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Effectiveness of palliative hemostatic radiotherapy for hemoptysis: a prospective single-arm observation study

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Background: Palliative radiotherapy (RT) is commonly used for malignancy-associated hemoptysis. This study aims to determine RT control probability, durability, and influencing factors.

Methods: This single-institution prospective observational study included patients ≥18 years old with any lung malignancy and active hemoptysis. Hemoptysis severity was captured and monitored via Common Terminology Criteria for Adverse Events (CTCAE) and an in-house developed Patient-Reported Outcome Measure (PROM) tool. Patients were interviewed at enrollment, 2 weeks, 3 months, and 6 months post-treatment. Descriptive statistics, the Kaplan-Meier (KM) method, the Wilcoxon signed-rank test, and Cox regression models were used.

Results: From April 2016 to November 2018, 41 patients were enrolled. One patient withdrew consent and was excluded. The median age was 68 years. Most patients were male (67%) with stage 4 (87.5%), lung primary (85%) disease, and Eastern Cooperative Oncology Group (ECOG) performance status ≥2 (55%). The most common fractionation scheme (72.5%) was 2,000 cGy in 5 fractions. Eight patients (20%) passed away before 2-week assessment. Median follow-up was 6.1 months (range, 0.9–6.2 months). The 6-month overall survival (OS) rate was 26% [95% confidence interval (CI): 13–41%]. The 6-month bleeding-related survival (BRS) was 95% (95% CI: 80–99%), and the 6-month freedom from hemoptysis rate was 37% (95% CI: 18–57%). No patient received re-irradiation for their hemoptysis. On univariate analysis, ECOG status (P=0.01) and prior radiation (P=0.006) were strongly associated with freedom from hemoptysis survival.

Conclusions: Hemostatic RT remains an effective modality for controlling hemoptysis. The short interval high mortality rate post-RT challenges whether fractionated palliative RT should be used for this patient population. Conducting a large clinical trial with a hemoptysis PROM tool is necessary to identify hemostatic durability and influencing factors properly.

Keywords: Hemoptysis; lung cancer; radiation; palliation

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Introduction

Lung cancer is the most commonly diagnosed cancer (excluding non-melanoma skin cancer), as well as the leading cause of cancer death in Canada (1). In the United States, it is the second most commonly diagnosed cancer, while being by far the leading cause of cancer death. The American Cancer Society estimates for 2023 indicate about 238,340 new lung cancer cases and about 127,070 lung cancer deaths (2).

A large proportion of patients (75–85%) with locally

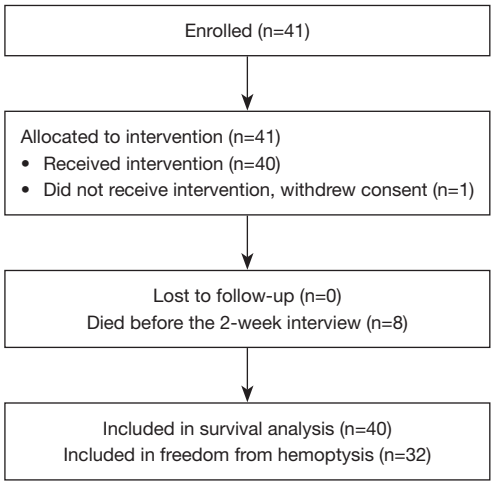

Figure 1 Flow diagram.

advanced or metastatic lung cancer demonstrate symptoms related to intra-thoracic tumor growth such as malignant airway obstruction (MAO), dyspnea, cough, hemoptysis, and pain (3-5). Hemoptysis is defined as the expectoration of blood originating at any location in the respiratory tract. It can range from blood-tinged sputum to life-threatening large volumes of bright red blood (6). Although central tumors such as small cell lung cancer and squamous cell lung cancer correlate highly with hemoptysis, any chest malignancy, including lung metastasis, can cause it (7).

