Prospective Evaluation of Foreign Body Airway Obstruction Interventions Among Infants: A Non-randomized Pilot Cohort Study

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

October 16th, 2025 – Version 1

October 27th, 2025 – Version 2

- Updated sample size calculation, and analysis of effectiveness outcomes.

Objectives

- Primary:
    - To determine the feasibility of prospectively identifying and recruiting patients with foreign body airway obstruction (FBAO) in Alberta, Canada.
- Secondary:
    - To determine the effectiveness and safety of basic life support (BLS) FBAO interventions among different patient age categories experiencing out-of-hospital FBAO

Research Question – Feasibility Study (Primary Objective)

1. What is the rate of eligible FBAO patients recruited per month through prospective identification in Alberta, Canada, and what proportion of satisfactory data collection is obtained?

Research Questions – Future Effectiveness and Safety Studies (Secondary Objective)

1. Among conscious infants with an out-of-hospital FBAO, which initial BLS FBAO intervention (abdominal thrusts, back blows or chest compressions) is more effective and safer?
2. Among conscious infants with an out-of-hospital FBAO who failed initial management, is continuing the same intervention more effective than changing interventions?
3. Among conscious infants with an out-of-hospital FBAO who failed initial management, which BLS FBAO intervention or combination of interventions is more effective and safer?

Methods

Study Design

We will conduct a study to assess the feasibility of identifying and recruiting a prospective cohort of patients who experience an out-of-hospital FBAO in Alberta, Canada. The results of this pilot study will inform a future appropriately powered prospective cohort study examining the effectiveness and safety of FBAO interventions.

We will follow two reporting guidelines to ensure inclusion of all relevant sections:

- Consolidated Standards of Reporting Trials (CONSORT) extension to randomised pilot and feasibility trials [1]
- STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guideline [2]

The Conjoint Health Research Ethics Board of the University of Calgary (REB25-0419) and Alberta Health Services approved the study.

Setting

The study will be conducted in Alberta, Canada, where a single, publicly funded health authority (Alberta Health Services) delivers healthcare services, including emergency medical services (EMS) delivered by paramedics, to a population of 4.4 million people. Three levels of EMS care exist: Emergency Medical Responder (EMR), Primary Care Paramedic (PCP), and Advanced Care Paramedic (ACP). ACPs can perform advanced FBAO interventions like Magill forceps removal and intubation, while all levels receive training on basic interventions.

Study Population

Eligible patients will be infants aged 2 years or younger who experience an out-of-hospital FBAO and are assessed by EMS or attend an emergency department for the incident. We define FBAO cases as individuals who present with a history of an object or substance not native to the airway introduced, followed by clinical signs of obstruction (e.g., stridor, cyanosis, hypoxemia, inability to move air) [3,4].

Only patients who are conscious when they received the first FBAO intervention will be included. We will exclude cases where the patient has abnormal airway anatomy such as a tracheostomy, or who were unconscious upon receipt of first FBAO intervention.

Patient Identification

FBAO cases will be prospectively identified through two strategies:

1. A notification will be sent to researchers using Alberta Health Services' EMS electronic Patient Care Record (ePCR; Siren ePCR Version 4.6.26, Medusa Medical Technologies, Halifax, NS) when a case meets validated FBAO identification criteria based on paramedic diagnosis, protocol use, or treatment applied [4].
    - The ePCR is the sole paramedic prehospital charting system used in Alberta and therefore includes population-based data for the province, including demographics, vital signs, and standardized reporting of incident, patient, and treatment details. It also includes a free-text narrative synopsis, including information on the events preceding the FBAO, interventions performed by bystanders, patient assessments, and all interventions

2. A notification will be sent to researchers when a patient presents to an Alberta emergency department with an FBAO-related complaint (e.g., respiratory foreign body, respiratory arrest, stridor, dysphagia, cardiac arrest).

An emergency medicine physician will review identified cases to determine whether they meet the FBAO definition, based on the paramedic and emergency medicine documentation, vital signs, and imaging. A second physician will review 10% of cases to ensure excellent interrater reliability (Cohen's kappa > 0.8).

Patient Recruitment and Consent

The primary parent(s)/caregiver(s) will be contacted by a healthcare provider not affiliated with the research team once identified as an FBAO case to seek their interest in participating by telephone. If agreeable to participate, a research assistant will subsequently follow up with the parent/caregiver to obtain informed consent and complete a short interview for data collection.

In the case that a parent/caregiver is unable to participate in an interview due to severe injury, death or inability to be contacted, then a waiver of consent has been obtained to use the medical record for data collection.

All eligible participants will be recruited consecutively. We will conduct the pilot over a period of 6 months from November 1st, 2025, to April 30th, 2026. If we proceed with a larger effectiveness study (see Sample Size below), the research team will decide based on available resources at that time if we will immediately continue with recruitment and include the pilot study's patients in the larger study's cohort.

