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N_2 gas egress from patients' airways during LN_2 spray cryotherapy

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ABSTRACT

Spray cryotherapy using liquid nitrogen (LN_2) is a general surgical tool used to ablate benign or malignant lesions. Adequate egress of the gaseous nitrogen (N_2) generated during this process must be provided for safe use when LN_2 is used within the body rather than topically. When delivered to either the gastrointestinal tract (requiring active venting via a suction tube) or body cavities open to room barometric pressure (such as lung airways) allowing for passive venting, the N_2 gas generated from the boiling process must be evacuated. This work will examine the egress of N_2 during procedures requiring passive venting from human airways undergoing liquid nitrogen spray cryotherapy. Venting characteristics for safe N_2 egress will be presented and discussed based on analytical modeling using fluid mechanics simulations and experimental studies of N_2 venting with laboratory and porcine models.

List of abbreviations

CFD	computational fluid dynamics
EES	engineering equation solver
ETT	endotracheal tube
N_2	gaseous nitrogen
ID	inside diameter
LN_2	liquid nitrogen
MFM	mass flow meter
OD	outside diameter

1. Introduction

Spray cryotherapy using liquid nitrogen (LN_2) has been used to ablate benign and/or malignant lesions in locations requiring active venting of gas (e.g. gastrointestinal tract) [1,2] or passive venting of gas (e.g. airway) [3–5]. During application of the LN_2, the spray is targeted at desired regions inside the body. Fig. 1 schematically shows the insertion of an endotracheal tube (ETT) into the trachea (left image) and also the insertion of a bronchoscope into the airways (right image).

In many situations, the bronchoscope passes through the ETT into the airway system. CSA Medical's (Lexington, MA) proprietary, commercially available medical device, the truFreeze™ System, employs a computer-driven method and apparatus to transport LN_2 from a Dewar inside a control console through a catheter that passes through the bronchoscope working channel and into a patient allowing LN_2 to be sprayed directly on the targeted tissue [8].

In the LN_2 Dewar, the pressure is approximately 20 psig so utilizing the curve in Fig. 2, the saturation temperature at this pressure is approximately −187 °C. When the LN_2 exits the tip of the catheter, it is at a pressure of less than 1 psig. At this pressure, the temperature of the saturated nitrogen mixture is approximately −195.2 °C [9]. The cryospray impinges on the walls of the airway where the LN_2 spray draws heat away from the tissue to produce a flash freezing of the unwanted material and create a localized kill region. As the LN_2 absorbs heat from the tissue, the LN_2 passes through a phase change from a liquid state to a gaseous state. The gaseous nitrogen (N_2) convectively warms on its path out of the lumen. The conversion from liquid to gaseous state and subsequent heating to room temperature is accompanied by an increase in the volume occupied by the N_2 of approximately 696 times that of the LN_2 (i.e., a 1 cm^3 vol of LN_2 at −195 °C results in a 696 cm^3 vol of N_2 at 20 °C) [9,10]. This gaseous nitrogen must egress from the patient to prevent an unsafe pressure increase within the application area to avoid undesired sequelae, such as a pneumothorax.

This work assesses the theoretical and experimental egress of gaseous N_2 expected from patients undergoing passively vented applications of LN_2. The airway will be discussed and modeled as a prototypical passive venting procedure due to several factors needing consideration for adequate egress. This study includes a mathematical analysis of the human airway system and evaluates the resulting model with inputs of typical levels of gaseous N_2 generated during LN_2 spray cryotherapy within the trachea and generations 1 through 3 of the lungs. The simulation outputs are compared

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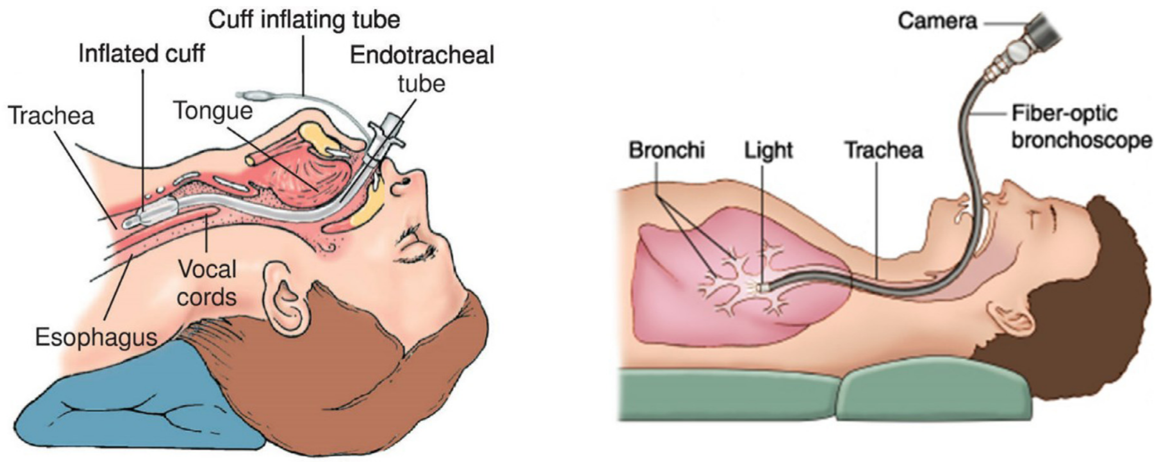

Fig. 1. Schematic representation of endotracheal tube insertion (left [6]) and bronchoscope insertion in airway (right [7]).

