**Assessment of Voice disorder among mechanically ventilated adult ICU survivors – A single-centre observational study (VOICE study)**

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# Summary of the research project in non-technical language

In hospitals, mechanical ventilation is crucial for critical conditions, commonly initiated in intensive care units through intubation. Unfortunately, about half of patients undergoing this process may suffer acute laryngeal injury, with limited information on its impact on post-ventilator speech. Our study focuses on how ventilator use for over 48 hours affects the voice in adult ICU patients. Utilizing the vocal handicap index (VHI-10) and voice-related quality of life (V-RQOL), we measure the impact on voice and overall well-being. The VHI-10, a 10-question questionnaire, assesses the impact of voice problems, with scores above 11 indicating a significant impact. The V-RQOL questionnaire gauges the burden of these issues. Our findings are crucial for identifying whether voice dysfunction exists after mechanical ventilation, if so to identify the predictive factors, enabling early intervention strategies like check-ups, speech therapies, and psychological support for those with voice issues, significantly improving their well-being.

# Background

There is an increase in the awareness of unique needs among intensive care unit (ICU) survivors.1 Most studies focus on patient’s physical, psychological and emotional problems once they go back into the community.2,3

Initiation of invasive mechanical ventilation is a common occurrence in ICUs. Invasive mechanical ventilation necessitates endotracheal intubation, which involves manipulation of upper airways, including the larynx, to facilitate mechanical ventilation. The literature suggests that approximately 50% patients develop acute laryngeal injury (ALgI) after receiving invasive mechanical ventilation and there a number of risk factors during the invasive ventilatory period, which may contribute to voice disorder.1 Voice is a very important means of communication and although voice disorder has been studied in the post-laryngeal surgical population,4,5 to our knowledge there is a paucity of literature determining whether endotracheal intubation and mechanical ventilation subsequent voice disorder and thereby reduction in voice related quality-of-life among ICU survivors.

# Aim

The aim of the study is to evaluate the burden of voice disorder as measured with VHI-10 in ICU survivors, who have 48 hours or more of invasive mechanical ventilation and determine predictors of voice disorder.

In doing so, the study seeks to meet the following Primary and Secondary objectives:

**Primary**

1. Quantifying voice disorder at 8 weeks after liberation from mechanical ventilation using Rosen’s VHI-10 instrument.

**Secondary**

1. To measure the effect of voice disorder on quality of life using voice related quality of life (V-RQOL) instrument.
2. Quantifying voice disorder at ICU discharge using Rosen’s VHI-10 instrument among patients who were mechanically ventilated (24-48 hours following extubation or at the time of ICU discharge, whichever comes sooner).
3. Evaluation of risk factors associated with voice disorder.
4. To formulate a risk scoring system to predict voice disorder.
5. **Hypothesis**

We hypothesize that ICU survivors will have a significant patient reported voice related morbidity after extubation from invasive mechanical ventilation.

# Study Methodology

# Study Design:

# This is a single-centre observational study. Convenient sampling will be performed since some patients may miss the recruitment due to public holidays or weekends.

Data will be collected from all patients who are liberated from mechanical ventilationafter more than 48 hours. This will include the review of background history, collection of demographic details and baseline characteristics (see appendix A). Various important risk factor for ALgI that are deemed important such as peri intubation events, experience of person who performed intubation, reason for intubation, any anatomical or physiological difficulties perceived during intubation, admission ICU severity score, fluid balance in ICU, details of steroid therapy, re intubation if any (see appendix A). Deidentified will be stored as per CHS Clinical Records Disposal Schedule policy on password protected computers.