Data Collection

Research assistants will conduct virtual structured interviews. We will develop a standardized data collection tool and pilot it among five individuals without healthcare or research training to ensure easy comprehension. Research assistants will be trained on the data collection tool before contacting patients.

In the situation where parents/caregivers are unable to be interviewed, two research team members will extract data directly from the medical record independently and in duplicate. Disagreement between data extractors will be resolved by a third researcher. Data extractor agreement will be measured using Cohen's kappa.

Variables and Analysis by Research Objective

Primary Objective: Feasibility Study

Outcome: This study's primary focus is on the feasibility of prospectively identifying and recruiting FBAO patients, with the following outcome measures:

- Number of eligible patients recruited per month (Primary)
- Proportion of eligible patients recruited (Secondary)
- Proportion of recruited patients with $\geq$ 90% of variables collected (Secondary)

Exposure: Given the primary aim of the feasibility study is a descriptive analysis of the outcome variables, no exposure variable is defined.

Sample Size: Back blows and chest compressions are the two primary FBAO interventions used on infants, so the sample size is based on data of these two techniques [3]. We estimate that 381 patients will need to be recruited to obtain 80% power using a statistical significance of 0.05 and two-sided z-test of independent proportions to detect, with successful proportion of back blows and chest compressions equal to 76.5% and 55.6%, respectively, with a ratio of patients who received back blows to chest compressions equal to 8.2 [3].

To complete an intervention effectiveness study in 48 months, we would need to recruit a mean of 7.9 patients per month. The slowest acceptable recruitment rate would be if recruitment required one additional year to obtain our desired sample size (60 months total). This would require recruitment of 6.4 patients per month. Using the traffic light approach for a feasibility study's sample size, we set the green criterion (progression, no concerns) to 8 patients or more per month and the red criterion (major problems, potentially not remediable concerns) to less than 6 patients per month. The amber zone will be set as 6-8 patients per month, which represents a recruitment rate range that may be compatible with a successful future study; however, we will first aim to identify and address remediable recruitment challenges before deciding whether to proceed [10].

Analysis: We will conduct a descriptive analysis of the recruited cohort's demographics, as well as the FBAO incident situational factors (categorical: frequency and proportions; continuous: medians and interquartile ranges). We will calculate the mean recruitment rate by dividing the number of recruited patients over the entire study period by the number of months recruitment was ongoing. We will track the number of patients who were eligible over the entire study period and determine our proportion of successful recruitment by dividing the count of recruited patients by the count of eligible patients. Finally, among our recruited patients, we will review the data collection forms and determine the number of patients who had 90% or more of variables obtained to ensure satisfactory data collection processes are in place.

Secondary Objectives: Effectiveness and Safety

Outcomes: The feasibility study will inform the development of several future studies investigating the secondary objectives focusing on FBAO intervention effectiveness and safety. These objectives' outcome variables will be:

- FBAO relief: defined as successful if the responder(s) determines that the patient did not require further FBAO intervention due to improvement/resolution of their respiratory distress (Primary)
- Survival to acute care discharge (e.g., Emergency Medical Services [EMS], emergency department, or hospital discharge). If transferred to a long-term care facility due to permanent neurological function decline, we will still consider this an acute care discharge (Secondary)
- Survival to discharge with favourable neurological outcome (Secondary): defined as the patient being able to be discharged to their previous home environment, with the ability to perform the same activities of daily living as before the FBAO incident
- Intervention-associated injuries (Secondary)

Question One: Among conscious infants with an out-of-hospital FBAO, which initial BLS FBAO intervention is more effective and safer?

- Exposure: Initial FBAO intervention (abdominal thrusts, back blows, chest compressions)

Question Two: Among conscious infants with an out-of-hospital FBAO who failed initial management, is continuing the same BLS intervention more effective than changing interventions?

- Population: Infants who experience an out-of-hospital FBAO and are attended by EMS or present to the emergency department in Alberta, Canada, and received at least 5 initial interventions (e.g., 5 abdominal thrusts)
    - For this question, we will require the patient received at least 5 unsuccessful initial interventions to capture only patients who do not respond immediately to initial treatment and require further intervention.
    - After 5 initial interventions, resuscitation guidelines recommend either continuing the initial intervention (Heart and Stroke Canada, and American Heart Association [5]) or alternating to another technique (European Resuscitation Council, Canadian Red Cross, and Lifesaving Society Canada [6-9]). By excluding the patients that initially respond to 5 or less attempts, we are creating a more similar patient population when comparing alternating techniques (e.g., chest compressions and back blows) versus those who continued the same technique (e.g., 20 back blows) to help address resuscitation time bias.
- Exposure: Receiving a single BLS FBAO intervention versus an intervention combination (abdominal thrusts [AT], back blows [BB], chest compressions [CC], AT and BB, AT and CC, BB and CC) after an initial 5 attempts

Question Three: Among conscious infants with an out-of-hospital FBAO who failed initial management, which BLS FBAO intervention or combination of interventions is more effective and safer?

