Published in final edited form as:

Anesth Analg. 2016 November ; 123(5): 1302–1306.

Hemodynamic instability following airway spray cryotherapy

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Abstract

Background—Spray cryotherapy (SCT) of airway lesions is used to effectively palliate respiratory symptoms related to airway obstruction but significant intraoperative hemodynamic complications have been noted. We reviewed the experience at a single institution using SCT for the treatment of obstructive airway tumors.

Methods—A retrospective review of a single institution experience with intraoperative and postoperative hemodynamic complications associated with SCT was performed. Descriptive statistics were performed.

Results—Between June 2009 and April 2010, 34 treatment sessions were performed on 28 patients. Median age was 60 years (range, 15–88 years). Tumor characteristics were as follows: 13 primary lung cancers (43%), 11 pulmonary metastases (50%), 1 direct extension of an esophageal cancer (3%) and 2 benign pulmonary lesions (7%). Twenty-one tumors (75%) were distal to the carina; 14 (50%) were >95% occlusive. Median procedure length was 78 min (range, 15–176 min). Eleven sessions (31%) led to severe hypotension and/or bradycardia, with 2 patients requiring cardiopulmonary resuscitation. One patient died intraoperatively after cardiac arrest; a second patient was stable intra-operatively but died within 24 h of SCT. Four patients required reintubation and short-term mechanical ventilation.

Conclusions—Unpredictable life-threatening hemodynamic instability can follow endobronchial SCT. We propose that the most likely cause is pulmonary venous gaseous emboli entering the right heart, the coronary arteries and the systemic circulation. Although SCT may offer advantages over airway laser therapy (such as no risk of fire and rapid hemostasis), further study is needed to delineate the relative likelihood of therapeutic benefit versus catastrophic complications.

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Conflicts of interest: None

Introduction

Endobronchial spray cryotherapy (SCT) has been used since the early 1990s to palliate the symptoms of obstructive airway lesions, with reports of immediate improvement. Endobronchial SCT involves the insufflation of liquid nitrogen at 2–4 psi and -196°C via a flexible catheter through an endoscope, causing rapid freezing and thawing of tissue, with cellular death and hemostasis (Joule-Thompson effect). It can be used in lieu of or in conjunction with mechanical debridement, laser therapy, electrocautery, argon plasma coagulation, or photodynamic therapy. One clear advantage of SCT over heat-producing methods is the absent risk of fire and, therefore, the ability to maintain higher FiO_2 during the treatment, making it a favorable option for patients with respiratory distress.

Several retrospective reviews of the benefits of SCT have found subjective improvements in dyspnea (70%–85%), resolution of hemoptysis (62%–100%), better oxygenation (66%), and improved Karnofsky performance status (63%).¹ However, hemodynamic instability has been reported during SCT, although the complications were not detailed.² To characterize the intraoperative complications associated with SCT, we reviewed our experience with SCT for the treatment of obstructive airway tumors.

Methods

After approval was obtained from the Institutional Review Board at Memorial Sloan Kettering Cancer Center, a retrospective review of all patients who had undergone endobronchial SCT was performed. Patients who underwent SCT from June 2009 to April 2010 were analyzed. Data were obtained from the electronic medical record.

All cases were performed by an attending thoracic surgeon or interventional pulmonologist in an operating room, under general anesthesia provided by an attending anesthesiologist. After placement of standard noninvasive monitors, general anesthesia was induced with propofol, and paralysis was achieved with either succinylcholine or rocuronium, at the discretion of the anesthesia team. Initially, additional large-bore intravenous access and arterial lines were placed, if felt indicated. After the initial experience demonstrated the risk of hemodynamic instability, subsequent patients had intraoperative transthoracic echocardiograms performed and arterial lines placed. To facilitate flexible bronchoscopy, a supraglottic airway device (laryngeal mask, LMA) was used in all cases. Patients were mechanically ventilated with either volume or pressure control. Total intravenous anesthesia (with propofol and remifentanyl infusions) was used during SCT and titrated to Bispectral index monitoring. In 30 patients, the LMA was removed and replaced by a rigid bronchoscope, whereas in 5 patients a suspension laryngoscope was used. Jet ventilation was used for this part of the procedure (Monsoon III, Acutronic, Susquehanna Micro, Windsor, PA). Glycopyrrolate and dexamethasone were administered in an effort to prevent bradycardia and airway edema, at the discretion of the provider. Either phenylephrine or ephedrine was used as intermittent intravenous bolus for temporary hemodynamic support. SCT was performed using the CryoSpray ablation system (CSA Medical, Baltimore, MD) through a 7-mm disposable catheter that was advanced through the 28-mm diameter side port of the flexible fiberoptic bronchoscope to the target tissue. Apnea was used during the