The underlying mechanism of hemoptysis is the impairment of small bronchial vessel flow leading to neovascularization, remodeling, and eventually rupture leading to blood-tinged sputum (7). In massive hemoptysis cases, it is the invasion of high-pressure bronchial arteries producing bright red blood or, less commonly, low-pressure pulmonary arteries (8). In chest malignancies, mild to moderate hemoptysis is often treated at the time of definitive treatment with surgery, external beam radiotherapy (EBRT), or endobronchial brachytherapy (9,10). EBRT is a widely used treatment modality for the control of tumor-related bleeding in the palliative setting with a median dose of 30 Gy (range, 6–50 Gy) (11,12).

Several studies establish the role of hemostatic palliative radiotherapy (RT) in chest malignancies (13-15). However, the factors that may influence hemostatic control such as disease stage, histology, anti-platelet/anti-coagulant use, and surgical interventions remain challenging to identify. The objective of our study is to prospectively observe patients presenting with active hemoptysis related to lung malignancies and determine bleeding control probability, hemostatic durability, and factors that influence both. This manuscript is written in accordance with the STROBE reporting checklist (available at https://apm.amegroups.com/article/view/10.21037/apm-24-45/rc).

Highlight box

Key findings

- Our cohort demonstrated a high mortality rate in the first 2 weeks post-radiotherapy (20%).
- The majority of patients received a hemostatic radiotherapy regimen of 20 Gy in 5 fractions (72.5%).
- Hemostatic radiotherapy remains an effective modality for controlling hemoptysis with a 6-month bleeding related survival of 95%. The 6-month freedom from hemoptysis was 37%.

What is known and what is new?

- Palliative radiotherapy remains a well-known modality for controlling hemoptysis. Fractionated regimens remain frequently used for hemostasis.
- Hemostatic radiotherapy provides durable control in surviving patients, our 6 months complete response (CR) rate was 80%. No patients received re-irradiation in our cohort.
- Defining hemoptysis severity and factors influencing hemostatic control remain challenging to capture without a hemoptysis specific validated Patient-Reported Outcome Measure (PROM) tool.

What is the implication, and what should change now?

- Conducting a large clinical trial with a hemoptysis PROM tool is necessary to properly identify hemostatic durability and influencing factors.

Methods

Study design

This was a prospective single-arm, single-institution observational study to better understand the effectiveness and durability of RT in controlling hemoptysis from lung malignancies. The study observed patients after the palliative hemostatic radiation treatment was offered by the primary radiation oncologist to control hemoptysis. The flow diagram is illustrated in (*Figure 1*).

Patient population and ethical considerations

All patients enrolled in the study had a histologically confirmed diagnosis of malignancy involving the respiratory tract (either primary or metastatic) and were referred to The Ottawa Hospital Cancer Center (TOHCC) for

consideration of palliative hemostatic RT. TOHCC is a tertiary cancer center and serves a population of 1.5 million in Ottawa and Eastern Ontario. For this observational study, we estimated that our center could accrue roughly 25 patients with hemoptysis per year based on historical data, the study was approved for 3 years so a sample size of 75 was determined.

Potential participants were assessed by a radiation oncology investigator to review eligibility at the time of consultation in the hospital's clinics, emergency room, intensive care unit, or wards. All necessary clinical investigations were performed per standard of care before study registration. Participants were registered only after the pre-treatment evaluation was completed and eligibility criteria were met. Inclusion criteria included the presence of active hemoptysis at the time of hemostatic RT decision, pathologically confirmed locally advanced or metastatic chest malignancy, age 18 years and above, and signed consent. We excluded patients receiving definitive RT doses (≥40 Gy) for hemostasis, and patients with prior overlapping definitive RT doses within <3 months before study entry. We also excluded patients unwilling to follow study protocol or have medical conditions preventing RT, or receiving investigational agents 30 days before study entry. Patients had to have active hemoptysis at the time of presentation that was amenable to palliation by thoracic RT. The presence of other symptoms like pain, cough, or shortness of breath was allowed, but the main purpose of the treatment had to be hemostasis. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by The Ottawa Health Science Network - Research Ethics Board (OHSN-REB 20150361-01H), and annual reapproval was obtained for as long as the trial was open. Written consent was obtained from all participating eligible patients.