# We intend to use well established vocal handicap index (VHI-10) and voice related quality of life (V-RQOL) instrument to quantify the voice disorder and reduction in quality of life (QOL) among mechanically ventilated ICU survivors (Appendix B and C).6,7 The VHI-10 is a patient-self-reported outcome measure used to record the patient's perception of impairment or handicap due to a voice problem. This instrument has 10 items, each has ratings from 0 to 4. Overall Scores ranges from 0 to 40 and scores above 11 are abnormal and indicate voice handicap. The V-RQOL consists of 10 questions aimed at capturing the subjective burden caused by a voice disorder, particularly in relation to physical functioning and social-emotional domains. VHI-10 will be given to these patients at 48-72 hours following extubation or before ICU discharge, whichever comes sooner. At 8 weeks following extubation, recruited patients will be provided by the research team with the VRQOL and VHI-10 to complete. The selection of an eight-week period is based on the assumption that it allows sufficient time for patients to contemplate their self-perceived voice disorder in relation to their voice handicap or quality of life, as assessed by the VHI-10 and V-RQOL measures.

# Study population

**Inclusion criteria**

* ICU patients aged 18 years or over, who have been invasively mechanically ventilated for 48 hours or moreare planned to transfer from ICU to a ward environment.

**Exclusion criteria**

* + Those who have refused to give consent
  + Extubated as a part of comfort care/end of life care/discharge against medical advice or to other hospital
  + Those who are incapable of interpreting and understanding the questionnaire.
  + Those who are unlikely to survive for next 3 months
  + Radiotherapy treatment of head and neck region in past 6 months
  + Pre-existing laryngeal pathologies
  + Those who had a tracheostomy

# Study Procedure

Participation Informed Consent Process

Written consent will be sought from the interested participants who meet the eligibility criteria. Participants would be asked to review the patient information sheet (PIS) and consent form (see Appendix D and E). Following consent, the participants will be enrolled to the study.

**Step 1:** Selection of patients is as per inclusion and exclusion criteria mentioned above. Informed consent will be obtained from all eligible patients. Informed consent will be conducted by investigators.

**Step 2:** Data Collection, questionnaire.

Both VHI -10 and V-RQOL are 10 item self-reported questionnaires. Each questionnaire will take probably 3-5 minutes to complete. Demographic and baseline characteristics such as sex, age, smoking status, comorbidities etc. including socioeconomic status, body mass index (BMI) and obstructive sleep apnoea (OSA) status will be captured. Details of intubating conditions (ie: grade of intubation, traumatic) and ICU severity of illness scores will be obtained from the Digital Health Records.

**Step 3:** Follow-up strategies

* Through Telephonic calls /E-mails by one of the researchers.
* If patient loses the form, one more questionnaire will be sent through post/E-mail
* Should any participant become distressed at any time during response to the questionnaire the ‘Distress Participant Protocol’ will be followed (Appendix F).

Sample Size

Following assumptions were made to calculate the sample size.

Since we do not know the incidence of actual voice disorder in the mechanically ventilated ICU survivors, therefore assuming patients who sustain ALgI to have significant voice disorder.

Assuming that 57% of the mechanically ventilated ICU survivors have the ALgI, the study would require a sample size of: 377 for estimating the expected proportion with 5% absolute precision and 95% confidence (52% and 62%). Factoring in dropout rate of 20% in the study we require 452 patients, rounded to 455 to test our study hypothesis.

Duration of the study

a. The recruitment of study ends once we reach our desired sample size of 455 patients. We anticipate the recruitment will end within 12-18 months’ time period. Overall study period will be 24 months.

b. Time taken for each subject (if it involves interviews, follow up period): Patients will be followed from the discharge from ICU to 8 weeks after extubation from mechanical ventilator.

**Ethics Review:** Ethics committee approval will be obtained prior to initiation of the study. Informed consent will be obtained from all the study participants. The results of this study may be useful to subsequent patients’ population admitting to ICU where we can implement strategies to minimize exposure to risk factors that may contribute to voice disorder.

