are associated with the rapid development of severe illness⁶.

At least one comorbidity was seen more commonly in severe cases (32.8%) than in non-severe cases (10.3%)⁷. Percentage of the severe and critical cases are 14% and 5% respectively in normal population. Mortality rates of these groups are 52% and 98% respectively⁸.

In COVID-19, the patient's immune function is very important to determine the severity of the disease⁹. It is clear that, anesthetic drugs, surgical stress, hypotension, hypothermia, pain, blood transfusion and hyperglycemia impair immune function¹⁰. The neuroendocrine system, proinflammatory cytokines and anti-inflammatory cytokines, synergistically act to impair the immune system¹⁰. It is known that, volatile anesthetics have high impairment on immune system, whereas propofol has moderate and synthetic opioids (fentanyl, remifentanyl, alfentanil) have low¹⁰. Additionally, extradural anesthesia (for example local anesthesia) decreases intraoperative and postoperative neuroendocrine stress responses¹⁰. As a result of this, during COVID-19, combination of total intravenous anesthesia with local anesthesia seems like a better option than volatile anesthesia. Personally, I always prefer this combination instead of volatile anesthesia.

ANESTHESIA TYPE	RISK OF IMMUNOSUPPRESSION
Volatile Anesthesia	High
Propofol	Moderate
Synthetic Opioids (Fentanyl, Remifentanyl, Alfentanil)	Low
Extradural Anesthesia (Local Anesthesia)	Decreases intraoperative and postoperative neuroendocrine stress responses

Q2: How can a rhino-surgery patient be infected by corona virus during rhino-surgery and in which circumstances, surgeon is responsible?

Can the surgeon be responsible for COVID-19 during rhinoplasty?

Abstain, it depends on situation

A2:

During pre-op consultation, operation or post-op follow up;

- Consultation and follow-up; surgeon may be responsible because the reason for infection is the surgical procedure but it is not easy to prove this during pandemic unless there is a COVID-19 staff

- Surgery, mainly hospital (maybe partially surgeon) is responsible, again not easy to prove during pandemic

2. During his/her social life before the surgery;

- Surgeon is not responsible for the infection
- BUT he might be responsible because of the consequences if he/she operate this patient!

3. During his/her social life after the surgery;

- Surgeon is not responsible for the infection
- BUT he might be responsible because of the consequences about the surgery

Q3: Complication or malpractice?

After the approval of health authority to perform elective surgeries, if the surgeon takes all recommended precautions and also inform the patient, in that case problem due to COVID-19; Is a complication?

Yes

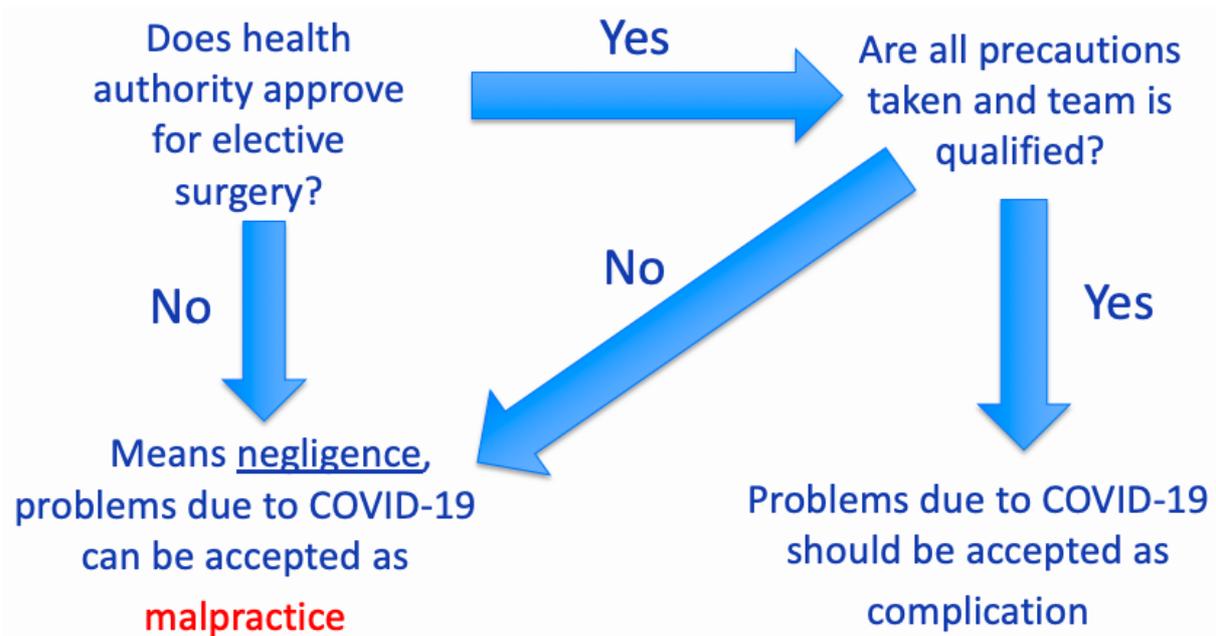
Is a malpractice?