Treatment

As this was an observational study, no study-specific treatment regimen was suggested. Standard of care EBRT was offered by the treating radiation oncologist. RT doses, fractionation schemes, beam energy, and field arrangements were left at the discretion of the primary radiation oncologist. RT techniques included 3D conformal RT (3DCRT), intensity modulated RT (IMRT), and volumetric modulated arc therapy (VMAT). A dedicated computed tomography (CT) scan was used for treatment planning for all patients. The safety of RT was assessed based on center-specific care plans and all plans had to meet safety criteria before patient enrollment. Cone beam CT (CBCT) scans were used for image guidance. Surgical interventions to control hemoptysis and palliative chemotherapy were allowed at the discretion of the multidisciplinary team but were not part of the study.

Assessments and evaluations

A baseline assessment was performed by the study investigators after the decision was made to proceed with hemostatic RT. Baseline demographics, tumor-specific, and treatment information were documented according to a predetermined questionnaire. Initial hemoptysis severity was assessed on the day of or the day before RT treatment. Follow-up telephone interviews following a predetermined format were conducted by the investigators at 2-week, 3-month, and 6-month intervals post-RT. During interviews, patient satisfaction was determined through a simple yes/no question along with reasons if not satisfied. Toxicity was determined per Radiation Therapy Oncology Group (RTOG) adverse event reporting. Hemoptysis severity was captured and monitored via the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0, in addition to an in-house developed Patient-Reported Outcome Measure (PROM). The tool captures bleeding description, amount, and frequency within 1 week before assessment, each scored from 0 to 4 and assigns a cumulative score ranging from 0–12. The PROM was designed so that a total score of 0 is equivalent to the absence of hemoptysis as the CTCAE's lowest grade for hemoptysis is one (mild symptoms, requiring no intervention). The data from this cohort was used for initial validation of the in-house PROM tool, which will be described in a separate publication.

Study outcomes

The primary outcome was to determine the freedom from hemoptysis rate following RT. The definition of complete response (CR) was a total score of 0 or absence of any hemoptysis based on CTCAE, partial response was a decrease from baseline score but >0, and progression was an increase from baseline score. Secondary outcomes included durability of bleeding control, defined as time to recurrence or progression of bleeding measured from the first evaluation at 2 weeks, influencing factors on hemostatic control, overall survival (OS), cancer-specific survival (CSS), and bleeding-related survival (BRS).

Table 1 Patient, tumor, and treatment characteristics

Characteristic	Value
Age (years), median [range]	68 [23–86]
Male, n (%)	27 (67.5)
ECOG performance, n (%)	
ECOG 1	17 (42.5)
ECOG 2	11 (27.5)
ECOG 3	11 (27.5)
Baseline status	
Prior bleeding, n (%)	15 (37.5)
Prior chemotherapy, n (%)	17 (42.5)
Prior radiotherapy at or near hemoptysis site, n (%)	6 (15.0)
Baseline hemoglobin, mg/dL, median [range]	117 [88–166]
Requiring blood transfusion, n (%)	6 (15.0)
Taking anticoagulants/antiplatelets, n (%)	24 (60.0)
Lung primary malignancy, n (%)	34 (85.0)
Staging (AJCC 8th edition), n (%)	
Stage II	2 (5.0)
Stage III	3 (7.5)
Stage IV	34 (85.0)
Radiotherapy regimen, n (%)	
Received 800 cGy in 1 fraction	3 (7.5)
Received 1,000 cGy in 2 fractions	1 (2.5)
Received 2,000 cGy in 5 fractions	29 (72.5)
Received 3,000 cGy in 10 fractions	7 (17.5)
PTV (cc), median [range]	364 [161–1,930]

ECOG, Eastern Cooperative Oncology Group; AJCC, American Joint Committee on Cancer; PTV, planning target volume.