1. **Privacy and Confidentiality**

The study will employ the following strategies to protect participants’ privacy and confidentiality:

1. Seek information only which is relevant to the study
2. Protect the confidentiality of the participants by ensuring identities are not ascertainable by:
   1. removing identifying information such as names
   2. demographic data will be aggregated and reported in a summary format only
   3. where there is a risk of re identification the participant’s demographic data will not be used
   4. storing only deidentified data
3. All the data stored on CHS servers are password protected and only accessible to the research team.
4. **Secure Data Storage**

The data collected from the study will be de-identified and stored on the password protected local network. The drive and folders are only accessible to the research team. All devices used by the research team are password protected. Access to the data for the purpose of the study will be supervised by the Chief investigators. Any handwritten documentation created will be immediately scanned and stored electronically and the originals disposed as confidential waste.

Study data will be archived for 7 years after the date of publication in accordance with the Canberra Health Services Clinical Records Disposal Schedule March 2023, after which time it will be deleted. Destruction of information and oversight of adherent data storage is the responsibility of the Chief investigators.

# Data Analysis

Data from the desktop review will be analysed descriptively. The analysis will be undertaken by the CHS research staff.

**Statistical analysis plan:**

Summary statistics will be reported using mean and standard deviation for continuous variables and median and IQR for non-normally distributed variables. VHI-10 is an ordinal scale which rates the voice disorder from 0 to 40. Multivariate logistic regression will be used to identify association between the predictors that determine the severity of VHI-10. V-RQOL is also an ordinal scale which rates the quality of life from 10 to 50. Magnitude of V-RQOL change will be reported as median with IQR. Association between VHI and V-RQOL will be tested using Correlation statistics. All the analyses will be carried out using STATA (version:17.0).

# Feasibility and Capability statement

Voice disorder is largely an unaddressed issue in adult critical ill ICU survivors who are invasively ventilated. Studies show that significant number of ICU survivors sustain acute laryngeal injury (ALgI) after receiving mechanical ventilation. However, implications of ALgI in the form of voice disorder is unknown and this study designed to evaluate this unknown.

This study will be conducted in the ICU. ICU survivors who are discharged will be followed after 8 weeks after extubating from mechanical ventilation and asked to fill-up a questionnaire to measures the subjective burden elicited by a voice disorder. With an average of 900 mechanical ventilated patients managed in our ICU each year, recruitment of 455 subjects is achievable over two years. Interim results of this study are also helpful to measure burden of voice disorder. Those who have such disorder can be directed to receive early speech therapies and psychological support in our ENT clinics.

This is a collaborative study involving specialists from intensive care and otorhinolaryngology. We have a diverse investigator population with registrars and staff specialists across different specialties and spanning early career and mid-career researchers. This enables us utilize respective skill sets to enhance the study quality and grow the capability and capacity of research at Canberra Health Services.

**Chief Investigator “A”**: Dr Kiran Kumar Gudivada is a Senior Registrar and Fellow, Intensive Care Medicine, Canberra Hospital who has 9 years’ experience in critical care and research. He has successfully completed GRANT research projects in the past and published findings in peer-reviewed journals. He conceptualising the study. He will be involved in co-ordinating project, participant recruitment, obtaining consent, data collection, sample collection or data analysis. Subsequently preparing and reviewing the manuscript.

**Chief Investigator “B”:** Dr Harshel G Parikh is a senior staff specialist in Intensive care medicine and has over 15 years’ experience in critical care. He was involved in conduct of multicentric trials. He has recently won best paper award in CHARMS 2023. He will be involved in data analysis, drafting and reviewing manuscript, monitoring overall study conduct.

**Chief Investigator “C”:** Professor Imogen Mitchell is Executive Director Research and Academic Partnerships, Canberra Health Services and the Australian National University and has over 20 years’ experience in an intensive care setting. She will be involve in data interpretation, drafting and reviewing manuscript, monitoring overall study conduct.

**Project (0.2 FTE project manager)** - For a duration of the project (0.2 FTE project manager) by the amount of work load involved – 16 hours fortnight for 2 years + 11% superannuation.