spray cycles, and an open system was confirmed before the beginning of the treatment. Each cycle of freezing lasted 5 s or less, and the tissue was allowed to thaw for at least 30 s before the start of the following cycle. The number and length of treatments were at the discretion of the treating physician. Adequate venting, necessary to allow escape of the gaseous form of liquid nitrogen, was measured subjectively, by feeling and hearing the gas exiting the airway, paired with visual examination of chest expansion. At the end of the procedure, the rigid bronchoscope (and/or the suspension laryngoscope) was removed, and the patient was awakened after further ventilation via mask, LMA or an endotracheal tube. Each patient recovered in the Memorial Hospital Postanesthesia Care Unit until meeting discharge criteria for admission to floor care.

This manuscript adheres to the applicable Equator guidelines.

Statistical Analysis

Continuous variables are presented as medians and ranges. Dichotomous variables are presented as percentages of the total.

Results

The complete MSKCC experience with SCT comprised a total of 34 treatment sessions on 28 patients, which were performed between June 2009 and April 2010. Demographic characteristics are presented in Table 1. Tumor characteristics are presented in Table 2. Twenty-two of 28 patients presented with dyspnea and/or hemoptysis attributable to variable degrees of airway obstruction. Twenty-one tumors (75%) were located distal to the carina, and 14 (50%) were >90% occlusive. Twenty-two lesions were located in part or wholly on the right side (in the distal trachea and/or the right main stem), and 15 in part or wholly involved the left side (Table 3). After a majority of the treatments, there was a median decrease in tumor size of 40%, which was associated with a symptomatic improvement. All but one treatment led to a decrease in tumor size.

Median procedure length was 78 min (range, 15–176 min). The median number of cycles of in cycles per procedure administered was 10 (range 3–36). The maximum duration of insufflation was 5 seconds in 34 sessions, 10 seconds in 3 sessions, and 20 seconds in 1 session. Patients received a median volume of 650 mL of Lactated Ringers solution (50–2500 mL). In 46% of patients, 4 to 8 mg of intravenous dexamethasone was administered to counteract airway edema.

The majority of cases (57%) were performed as outpatient procedures; 34% were on inpatients, and 9% required conversion from outpatient to admission for complications.

Marked hemodynamic instability occurred in one-third of treatments, and was largely unresponsive to ephedrine or phenylephrine boluses. Severe hypotension (systolic blood pressure <90 mmHg) and/or bradycardia (heart rate <60) occurred in 11 treatment sessions (31%), requiring phenylephrine infusion; 2 patients (7%) required cardiopulmonary resuscitation, and 1 (4%) died intraoperatively (Table 4 and 5). One patient (4%) who was stable intra-operatively died within 24 h of SCT. Intra-operative ST segment changes were

observed for 3 patients and resolved after the administration of sublingual nitroglycerin spray. None of these patients had perioperative myocardial ischemia. Two patients had stridor at the end of the procedure despite receiving intraoperative steroids. Four patients required reintubation and short-term mechanical ventilation. Of these, 3 were treated as inpatients, whereas 1 was able to be discharged home after 6 h in the postanesthesia care unit.

There was no correlation between hypotension and the duration or the number of cycles of SCT. All patients with hemodynamic instability presented with hemoptysis, and with the exception of 1, all had right-side disease. The presence of hemoptysis or baseline cardiovascular disease did not predict perioperative cardiovascular complications.

Discussion

SCT is a noncontact modality used to palliate respiratory symptoms caused by obstructive airway tumors. Several retrospective reviews have reported a significant decrease in tumor size and improved symptoms after single or repeated sessions of SCT.^{1–5} Our surgical results are consistent with those reported in the literature: 82% of cases in our study experienced a decrease in tumor size and symptoms after 1 session of SCT. However, we observed significant hemodynamic complications in one-third of patients, leading to changes in both the anesthetic and the surgical techniques used for this procedure. Invasive arterial pressure monitoring became standard practice for these cases, paired with intraoperative echocardiographic exam. The duration and the total number of cycles of SCT were decreased and the interval between cycles was increased.