Statistical analysis

The cumulative hemoptysis scores were recorded at each interview period and were compared to the baseline using the Wilcoxon signed rank test. OS was defined as the time from treatment until death due to any cause or last follow-up. CSS was defined as the time from treatment until death due to disease or last follow-up. BRS was defined as the time from treatment until death due to bleeding or last follow-up. Freedom from hemoptysis rate was defined as the time from treatment until a hemoptysis score greater than 0 or the last follow-up. The 6-month freedom from hemoptysis rate was assessed using Kaplan-Meier (KM) curves. Patients who died before the 2-week interval were not included in the primary outcome analysis. The 6-month OS, CSS, and BRS were estimated using the KM method. All patients were included in the survival analysis. Descriptive statistics were generated to provide an overview of the study population. COX proportional hazard model was used to analyze potential associations between freedom from hemoptysis and clinical variables. Because of the small number of patients and events, only univariate analysis was performed. The criterion for significance was a $P \leq 0.05$. The data was analyzed in Statistical Package for Social Sciences (SPSS) (IBM SPSS Statistics for Windows, Version 25.0; IBM Corp., Armonk, NY, USA).

Results

A total of 41 patients were enrolled in this single-institution prospective observational study from April 2016 to November 2018. One patient withdrew consent and was excluded. Study accrual was very slow, after 2 years the decision was made to prematurely close the study. The median age of the study population was 68 years (range, 23–86 years), with 27 male patients (67.5%). A total of 34 patients (85%) had a primary locally advanced lung tumor of which 31 had stage IV disease, and 3 locally advanced stage III disease. There was a total of 6 patients (15%) with lung metastasis from other sites including colon cancer, melanoma, nasopharyngeal cancer, skin SCC, prostate cancer, and angiosarcoma. Twenty-two patients had an Eastern Cooperative Oncology Group (ECOG) performance status of ≥2 (55%). Six patients had a history of deep venous thrombosis, and only one patient had a history of a bleeding disorder. Before enrollment, six patients received a blood transfusion and two underwent a bleeding-associated intervention. A total of 6 patients (15%) had prior RT near or at the hemostatic RT site. Three had palliative RT, of which one was within 1 month before accrual, the remaining three had definitive RT more than 2 years before accrual, and one around 6 months before study inclusion. RT techniques used included 3DCRT for 15 patients (37.5%), and IMRT or VMAT for 25 patients (62.5%).

All patients had a pre-treatment CTCAE score of 3 and above. The median pre-treatment PROM cumulative bleeding score was 7 [interquartile range (IQR), 5–8]. The median pre-treatment hemoglobin level was 117 mg/dL (range, 88–166 mg/dL). The most common fractionation scheme used was 2,000 cGy in 5 fractions (72.5%) followed by 3,000 cGy in 10 fractions (17.5%). The median planning target volume (PTV) was 364 cc (range, 161–1,930 cc). Patient, tumor, and treatment characteristics are outlined in (*Table 1*).