**Justification**: A project manager is indispensable for screening patients, overseeing data entry, consent procedures, and document maintenance, most importantly for patient follow-up. Although other co-investigators contribute to consent and data capture, relying solely on them is impractical due to their clinical responsibilities and rotations across different departments. Thus, having a dedicated project manager is crucial to ensure the seamless execution of the project.

**Consumer Representative –** We will consult a consumer representative to know about what are the best patient centred outcomes. Their opinion on VHI-10 and V-RQOL scores and their advice on logistics of administration of these scores at follow up.

**Co-Investigators**

Dr Sumeet Rai: Sr Staff Intensivist, Clinical Lead – Research ICU, Intensive Care Medicine, Canberra Hospital

1. Dr Manoj Singh: Sr Staff Intensivist and Director, Intensive Care Medicine, Canberra Hospital

Dr Connor O’Meara: Visiting Medical Officer, Otolaryngology, Head & Neck Surgery, Canberra Health Services

Dr Timothy Makeham: Visiting Medical Officer, Otolaryngology, Head & Neck Surgery, Canberra Health Services

Dr Bryn Stamford: Registrar, Intensive Care Medicine, Canberra Hospital

Dr Ashley Vu: Registrar, Intensive Care Medicine, Canberra Hospital

Dr Anirudh Deshpande: Registrar, Intensive Care Medicine, Canberra Hospital

All the co-investigators will be involved at various phases of the project. Such as consenting, data capture, data analysis, scientific inputs while analysing and drafting manuscript.

This is a clinical services delivery focused research and will benefit the patient population in Canberra and its surrounding regions. The research project also aligns with the CHS research strategy which focuses on building research capability and capacity at CHS. Notably, this is the first time Dr Kiran Gudivada has applied for PPAF funding and will be supported and mentored by Prof Imogen Mitchell who last received PPAF funding as a CI in 2020. This application will also build research capability and capacity by involving registrars in intensive care training who will be supported and mentored by Dr Harshel Parikh, winner of a CHARM award in 2023.

Evidence of collaboration with local academic institutions with scope for growth in this direction:

This collaborative project engages faculty from ANU alongside clinical specialists from ICU, ENT, and allied sciences. The potential impact of this research is twofold: Firstly, it aims to offer recommendations and guidelines for minimizing disease burden and developing strategies for early speech rehabilitation in these patients. Secondly, it seeks to lay the groundwork for larger multicentre trials across other Australian ICUs to validate our hypotheses in diverse settings.

1. **Budget outline**

**Income**

**Source of Funding:**

**Details of Funding**

External support of project $ 0

Total $ 0

Period of Funding 24 months

CHS Special Purpose Account:

**Expenditure**

**Personnel – specifically salaried or part salaried for this project**

All salaries are in kind commitments.

For a duration of the project (0.2 FTE project manager) by the amount of work load involved –

16 hours fortnight for 2 years + 11% superannuation.

Following discussion with the Finance Manager, clinical trial support the salary for Registered Nurse has been calculated as outlined below:

For Financial year 2025: Registered Nurse 0.2 FTE = 16 hrs per fortnight - **$30,631**

For Financial year 2026: Registered Nurse 0.2 FTE = 16 hrs per fortnight - **$30,669**

Salary (inclusive 11% Superannuation) $ 61300

**Total expenditure $** 61300

**Patient/Participant Costs**

Follow-up data collected through emails. Therefore, no additional cost involves

**Travel (study related for investigators and/or participants)**

Nil travel required $ 0

**Consumer Representative ($ 50 X 4 hours)**

Total $ 200

**Miscellaneous stationery (paper for printing)** $1000

**Other Costs (e.g., payments to volunteers)** $ 0

**Ethics Committee Fee**

Total $ 200

**Total Expenditure**

Total Expenditure **$62700**

1. **Project Duration and Timelines**

**Duration Timeline**

Recruitment of staff and procurement equipment: 3 months 1st 3 months

Enrolment Participants 17 months 1st 3 to 20 months

Follow up of Participants at 8 weeks post extubation 18 months 1st 4 to 22 months

Data Analysis 2 months Final 22 to 24 months

# Expected Outcomes

The results of this study will be useful to determine the prevalence of voice disorder, impact on voice related quality of life among ICU survivors and identify risk factors of voice disorder. Further, this will also help in identifying high risk patient groups and implementing strategies for early follow-up and speech therapies to those most likely develop voice disorder.