Cold gas has been used for many years as a means to destroy pathological tissue, either as a single modality or in combination with other techniques.^{1,6,7} The insufflation of liquid nitrogen at 2–4 psi and –196° C causes rapid freezing and thawing of the exposed tissue by the Joule-Thompson effect, with localized cell death, hemostasis, and preservation of the extracellular matrix. The success of the technique depends on the temperature needed for tissue destruction, the rate of freezing and thawing, the number of freeze/thaw cycles, the mass of tissue to destroy, and the contact area between the tissue and the probe.⁸ Once a lesion that is amenable for SCT is identified, it is recommended that the probe is placed next to the lesion, under direct vision, with insufflation lasting no longer than 5 s. Cycles are usually repeated in sets of 3,⁸ until the lesional tissue is judged to have been frozen. One advantage of this technique is the ability to use high FiO₂, making it a good option for patients with respiratory distress, which is common in patients with significant airway obstruction.

At present, there are limited data available on the safety of liquid nitrogen application into the tracheobronchial lumen. Krinsky et al.³ reported their experience in a prospective Brief Communication. Twenty-one patients with normal airway anatomy who were scheduled to undergo lung resection for lung cancer received 2 applications of liquid nitrogen (5 s per cycle, with 60 s between cycles) as part of their preoperative bronchoscopic evaluation. No intraoperative complications or unanticipated side effects were observed. In a retrospective review of 35 patients who underwent SCT for treatment of benign lesions of the trachea (9

patients), subglottic region (18 patients), or bronchial tree (8 patients), Fernando et al.⁹ reported 2 intraoperative complications: a subglottic edema requiring a tracheostomy and a pneumothorax. No episodes of hemodynamic instability were observed. Finley et al.¹⁰ were the first to report hemodynamic complications associated with the use of SCT to palliate obstructive airway disease. Their data are the result of a retrospective review of a multicenter experience with 80 patients undergoing 114 treatments, all for malignant disease. Twenty-eight of these cases were performed at our institution and are part of this current report. Hemodynamic complications were noted in 22 procedures (19%), including hypotension (11%), bradycardia (5%), and desaturation (6%). Two deaths were described as intraoperative, but minimal other characterization was provided.

The Food and Drug Administration MAUDE (Manufacturer and User Device Experience) database (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>) was searched for the term “cryospray” on February 13, 2016. Eighteen events of hemodynamic instability were reported to have occurred during endobronchial cryospray. In 15 of these events, the patients had tension pneumothorax. Of the 3 hemodynamic-unstable patients without pneumothorax, 1 died intraoperatively and 1 died during the same hospitalization. The denominator from which these 18 cases are derived is not known. An intraoperative death was also reported in a small-animal study.¹¹ Cellular and extracellular histological changes were investigated in relation to the duration and frequency of SCT cycles when applied to the airway, esophagus, lung parenchyma, and thoracic vasculature. Of the 6 pigs studied, 1 died 20 s after the start of the midesophageal SCT cycle, following SCT of the lung (right upper + right middle and left upper bronchus). Inverted T waves progressed to ventricular tachycardia and ventricular fibrillation. Resuscitation failed due to the absence of a defibrillator.

Our review of the intraoperative events during airway SCT was intended to provide detailed information about the intraoperative anesthetic course of patients undergoing spray cryotherapy. We found that patients commonly showed marked hemodynamic instability, which occurred in one-third of treatments and was largely unresponsive to standard anesthetic manipulations. During 35 applications in 28 patients, 11 treatment sessions (31%) led to hypotension and/or bradycardia, 2 patients (7%) required cardiopulmonary resuscitation, and 1 (4%) died intraoperatively. One patient died in the first 24 hours after SCT with progressive hypoxia despite being stable during the case. As his intra-operative course was dissimilar to those of the other patients, it appears unlikely to be attributable to the application of SCT.

Four possible explanations for the hemodynamic instability observed were advanced by the clinicians involved in the cases: first, direct cooling of the cardiac structures; second, a reflex response to cold air in the trachea; third, direct toxicity of nitrogen to the lung tissues; and fourth, air trapping due to high-frequency jet ventilation. The first explanation (direct cooling) appears improbable, as the conduction system and the coronary arteries are distant from the bronchus and the pulmonary venous system. We found no studies in the literature addressing the possibility of hemodynamic instability secondary to a reflex response to cold gases under pressure in the airway. We also found nothing in the literature suggesting that nitrogen, which is an inert gas, is directly toxic either to the cardiopulmonary structures or

systemically. Inhaling pure nitrogen leads to death, but only because of the inevitable eventual hypoxia. Air trapping due to high-frequency jet ventilation in the presence of decreased air escape mechanisms could also be implicated as causing hemodynamic instability, but the likelihood of this appears low given the frequency with which jet ventilation for similar airway procedures (such as laser ablation, stenting, or mechanical debridement) is used at Memorial Hospital without significant hemodynamic instability being encountered.