No

A3:

Malpractice: The undesired conditions due to negligence, lack of knowledge or expertness

Complication: The undesired conditions although there is sufficient care, knowledge and expertness



Q4. What is the correct timing for resuming elective surgery? Does it worth to take risk? What should be the threshold corona virus positive case number in your country to feel safe?

Is resuming elective surgery now appropriate?

No for almost whole of the world

A4:

There are different perspectives between countries and health systems. But it is generally recommended elective surgeries to be postponed to a time when COVID-19 crisis calms down¹¹⁻¹³. Now, in most of the countries, COVID-19 is in its plateau state and surgeons and health systems are planning to resume elective surgeries. American College of Surgeons, American Society of Anesthesiologists, Association of Perioperative Registered Nurses and American Hospital Association recommended to resume surgeries after a sustained reduction in rate of new COVID-19 cases in the relevant geographic area for at least 14 days with the authorization by the appropriate municipal, county and state health authorities¹⁴. Also, it is recommended that, appropriate number of ICU and non-ICU beds, PPE, ventilators, medications, anesthetics, medical surgical supplies and trained untired staff should be in the facilities. Although these suggestions make sense, there is not a clear suggestion about elective surgery.

Aesthetic procedures are elective, which means surgeon and patient can elect the time of the surgery without negative impact on the surgical outcome or disease process. On the other hand, for 'semi-elective' surgeries, 'medically necessary time sensitive procedure' concept is recommended during COVID-19 pandemia¹⁵. This scoring system was generated recently but interobserver reliability of the scoring process was not assessed. Limitations of the study are, each subject had been given an equal weight, and possible other important factors about the disease might have been omitted because lack of data. According to this system, when we calculate the MeNTS score of septoplasty, it is approximately between 41 and 55, whereas MeNTS score of rhinoplasty is approximately between 47 and 61, which means both have moderate risk and should be postponed. Having said that, although rhinoplasty can be accepted medically necessary in a of 'psychological surgery', this scoring system is for time sensitive operations, not for the elective ones.

So, does it worth to take the risk? I think we should consult the micromort concept, which was introduced by Ronald A. Howard in 1980¹⁶. This terminology defines the risk of death with one-in-a-million chance. For example, living 2 days in New York City increases risk of death by 1 micromort, which means the risk to die is 1/1.000.000. Micromort value of driving a car 1 hour/day is 2, operating ASA-I patient under general anesthesia is 4, driving a car 8 hours/day is 16, ASA-II patient is 50, in ASA-III patient is 270, and in ASA-IV patient is 550^{17,18}. Nearly zero risk, there should be no corona virus positive case in your country for at least 14 days. '14 days concept' is accepted as standart¹⁹, however one should keep in mind that there may be longer incubation period cases. That means if there is 20 corona virus positive patient in your country which has a population of 1.000.000, you have the equal risk ASA-I patient in normal conditions. (%20 mortality rate is accepted according to the study of Lei et al. although those patients were not ASA-I) On the other hand there may be more patient than the detected because of the asymptomatic ones and inadequacy of filtration.

RISK PERCEPTION	Micromort (Chance of Death in 1 / 1.000.000)
Living 2 Days in NYC ¹	1
Driving a car 1 hour/day ¹	2
ASA – I Patient General Anesthesia ²	4
Driving a car 8 hours/day ¹	16
ASA – II Patient General Anesthesia ²	50
ASA – III Patient General Anesthesia ²	270
ASA – IV Patient General Anesthesia ²	550
20 Corona Virus Patient in a Country of Which Its Population is 1.000.000	4 = ASA – I Patient General Anesthesia Micromort ★ %20 mortality rate is accepted according to the study of Lei et al. although those patients were not ASA-I ★ There may be more patient than detected because of the asymptomatic patients and inadequacy of filtration
Nearly '0' Risk	No corona virus positive patient should be in the country at least 14 days ³ .