# Interim results of this study are vital to evaluate voice disorder. If we identify a patient who has significant voice disorder, we can implement strategies for follow-up of those patients by their General Practitioner.

# Future plans based on expected outcomes

Results of this study are vital to carry forward a large multi-center study to include diverse population. Also, to evaluate varied risk factors for voice disorder. To formulate a risk scoring system to predict voice disorder so as to identify high risk groups and implementing strategies for early follow-up of such patients and administering speech therapies and psychological support to high-risk ICU survivors. Overall, this study becomes a primer to initiate a larger multi center trial to have a broader understanding of problem burden, the results will lead to application of an external grants.

# References

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# Appendices

# Appendix A - Case record form

Appendix B - Voice Handicap Index (VHI)-10

Appendix C - Voice Related Quality of Life (V-RQOL)

Appendix D - Patient information sheet (PIS)

Appendix E - Consent form

Appendix F – Distressed participant protocol

# Appendix A

Case Record Form

**Data will be captured from Digital Health Records**

Sl.No:

Inc No:

DOA Hosp:

DOA ICU:

Date of Enrollment in study: DOD ICU:

DOD Hosp:

Date of F/P(8wk):

# Demographic Variables

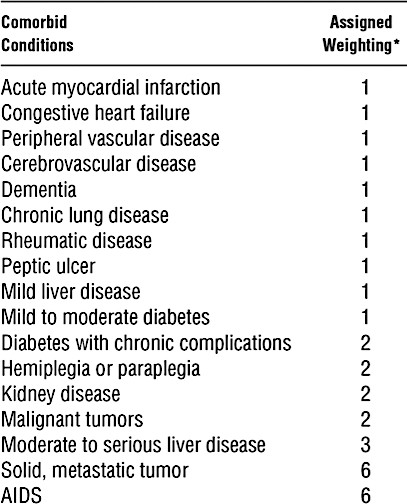
* Age:
* Gender:
* Occupation:
* Ht: Wt: BMI:
* Smoking or any substance use
* Socioeconomic status (SES)

# Health status/Co-morbidities

* Admission APACHE II:

Charlson comorbidity index

* List of Co morbidities:



# Predictors for Acute laryngeal injury

* Reason for intubation: Medical (Resp/CNS/CVS)/Surgical/Trauma/Burns:
* Emergency or elective intubation:
* Peri – intubation CPCR: (yes/no)
* Difficult intubation: (yes/no)
* CLG grade & POGO
* Experience of operator if available (in years):
* Size of ETT
* Duration of Ventilation (days)
* Re-intubation (yes/no), if Yes: Reason: and Timing of re-intubation
* Elective tube exchanges performed: (yes/no), Reason:
* Steroid use within 12 hours of extubation (yes/no)
* Cumulative fluid balance at extubation
* Cuff leak test (Yes/No)
* Prior mechanical ventilation in past 1 year

(This includes any General anesthetic procedures performed with invasive ventilation) (yes/no)

* Pre-existing voice problems (yes/no)