Because of the limited number of peer-reviewed studies and other materials addressing the specific subject of liquid nitrogen applied into the airway, we performed a search for data on the pathophysiological effects of other gases placed under pressure within the tracheobronchial tree and the pulmonary parenchyma. A review of the literature documenting complications associated with ablation of airway tumors with other gases (such as CO₂, argon, or air) suggests that similar hemodynamic instability has been seen with these treatments, and has been attributed the creation of systemic air emboli. We found 13 clinical reports describing 24 patients whom the treating physicians felt developed systemic air emboli as a result of gas insufflations into the airway.^{12–24} CO₂ was insufflated under pressure, along the fiber of an yttrium aluminium garnet laser, to cool its tip and disperse debris. In the majority of cases, the hemodynamic changes reported were similar to those in our series, including hypotension, bradycardia, and ST changes. The common pathological mechanism in these reports seems to be the transmission of gas under pressure from the alveoli to the blood stream, across the alveolar capillary membrane. SCT uses nitrogen, which crosses the alveolar membrane more readily than either oxygen or CO₂. Therefore, it is likely that when introduced into the airway as a cold gas under pressure, it can readily be absorbed by the pulmonary venous blood stream, and once in a warm, low-pressure environment, the nitrogen expands to form bubbles that embolize in the systemic circulation. According to the reports on the risks of using CO₂, the right ventricle appears to be at particular risk, as the ostium of the right coronary artery is anterior when the patient is in supine position, which favors passage of the gas emboli into its circulation.

In an animal study of bronchoscopic ablation, Feller-Kopman et al.²⁵ found a dose-dependent risk of gaseous emboli with the use of CO₂ laser and plasma coagulation in the airway. This was confirmed in humans undergoing neodymium-doped:yttrium aluminum garnet laser treatment.²⁴ Emboli were not noted following insufflation in the absence of ablation therapy, suggesting that the creation of bronchovascular defects by ablation was needed for the gas to enter into the pulmonary venous circulation. Furthermore, thermal ablation in the trachea led to gas bubbles being observed in the right atrium, possibly due to drainage to the superior vena cava. Laser use within the bronchial tree caused emboli to be observed in the left atrium, suggesting access in the pulmonary veins. We would suggest that it is likely that all patients undergoing SCT treatment are at risk of developing systemic gas embolism, and no preoperative evaluation seems likely to identify patients at elevated risk. It is important to note that we do not have direct evidence supporting our hypothesis that gaseous emboli entering the heart and the great vessels was the source of the hemodynamic instability observed. In fact, in a subgroup of patients, intraoperative transthoracic echocardiography was used, and no evidence of gaseous emboli in the heart or great vessels

was found. However, due to the chest excursions related to the use of jet ventilation, the exams were of poor quality and did not provide detailed information.

Measures that can be taken after systemic air emboli have formed include (1) increasing the systemic blood pressure; (2) turning the patient into the lateral decubitus position, with the treated side elevated, and/or the Trendelenburg position, to place the cerebral circulation in a dependent position; (3) using 100% oxygen; (4) administering steroids and heparin; and (5) using hyperbaric oxygenation. The use of hyperbaric oxygenation appears to be the only effective treatment. Intraoperative monitoring, such as transesophageal echocardiography, might detect atrial gaseous emboli after they have formed. However, its utility appears limited, given that the volume of a gas embolus needed for a catastrophic effect is small, probably falling at or below the detection level of transesophageal echocardiography.

There is likely a therapeutic benefit to treating tumors in the tracheobronchial tree with SCT. This technique can achieve near-instantaneous hemostasis from diffusely bleeding raw surfaces. However, the therapeutic range between the dose needed for tumor destruction and what would lead to systemic arterial gaseous nitrogen emboli is not known. It is also possible that the likelihood of embolism is stochastic, and not dose related. At this time, there are no data to help distinguish between the relative likelihood of therapeutic benefit and that of catastrophic complications. Because of the unpredictable nature of the hemodynamic instability that was observed and the availability of effective alternative means of debriding the airway, SCT has not been being performed at MSKCC since 2010.

