

HMC RESEARCH PROTOCOL

Study Title:	Anesthetic Management for Burn Injuries During SARS-CoV-2
Local IRB Serial number	MRC-01-20-1074

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1.Synopsis

Objective Anesthetic management of burn patients is a real challenge to the anesthesiologist. Recently, in the presence of COVID-19 epidemic, we tried to manage safely our patients and provide protection for our health care professionals. There is a lack of information about Survival of burn patients under these conditions.

Aim of this work:

Primary outcome is to investigate survivals, ICU admission and length of hospital stay of those critical patients.

Secondary outcome is to analyses perioperative factors that affected their survival outcome.

2.Abbreviations and Acronyms

Severe acute respiratory syndrome coronavirus-2, (SARS-Cov-2), coronavirus disease 2019, COVID-19; American Society of Regional Anaesthesia and Pain Medicine, ASRA; European Society of Regional Anaesthesia and Pain Therapy, ESRA

3. Introduction / Background

The rapidly spreading severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) the causative agent of coronavirus disease 2019 (COVID-19) epidemic is attacking the whole world and exaggerating an economic crisis (1). It is transmitted via contact with respiratory droplets that exposes anaesthetists to the risk of viral infection during their routine work (2),(3).

All countries have implemented protective and preventive measures which subjected persons to stay longer period at home. A Brazilian study found that spending more time in the domestic environment and, consequently, leading to a greater exposure to sanitizer products, which contain ethanol and hydrogen peroxides that can lead to burn injuries during the pandemic period of COVID-19 (4),.

Many burn centers have revised their policy during COVID-19 pandemic (5),(6). Burns are an acute emergency condition, and burn management needs to be initiated before COVID-19 infection status can be confirmed. Our institute already developed an algorithm for protection during COVID-19 infection. However, anesthesia management is challenge for burn patient particularly if the patient is suspected or diagnosed to be positive for corona virus.

In the era of COVID-19, Both the American Society of Regional Anaesthesia and Pain Medicine (ASRA) and the European Society of Regional Anaesthesia and Pain Therapy (ESRA) established a joint statement which recommends neuraxial and peripheral nerve blocks for patients with COVID-2019 infection and describe the benefits of regional anesthetic and analgesic techniques over general anaesthetics especially in patients with underlying metabolic derangements such as burns (7). Those critical patients with COVID-19 were subjected to coagulation abnormalities which may affect their survivals (8).

Aim of our Study:

Primary outcome is to investigate survivals, ICU admission and length of hospital stay of those critical patients.

Secondary outcome is to analyses perioperative factors that affected their survival outcome.

4. Objectives

In this section provide a clear statement of the primary and any secondary objectives of the study

To investigate survivals, ICU admission and length of hospital stay of those critical patients.

And to analyze perioperative anesthetic factors that affected their primary outcome.

5. Indicate if this is a retrospective data review

- **Retrospective Chart/data Review** *(Retrospective means the data is already in existence when the project is submitted to the IRB for initial review.)*
- **Provide the date range of the chart review** *(if this is a retrospective chart review, the end date must come before the submission date April 1, 2020, and November 16, 2020.)*

6. Study Methodology

Patients who had the burn graft surgery at Al Wakrah Hospital; Hamad Medical Corporation between from April 1, 2020, and November 16, 2020. **Planned sample size will include all COVID-19 positive and negative cases. Our institution as Al Wakrah Hospital is the ONLY center at HMC which deals with those unique Burn patients allover Qatar. By increasing sample size, we can get our expected results statistically.**

Data Source

The electronic medical record (Cerner) used in order to identify patients who match study defined criteria. We can Collect data directly from Cerner to excel sheet

Variable Abstraction

Patient demographic and clinical data will be collected including age, morbidities, presenting symptoms, physical examination, laboratory investigations, intraoperative data, type of surgery, postoperative course, survival, and length of hospital stay and follow up.

In addition, the type of anesthesia is also included as factor for further complications ex general anesthesia, spinal or combined spinal epidural type.

Retrospective full reviewing of their medical illness and chart laboratory and investigations will be collected after getting approval of MRC and IRB committee.

7. Study Population and Study Setting/ Location

All adult patients who had undergone burn graft surgery at Al Wakrah (AWH) Hospital; Hamad Medical Corporation between April 1, 2020, and November 16, 2020. We will include all Consecutive Adult patient underwent burn grafting surgery at AWH either

they are COVID positive or negative.

8. Study procedures

Provide an outline and describe in detail the processes and operations of the study, including logistics

Study Duration and Timelines

Expected duration of the study & start times, stages of the study such as screening, treatment phase, visit numbers, etc

6 months data collection & another 6 months writing manuscript and trial to submission to a suitable journal

Informed Consent

Informed Consent will be waived for such a retrospective analysis.