- Exposure: FBAO intervention combination (abdominal thrusts [AT], back blows [BB], chest compressions [CC], AT and BB, AT and CC, BB and CC)

Analysis: As this pilot study will be underpowered to accurately estimate precision of the outcomes, we will limit reporting of these results to a descriptive analysis. We will include descriptive statistics of the patients' demographics and FBAO incident situational factors for the total study population, as well as stratified by the exposure variable (categorical: frequency and proportions; continuous: medians and interquartile ranges). We will also report descriptively the outcome variables listed above.

We will summarize missingness of all variables to determine appropriateness of imputation for future studies.

We will perform similar analyses for one subgroup: patients who received first intervention with bystanders versus paramedics.

Covariates

Variable Name	Variable Type	Possible Values
Patient		

Age	Continuous	0 - 100
Sex	Categorical	Male, Female, Other
Estimated Patient Weight	Numerical	
Estimated Patient Height	Numerical	
History of FBAO	Categorical	Yes, No, Unknown
Medical Comorbidities	Open response	Free Text
Specifically ask: Stroke, Dementia or Alzheimer's, Difficulty Swallowing or Chewing, Parkinson's Disease	List, select all that apply	Any of the specific answers
Pre-FBAO ADL Independence	Categorical	Independent, Dependent, Unknown
If Dependent: Which ADLs require assistance? Which ADLs are completely dependent?	List, select all that apply	Ambulation/mobility, Eating/feeding, Personal hygiene/bathing, Dressing, Toileting
If Limited Mobility: What is their mobility?	Categorical	Walk independent, Uses cane, Uses walker, Uses wheelchair, Limited to bed
Long term care resident	Categorical	Yes, No, Unknown
Situation		
Location	Categorical	Home, Long term care residence, Restaurant, School, Other public place, Unknown
Foreign body	Open response	Free text
Witnessed Status	Categorical	Witnessed, Unwitnessed, Unknown
Witness Relation	Categorical	Family or friend (known person), bystander (unknown person), Unknown
Bystander Response		
Dispatcher Instruction	Categorical	Given, Not Given, Unknown
Bystander Response	Categorical	Yes, No, Unknown
If Bystander Responded:		
Bystander Sex or Gender	Categorical	Male, Female, Other, Unknown
Bystander (estimated) Age	Continuous	0 - 100

Bystander (estimated) Weight	Continuous	
Bystander (estimated) Height	Continuous	
Bystander Training	Categorical	Healthcare training, First aid/CPR/BLS, None, Unknown
Patient Status During Bystander Response	Categorical	Conscious/responsive + talking/crying/effective cough; Conscious/responsive + ineffective cough/no sounds; altered; unresponsive/unconscious
Initial Bystander Intervention	Categorical	Abdominal Thrusts, Back Blows, Chest Compression, Suction Devices, Other, Unknown
Number of Initial Intervention Attempts	Numeric	0 - 100
Initial Intervention Success	Categorical	Yes, No, Unknown
How Was Success Determined	Open response	Free text
Repeat for Each Bystander Intervention		
EMS and Emergency Department Response		
EMS Called	Categorical	Yes, No, Unknown
If EMS Attended		
Patient Still Choking when EMS Arrives	Categorical	Yes, No, Unknown
Patient Status During Paramedic Response	Categorical	Conscious/responsive + talking/crying/effective cough; Conscious/responsive + ineffective cough/no sounds; altered; unresponsive/unconscious
Initial Paramedic Intervention	Categorical	Abdominal Thrusts, Back Blows, Chest Compression, Suction Devices, Other, Unknown
Number of Initial Intervention Attempts	Numeric	0 - 100

Initial Intervention Success	Categorical	Yes, No, Unknown
How Was Success Determined	Open response	Free text
Repeat for Each Paramedic Intervention		
Intubated on scene	Categorical	Yes, No, Unknown
Cardiac arrest on scene	Categorical	Yes, No, Unknown
Transported to hospital	Categorical	Yes, No, Unknown
Management in the Emergency Department	Open Response	Free text
Other Outcomes		
Survived to acute care discharge	Categorical	Yes, No, Unknown
Post-FBAO ADL Independence	Categorical	Independent, Dependent, Unknown
If Dependent: Which ADLs are dependent?	List, select all that apply	Ambulation/mobility, Eating/feeding, Personal hygiene/bathing, Dressing, Toileting
If Limited Mobility: What is their mobility?	Categorical	Walk independent, Uses cane, Uses walker, Uses wheelchair, Limited to bed
Discharged Location	Categorical	Home, Long term care, other acute care facility, dead
Intervention-associated injuries	Open response	Free text
Hospital Length of Stay	Numeric	0 – 100
Intensive Care Length of Stay	Numeric	0 – 100
Intubated at any time	Categorical	Yes, No, Unknown

ADL = Activities of daily living; EMS = Emergency medical services; FBAO = Foreign body airway obstruction

References

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