This study has several limitations. This was an observational study done at a single center; therefore, our results may not be applicable to other institutions. Our complication rates may be related to the specific population that was treated or to the technical skills/level of expertise of the provider. However, even after standardizing the number of cycles, duration, and intervals, we continued to observe hemodynamic complications, and despite the use of invasive monitors, we were not able to predict who would develop those complications.

In conclusion, SCT offers several advantages over conventional thermal treatment for palliation of airway tumors. However, at present, there is insufficient information in the literature on how to stratify patients at risk of severe hemodynamic compromise and adverse outcomes. Further studies are needed to decrease the morbidity and mortality related to this technique, which is often used in debilitated patients with no other treatment options.

Acknowledgments

Funding: This work was supported, in part, by NIH/NCI Cancer Center Support Grant P30 CA008748.

IRB: This study was approved by the Memorial Sloan Kettering Cancer Center Institutional Review Board, Office of Clinical Research. Contact person: Margaret Isaacs, IRB Administrator (isaacsm@mskcc.org/646-888-0291) Or Institutional Review Board/Privacy Board (212-639-7592).

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Table 1

Demographic and clinical characteristics of 28 patients treated with endobronchial spray cryotherapy

Characteristic	No. (%) / Median (range)
Male	20 (71)
Female	8 (29)
Age, years	60 (15–88)
Weight, kg	74 (39–150)
Height, m	1.69 (1.49–1.90)
BMI, kg/m ²	26.3 (14.7–49.5)
CAD	6 (21)
HTN	13 (46)
Atrial fibrillation	4 (14)
CHF	0
Ejection fraction, ^a %	59 (35–89)
CABG	2 (7)
Angioplasty	1 (4)
Valve replacement or repair	0
CVA	0

BMI=body mass index; CABG=coronary artery bypass graft; CAD=coronary artery disease; CHF=congestive heart failure; CVA=cerebrovascular accident; HTN=hypertension.

^a Available for 18 patients.

Table 2

Histological diagnoses (N=28)

Diagnosis	No. (%)
Primary pulmonary	13 (46)
Non-small cell lung cancer	11
Mucoepidermoid carcinoma	1
Adenoid cystic carcinoma	1
Pulmonary metastases	12 (43)
Renal	5
Colon carcinoma	3
Melanoma	2
Sarcoma	2
Other malignancy – direct extension	1 (4)
Esophageal carcinoma	1
Benign	2 (7)
Wegener's granulomatosis	1
Inflammatory pseudotumor	1

Table 3

Areas of airway involvement (N=34 procedures) – can be multiple areas per procedure

Area of involvement	No. (%)
Tracheal	
Yes	10 (29)
No	24 (70)
Right side	
Main stem	9 (26)
Bronchus intermedius	10 (29)
Upper lobe	6 (17)
Middle lobe	4 (11)
Lower lobe	4 (11)
Left side	
Main stem	10 (29)
Upper lobe	8 (23)
Lower lobe	4 (11)

Table 4

Characteristics of the procedure (N=34)

Characteristic	No. (%)
Patients treated	28
Patients treated once	22
Patients treated twice	5
Patients treated thrice	1
Airway management	
Endotracheal tube	19 (54)
Laryngeal mask	29 (83)
Jet ventilator	31 (89)
Surgical approach	
Flexible bronchoscopy	35 (100)
Rigid bronchoscopy	30 (86)
Laryngeal suspension system	5 (14)
Administration of endobronchial spray	
Applications per session – median (range)	10 (3–36)
Duration of spray application (in seconds) – median (range) ^a	5 (5–20)

^aFour patients had spray applications of >5 s duration.

Table 5

Complications (N=35)

Complication	No. (%)
Hypotension (SBP <90 mmHg, DBP <50 mmHg)	11 (31)
Bradycardia (HR <60)	7 (20)
Desaturation (satO ₂ <90%)	6 (17)
Reintubation required	4 (11)
Pneumothorax	2 (6)
Tachycardia (HR >100)	3 (9)
ST segment change	3 (9)
Bronchospasm	2 (6)
Airway tear	1 (3)
Atrial fibrillation	0 (0)
Supraventricular tachycardia	0 (0)
Myocardial infarction	0 (0)
Congestive heart failure	0 (0)
Cerebrovascular accident	0 (0)
Cardiopulmonary arrest	2 (6)
Intraoperative death	1 (3)
Death within 24 h	1 (3)