# Appendix B

**Voice Handicap Index (VHI-10)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| These are statements many people have used to  describe their voices and the effects of their voices on their lives.  Please circle the response that indicates how  frequently you have the same experience. | 0 - 4 Rating Scale | | | | |
| 0 = Never  1 = Almost never  2 = Sometimes  3 = Almost always  4 = Always | | | | |
| Situation | Frequency of Problem | | | | |
| My voice makes it difficult for people to hear me | 0 | 1 | 2 | 3 | 4 |
| People have difficulty understanding me in a noisy room | 0 | 1 | 2 | 3 | 4 |
| My voice difficulties restrict my personal & social life | 0 | 1 | 2 | 3 | 4 |
| I feel left out of the conversations because of my voice. | 0 | 1 | 2 | 3 | 4 |
| My voice problem causes me to lose income. | 0 | 1 | 2 | 3 | 4 |
| I feel as though I have to strain to produce voice | 0 | 1 | 2 | 3 | 4 |
| The clarity of my voice is unpredictable. | 0 | 1 | 2 | 3 | 4 |
| My voice problem upsets me | 0 | 1 | 2 | 3 | 4 |
| My voice makes me feel handicapped | 0 | 1 | 2 | 3 | 4 |
| People ask, “What’s wrong with your voice?” | 0 | 1 | 2 | 3 | 4 |

|  |  |
| --- | --- |
| **TOTAL** |  |

*Rosen, C. A., et al. (2004). "Development and validation of the voice handicap index-10.*

*" Laryngoscope 114(9): 1549-1556.*

# Appendix C

**VOICE-RELATED QUALITY OF LIFE (V-RQOL) MEASURE**

We are trying to learn more about how a voice problem can interfere with your day-to-day activities. On this paper, you will find a list of possible voice-related problems. Please answer all questions based upon what **your** voice has been like over the past **two weeks**. There are no “right” or “wrong” answers.

Considering both how severe the problem is when you get it and how frequently it happens, please rate each item below on how “bad” it is (that is, the **amount** of each problem that you have). Use the following scale for rating the amount of the problem.

1 = **None, not a problem**

2 = **A small amount**

3 = **A moderate (medium) amount**

4 = **A lot**

5 = **Problem is as “bad as it can be”**

**Because of my voice, How much of a problem is this?**

1. I have trouble speaking loudly or being heard in noisy situations. 1 2 3 4 5

2. I run out of air and need to take frequent breaths when talking. 1 2 3 4 5

3. I sometimes do not know what will come out when I begin speaking. 1 2 3 4 5

4. I am sometimes anxious or frustrated because of my voice. 1 2 3 4 5

5. I sometimes get depressed because of my voice. 1 2 3 4 5

6. I have trouble using the telephone because of my voice. 1 2 3 4 5

7. I have trouble doing my job/practicing my profession because of my voice. 1 2 3 4 5

8. I avoid going out socially because of my voice. 1 2 3 4 5

9. I have to repeat myself to be understood. 1 2 3 4 5

10. I have become less outgoing because of my voice. 1 2 3 4 5

Total Raw Score \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PATIENT QUESTIONNAIRE**

How long have you been having a problem?

How would you describe your problem?

What is your occupation?

Are the demands of your work on your voice (please check the appropriate box):

🞏 Minimal 🞏 Moderate 🞏 Excessive

Do you use your voice in other activities (for example, coaching little league games, running meetings, preaching)? If so, please explain

Do you sing? 🞏 Yes 🞏 No If so, please answer the following questions:

In what context do you sing (church, solo, choral, band, etc.)?

What kind of music do you sing?

Have you had any vocal training?

Do you warm up your voice? (If so, how?)

*Please check any of the following symptoms which apply to you:*

🞏 Sore throat with talking 🞏 Vocal fatigue/tired voice with excessive use

🞏 Hoarse/rough/scratchy voice 🞏 Voice cuts off/breaks

🞏 Increased effort when producing voice 🞏 Pain while or after using voice

🞏 Decreased loudness 🞏 Decreased range/loss of pitches (High/Low)

🞏 Feeling of a lump/burning in throat 🞏 Throat clearing/coughing

🞏 Excess phlegm 🞏 Loss of voice (intermittent/complete)

🞏 Shaky voice 🞏 Shortness of breath

🞏 Difficulty swallowing 🞏 Prolonged warm up time