Risk

This study has no physical, psychological, economic or societal harms that may befall a subject as a result of their data being included in this study.

Bio-Specimens & Sample Collection

Not applicable

Outcomes

Primary outcome is to investigate survivals, ICU admission and length of hospital stay of those critical patients.

Secondary outcome is to analyses perioperative anesthetic factors that affected their primary outcome.

Data Collection, Management&Confidentiality

a) Indicate below HOW study data will be collected for the proposed research.

Study Forms Study Database Study Web-Based/App Other

Please detail how study data will be coded:

Special encryption codes will be used to separate research data from subject identifiers and the data will be dealt with privacy and confidentiality. Each patient will be assigned a random code and any information relating to the patient will now only be related to the patient by the random code and not by their name or health card number. Then any link to the actual record will be destroyed after data collection is completed. The anonymized data set will be kept for at least 5 years after study completion. Data will be collected in excel format.

b) Describe below WHERE and HOW the study data is physically stored.

Primary investigator will store the electronic data on a password protected computer which is secured by a firewall. Data collection form will be kept in a safe cabinet. The anonymized data set will be kept for at least 5 years after study completion.

kept in a safe cabinet

c) Describe below WHO controls access to the study data

PI

d) Describe below WHO has access to the study data.

PI

e) Describe below HOW the study data is accessed.

The lead PI will have the control over the access to study data through password secured computers.

f) Will subject identifiers be shared outside of HMC? If YES describe below WHOM the study data is shared

No

Subject Withdrawal/ Withdrawal of Consent

Not applicable

9. Statistical Consideration and Data Analysis

Descriptive statistics will be used to summarize all demographic, clinical, laboratory

tests, intraoperative data, postoperative course and outcomes. The normally distributed data and results will be reported with mean and standard deviation (SD); the remaining results will be reported with median and interquartile range (IQR). Categorical data will be summarized using frequencies and percentages.

Survival can be performed using Kaplan Meir Curve; risk factors can be identified by using Univariate Analysis and Multivariate Logistic Regression Analysis.

All P values presented will be two-tailed, and P values <0.05 will be considered as statistically significant. All Statistical analyses will be done using statistical packages SPSS 22.0 (SPSS Inc. Chicago, IL) and Epi-info (Centers for Disease Control and Prevention, Atlanta, GA) software.

10. Adverse Event Reporting

No adverse events are expected.

11. Ethical Consideration

The study will be conducted in full conformance with principles of the “Declaration of Helsinki”, Good Clinical Practice (GCP) and within the laws and regulations of MoPH in Qatar.

12. Sponsor, Funding & Collaborator Information

Funding is needed for publication this research.

13. Dissemination of Results and Publication policy

After finish data collection, may be 3-4 months to finalize the statistics and writing the manuscript to submit in a suitable anesthesia journal after MRC approval.

14. Appendices

List in this section all intended forms or resources that will be used in the conduct of research to collect data, interview people, recruit participants.

Protocol. + Research information-DCF

15. References:

1. Wong J, Goh QY, Tan Z, Lie SA, Tay YC, Ng SY, et al. Preparing for a COVID-19 pandemic: a review of operating room outbreak response measures in a large tertiary hospital in Singapore. Can J Anaesth. 2020 Jun;67(6):732-45.

2. Plaat F, Campbell JP. Is spinal anaesthesia an aerosol-generating procedure? Transmission of SARS-CoV-2 from patient to anaesthetist. Br J Anaesth. 2020 Sep;125(3):e315.

3. Zhong Q, Liu YY, Luo Q, Zou YF, Jiang HX, Li H, et al. Spinal anaesthesia for patients with coronavirus disease 2019 and possible transmission rates in anaesthetists: retrospective, single-centre, observational cohort study. Br J Anaesth. 2020 Jun;124(6):670-5.

4. Valente TM, Ferreira LPS, Silva RAD, Leite J, Tiraboschi FA, Barboza MCC. Brazil Covid-19: Change of hospitalizations and deaths due to burn injury? Burns. 2020 Oct 17.

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6. Young AW, Graves C, Kowalske KJ, Perry DA, Ryan CM, Sheridan RL, et al. Guideline for Burn Care Under Austere Conditions: Special Care Topics. J Burn Care Res. 2020 Mar/Apr;38(2):e497-e509.

7. Uppal V, Sondekoppam RV, Landau R, El-Boghdadly K, Narouze S, Kalagara HKP. Neuraxial anaesthesia and peripheral nerve blocks during the COVID-19 pandemic: a literature review and practice recommendations. Anaesthesia. 2020 Oct;75(10):1350-63.

8. Tang N, Li D, Wang X, Sun Z. Abnormal coagulation parameters are associated with poor prognosis in patients with novel coronavirus pneumonia. J Thromb Haemost. 2020 Apr;18(4):844-7.