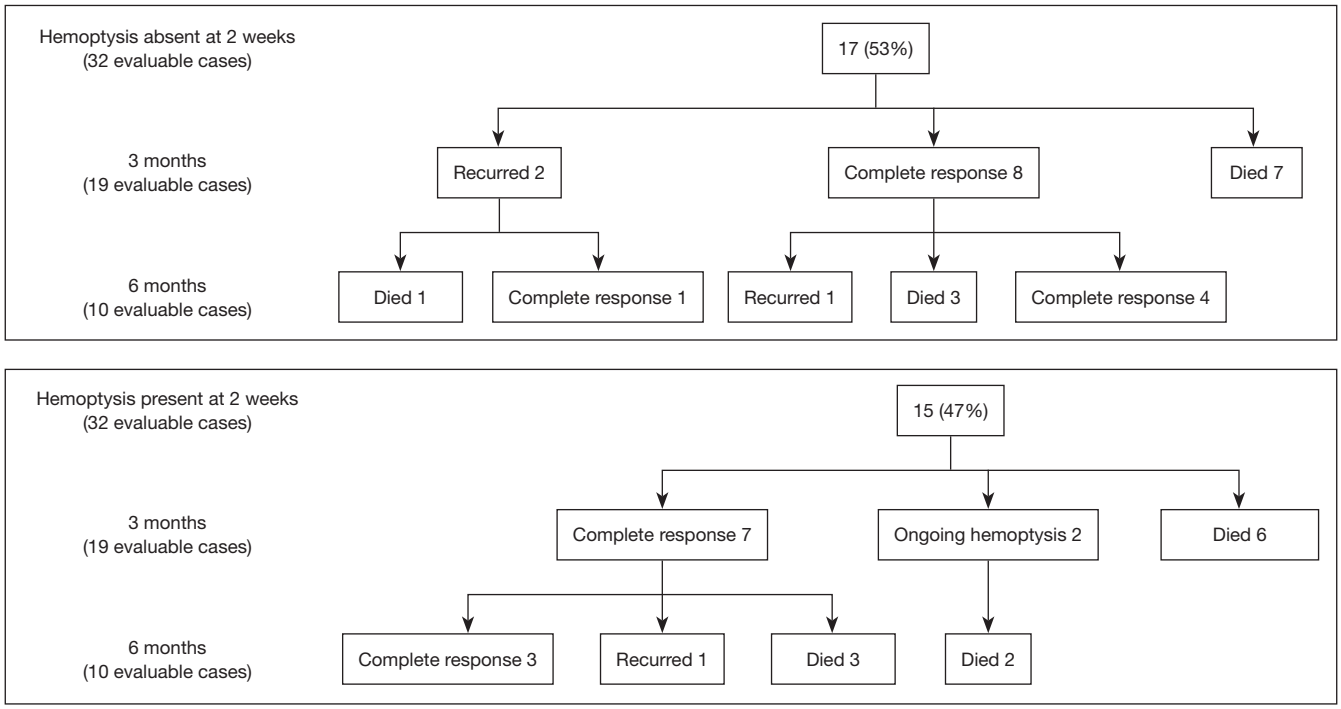

Figure 2 Hemoptysis response to RT (n=40). RT, radiotherapy.

The median follow-up was 6.1 months (range, 0.9–6.2 months). Out of the 40 patients who had scores available at baseline, 32 had scores available at 2 weeks, 19 at 3 months, and 10 at 6 months. A CR was achieved in 17 (53%) of surviving patients at 2 weeks (z=−4.2, P<0.001), 15 (79%) at 3 months (z=−3.5, P<0.001), and 8 (80%) at 6 months (z=−2.6, P=0.004). In patients with a complete hemoptysis response, 2 (20%) recurred at 3 months and 1 (16%) at 6 months. Only one patient with hemoptysis recurrence passed away due to disease progression. A diagram representing the hemostatic response for evaluable cases is represented in (*Figure 2*). The median post-treatment PROM cumulative bleeding score at 2 weeks was 0 (IQR, 0–6), at three months was 0 (IQR, 0–0), and at 6 months was 0 (IQR, 0–0). The 2 weeks post-treatment median hemoglobin level was 113 mg/dL (range, 94–164 mg/dL). Two patients required post-RT blood transfusions, one at 2 weeks and the other at 6 months. The majority of patients continued with post-RT palliative chemotherapy and none had any surgical intervention for re-bleeding. The vast majority of patients were satisfied with their RT treatments at 2 weeks (97%), three months (89.5%), and 6 months (100%). Patients not satisfied with their treatment mentioned that their other symptoms have not improved, such as dyspnea, cough, and dysphagia. The 6-month OS rate was 26% [95% confidence interval (CI): 13–41%]. The 6-month BRS was 95% (95% CI: 80–99%), and the 6-month freedom from hemoptysis rate was 37% (95% CI: 18–57%). The majority of patients passed away from disease progression, two patients passed away with bleeding as a possible cause of death. KM curves for cancer and bleeding survival are shown in (*Figures 3*,*4*). None of the patients received re-radiation for their hemoptysis. On univariate analysis, ECOG status (P=0.01) and prior radiation (P=0.006) were strongly associated with freedom from hemoptysis survival, while baseline hemoptysis score (P=0.07) and PTV volume (P=0.71) were not statistically significant (*Table 2*). Multivariate analysis was not performed due to the small sample size. Treatment-related response and toxicity rates are outlined in (*Table 3*). Our study included three patients with elevated PROM hemoptysis scores of 10 and above. All three patients passed away due to disease progression. One patient with an initial CTCAE grade 3 passed away 5 days following hemostatic RT, before the first evaluation at 2 weeks. Another patient with an initial CTCAE grade 3 achieved a complete hemostatic response at 2 weeks post-RT but passed away 3 months later. The final patient with an initial CTCAE grade 4 achieved a complete hemostatic response at 2 weeks but