So, after the health authorities approve the beginning of elective surgeries, surgeon should decide on the risk and resuming time him/herself. We may look this situation with the philosophy of Aristotle's 'Golden Mean' or Buddha's 'Middle Way'. But we shouldn't forget that, we earn our lives with the operations we do and earn reputability with the ones that we don't do. One single intubated corona virus positive rhinoplasty patient in ICU might be your worst nightmare in your whole life. Also, ask yourself; 'Can you have your best result under stress?'. On the other hand, good news is, according to the predictions and simulations, COVID-19 seems to end (if the countries don't let go) in August and September in the most of the countries²⁰.

Q5: Do informed consent forms protect us?

(Does informed consent has to be adapted? Yes)

A5:

Informed consent forms are not a protective shield for any kind problem. Because their aim is to prove that we inform the patient and receive their consent. If you don't take consent, it means you did not inform the patients which is a malpractice. By the approval of the elective operations by the health authority, having informed consent forms including COVID-19 is mandatory.

Q6: If any risk occurs, does insurance policy cover it?

A6:

This subject depends on your insurance policy and the juridical system of your country but if there is no statement against pandemia, then it should cover the complications.

References

1. Lei S, Jiang F, Su W, et al. Clinical characteristics and outcomes of patients undergoing surgeries during the incubation period of COVID-19 infection. *EClinicalMedicine* 2020;100331.
2. Wang D, Hu B, Hu C, et al. Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus-Infected Pneumonia in Wuhan, China. *JAMA* 2020.
3. Rodriguez-Morales AJ, Cardona-Ospina JA, Gutierrez-Ocampo E, et al. Clinical, laboratory and imaging features of COVID-19: A systematic review and meta-analysis. *Travel Med Infect Dis* 2020;101623.
4. Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72314 Cases From the Chinese Center for Disease Control and Prevention. *JAMA* 2020.
5. Kumar P, Renuka MK, Kalaiselvan MS, Arunkumar AS. Outcome of Noncardiac Surgical Patients Admitted to a Multidisciplinary Intensive Care Unit. *Indian J Crit Care Med* 2017;21:17-22.
6. Hu Y, Sun J, Dai Z, et al. Prevalence and severity of corona virus disease 2019 (COVID-19): A systematic review and meta-analysis. *J Clin Virol* 2020;127:104371.
7. Guan WJ, Liang WH, Zhao Y, et al. Comorbidity and its impact on 1590 patients with Covid-19 in China: A Nationwide Analysis. *Eur Respir J* 2020.
8. Siordia JA, Jr. Epidemiology and clinical features of COVID-19: A review of current literature. *J Clin Virol* 2020;127:104357.
9. Chen N, Zhou M, Dong X, et al. Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. *Lancet* 2020;395:507-13.
10. Kurosawa S, Kato M. Anesthetics, immune cells, and immune responses. *J Anesth* 2008;22:263-77.
11. Zarrintan S. Surgical operations during the COVID-19 outbreak: Should elective surgeries be suspended? *Int J Surg* 2020;78:5-6.

12. Topf MC, Shenson JA, Holsinger FC, et al. A Framework for Prioritizing Head and Neck Surgery during the COVID-19 Pandemic. *Head Neck* 2020.
13. COVID-19: Recommendations for Management of Elective Surgical Procedures. at <https://www.facs.org/covid-19/clinical-guidance/elective-surgery>.)
14. Joint Statement: Roadmap for Resuming Elective Surgery after COVID-19 Pandemic. at <https://www.facs.org/covid-19/clinical-guidance/roadmap-elective-surgery>.)
15. Prachand VN, Milner R, Angelos P, et al. Medically Necessary, Time-Sensitive Procedures: Scoring System to Ethically and Efficiently Manage Resource Scarcity and Provider Risk During the COVID-19 Pandemic. *J Am Coll Surg* 2020.
16. Howard RA. On making life and death decisions. *Societal Risk Assessment: How Safe is Safe Enough?*1980:89-113.
17. Gottschalk A, Van Aken H, Zenz M, Standl T. Is anesthesia dangerous? *Dtsch Arztebl Int* 2011;108:469-74.
18. Sieber DA, Adams WP, Jr. What's Your Micromort? A Patient-Oriented Analysis of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). *Aesthet Surg J* 2017;37:887-91.
19. Backer JA, Klinkenberg D, Wallinga J. Incubation period of 2019 novel coronavirus (2019-nCoV) infections among travellers from Wuhan, China, 20-28 January 2020. *Euro Surveill* 2020;25.
20. COVID-19 End Date Estimations. at <https://ddi.sutd.edu.sg/when-will-covid-19-end>.)