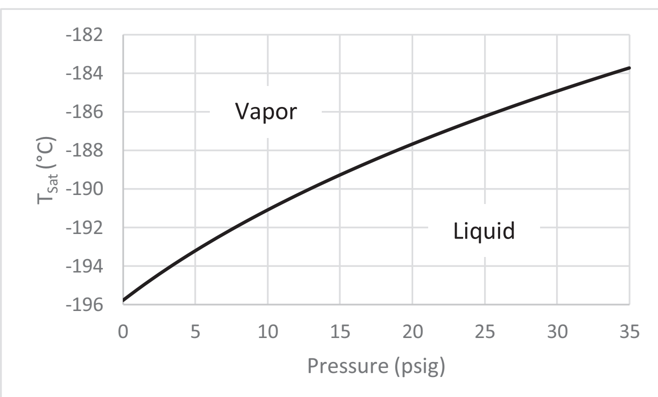

Fig. 2. Nitrogen liquid–vapor saturation curve [9].

to experimental results acquired from pressure and flow measurements of anatomical lung models inputted with gaseous N_2. Lastly, results from spray cryotherapy performed in porcine models will be discussed in light of the analytical and experimental measurements.

These results provide theoretical and experimental foundations to understand the volumes of gaseous N_2 inputted into a patient and its egress during spray cryotherapy procedures requiring passive venting of the resulting N_2 gas. Requirements for adequate N_2 egress conditions are also presented.

2. Analytical modeling methods and results

2.1. Modeling methods

The morphology [11–13] and hydrodynamics [14,15] of human airway flows have been extensively studied and modeled. This information is important to understanding patterns resulting from flow area reductions, expansions, turns, and entrance and exit conditions which are all variables that must be characterized in order to model the airflow in the lungs.

Weibel [16] previously reported quantity, geometry, and impedance data for the various generations of the bronchial tree, which are reproduced in Table 1.

In Weibel's model, each generation bifurcates from an existing generation to the next with reductions in diameters and lengths with increasing generation (exception of generation 3 that exhibits a shorter length (0.76 cm) than anticipated). It is to be noted that a number of the values articulated in Table 1 will vary during respiration as the muscles of the diaphragm expand and contract to bring air into or expel air from the lung and airways.

To model the airflow in the lungs, one can use fluid mechanics simulations to determine which flow passages exhibit turbulent, transitional and laminar flow with details presented in the following paragraphs. By evaluating the Reynolds number, *Re*, it can be determined that the trachea and generations 1 to 5 all exhibit primarily turbulent flow [17] during maximal forced expiration and spray cryotherapy. Generation 6 exhibits primarily transitional flow and the remaining generations (7 to 23) exhibit laminar flow [17].

The following describes the physics associated with spray cryotherapy during passive venting. Subsequent to the cryogen exit from the catheter to the point of expiration, myriad complex thermal and hydrodynamic processes are experienced. The cryospray is a mixture of saturated liquid and gas in a dispersed multiphase flow regime (misty flow) at the saturation temperature corresponding to the cavity pressure of the lung. As the flow travels toward the tissue, droplet breakup occurs concurrent with boiling due to ambient heating and the spray spreads conically. Interacting with moist tissue, the impinging droplets wet the mucosa due to the momentum of the impinging droplets and the miscibility of nitrogen and water-based fluids. The wetted LN_2 absorbs heat from the tissue during the boiling process, and transitions to a saturated vapor. As the pressure-driven gas traverses the bronchial network, it convectively absorbs sensible heat and evaporates moisture from the mucosa, increasing the gas temperature and humidity. Simultaneously, the expanding gas flow dissipates energy due to aerodynamic drag, turbulent mixing, imperfect expansion at bifurcations between lung generations, as well as flow constrictions and turns as it passes through the annulus between the bronchoscope and endotracheal tube and finally of the patient.

Assessment of all of the aforementioned contributions would be impractical; therefore only primary flow drivers and losses are considered. The complicated 3-dimensional geometry of the bronchial tree, if modeled explicitly, requires significant computational power, but could be solved using computational fluid dynamics (CFD) simulation software. In order to provide a tractable scoping model for assessing the impact of surgical equipment geometry on egress pressures, the flow path can be modeled to first order as an isothermal network of straight tubes and annuli with minor loss in fidelity. Geometry, thermal effects, and multiphase phenomena are secondary and are therefore not used in the simple scoping model. The following describes the semi-empirical modeling method used to simulate gas egress as a function of injection