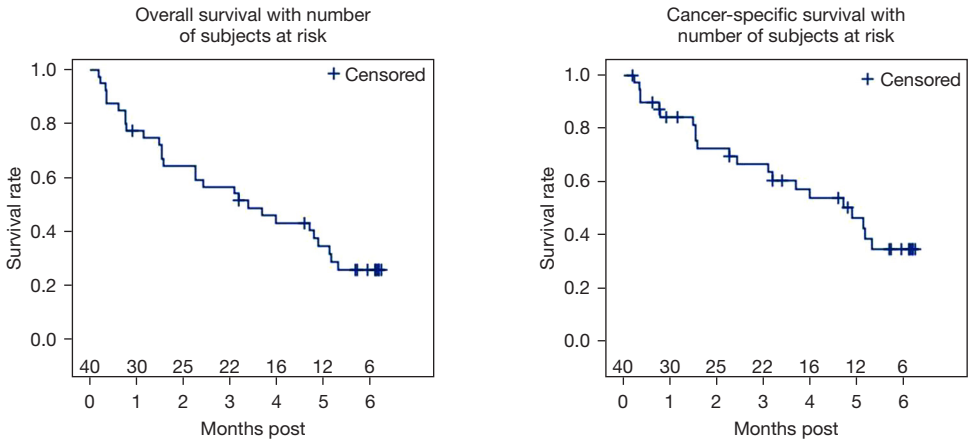

Figure 3 Kaplan-Meier curves for overall survival and cancer-specific survival post-hemostatic radiotherapy.

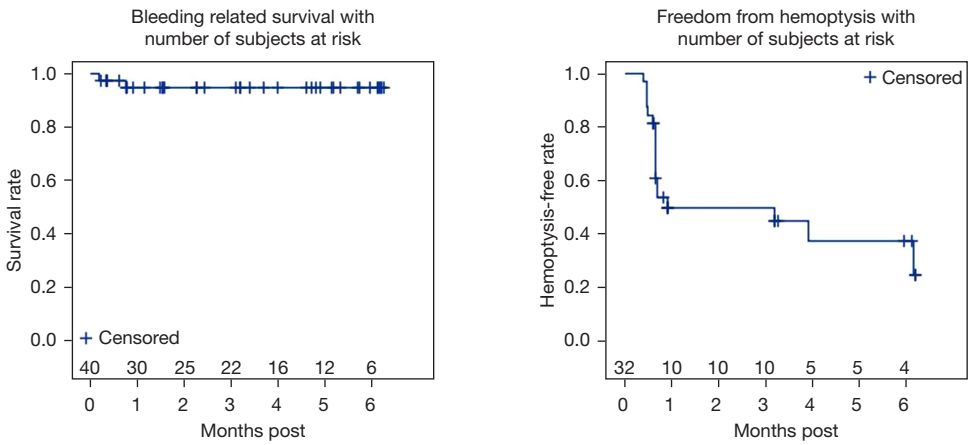

Figure 4 Kaplan-Meier curves for bleeding related survival and freedom from hemoptysis post-hemostatic radiotherapy.

Table 2 Univariate analysis for freedom from hemoptysis

Variable	Hazard ratio (95% CI)	P value
ECOG performance		0.01
0/1	1.00	
2	0.29 (0.06, 1.35)	
3	3.45 (1.09, 10.94)	
Prior radiotherapy		0.006
Yes	4.23 (1.52, 11.79)	
No	1.00	
Planning target volume (50 cc increase)	0.99 (0.91, 1.07)	0.71
Baseline hemoptysis score	1.19 (0.98, 1.43)	0.07

CI, confidence interval; ECOG, Eastern Cooperative Oncology Group.

later developed a minor bleeding recurrence before passing away 4 months post-RT.

Discussion

The purpose of this single-institution prospective observational study was to evaluate the effectiveness of palliative radiation in controlling hemoptysis caused by chest malignancies.

In this cohort, RT achieved a BRS of 95% and freedom from hemoptysis of 37% at 6 months, with only two patients passing away due to a bleeding event. The study included patients with advanced lung cancer (stage ≥III) and poor performance status (ECOG ≥2) not eligible for more aggressive therapies. The majority of our patients were taking anticoagulant/antiplatelet therapies throughout the study. RT was effective in controlling bleeding in 53%

Table 3 Treatment-related response and toxicity rates

Variables	Value
Baseline PROM hemoptysis score, median [range]	7 [0–12]
Baseline CTCAEv4 score, median [range]	3 [2–4]
Hemoptysis complete response rate, n [%]	
Two weeks post-radiotherapy	17 [53]
Three months post-radiotherapy	15 [79]
Six months post-radiotherapy	8 [80]
Treatment-related adverse events (per RTOG) (Grade ≥1), n [%]	
Two weeks post-radiotherapy	
Skin	8 [25]
Esophagus	10 [31]
Lung	8 [25]
Larynx	6 [19]
Three months post-radiotherapy	
Skin	2 [10]
Esophagus	1 [5]
Lung	6 [30]
Larynx	6 [30]
Six months post-radiotherapy	
Skin	0
Esophagus	1 [9]
Lung	3 [33]
Larynx	2 [17]

PROM, Patient-Reported Outcome Measure; CTCAE, Common Terminology Criteria for Adverse Events; RTOG, Radiation Therapy Oncology Group.

of patients surviving at 2 weeks and over 80% of patients surviving at 6 months. Although our study allowed for several fractionation regimens the majority of participating physicians chose moderate dose fractionation schemes such as 20 Gy in 5 fractions and 30 Gy in 10 fractions. Available evidence shows that higher doses and more fractionated regimens increase acute toxicity, and do not necessarily provide better or more durable palliation, and their use in prolonging survival is not supported by strong evidence (16-18). Our study did not mandate re-irradiation and was left at the discretion of the primary oncologist to pursue reirradiation or not. It was challenging for us to identify the influencing factors for these decisions. Our study found that patients who had a prior history of radiation and those with better performance status (ECOG 0–1) had higher rates of freedom from hemoptysis survival. These findings should be interpreted with caution as there was a limitation in the number of patients accrued. The very short survival of included patients challenge whether fractionated palliative RT should be used for this patient population, especially in case of mild to moderate bleeding.

EBRT is a widely utilized modality for hemostatic control in the palliative setting with a median dose of 30 Gy (range, 6–50 Gy) (11,12). Several meta-analyses and prospective studies reported single fractions as effective as protracted radiation schedules for symptom palliation, but less effective for survival (14-17). Prior randomized trials employing palliative RT for lung cancer have reported hemoptysis with the highest palliation rates. The control rate ranged from 50–97% using various fractionation schemes. Many of these studies were conducted to assess toxicity and symptom palliation effectiveness (19,20). One randomized study evaluated hemoptysis as one of nine symptoms. It is noteworthy that of the 230 accrued patients only 25 presented with coughing up blood. They reported improvement in hemoptysis at 1 month with no further details on control rate or durability. Another randomized study (21) accrued 81 patients with hemoptysis. They reported a hemostatic control rate of over 50% at 8 weeks using two palliative fractionation schemes. They did not report on CR rates or durability, with most of their patients reporting only a slight improvement in the severity of their hemoptysis. The design of these randomized trials limits our ability to generalize their findings and make conclusive recommendations for hemostatic RT.

There are a few recent retrospective studies that have focused on hemostatic RT for mild to moderate hemoptysis. Sapienza *et al.* (22) evaluated hemostatic RT in several cancers including 14 thoracic malignancies. They reported a hemostatic control rate of 93% and a re-bleeding rate of 25% with ≥5 fractionation regimens. They also reported that longer regimens (>5 fractions) were associated with more treatment interruptions and hospital days. Fleming *et al.* (23) evaluated 29 patients with hemoptysis of which 86.2% had an improvement with conventional fractionated RT of ≥20 Gy. However, the durability of the palliative effect was limited, and most patients (>50%) progressed with recurrent symptoms within 1 year of treatment. Cihoric *et al.* (24) evaluated 10 patients with lung cancer-induced bleeding of which 80% achieved improvement in their symptoms by the end of follow-up using a wide

variation of dose regimens. The reported local control rates in these studies are consistent with our findings.

The role of palliative RT in the setting of massive hemoptysis is still not well established, and our study cannot make any conclusive recommendations for it. Massive hemoptysis should be initially managed by establishing airway security and ventilation. Followed by temporary treatments including thrombus aspiration, vasoconstrictive drugs, and plasma coagulation, among others (25). Bronchial artery embolization (BAE) is the next step with a bleeding control rate as high as 75–98%, however with a poor rebleeding-free survival (34% 1-year post-intervention) (26,27).

There are several limitations related to this study. First, the pre-specified eligibility criteria required that hemoptysis be present at the time of treatment which substantially limited the study population. Our study was originally designed to run for 3 years and the planned accrual was 75 patients. However, due to the slow accrual rate only 40 patients were included in our final analysis. This limited our ability to perform a multivariate analysis which would have identified possible factors that influenced hemostatic control and durability. Our study did not take into account the possible use of anti-hemorrhagic medications for eligible bleeding patients in our cohort. The use of these medications may have impacted the results of our study in terms of hemostatic control attributed to RT. Another limitation is the lack of a validated PROM tool to aid in defining hemoptysis severity and response to treatment. We therefore developed an in-house hemoptysis PROM tool to be used in addition to CTCAE and standard physician assessment. Despite these limitations, our findings are consistent with previous studies. Future trials that aim to further study hemostatic control in chest malignancies should design prospective multi-institutional studies to acquire a larger sample size and aim to use a validated hemoptysis PROM tool for consistent post-treatment response evaluations.

Conclusions

Hemostatic RT remains an effective modality for controlling hemoptysis in lung cancer patients with poor prognosis. Defining hemoptysis severity and factors influencing hemostatic control remain a challenge. The short interval high mortality rate post-RT challenges whether fractionated palliative RT should be used for this patient population, especially in case of mild to moderate bleeding. Conducting a large clinical trial with a hemoptysis PROM tool is necessary to properly identify hemostatic durability and influencing factors.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://apm.amegroups.com/article/view/10.21037/apm-24-45/rc

Data Sharing Statement: Available at https://apm.amegroups.com/article/view/10.21037/apm-24-45/dss

Peer Review File: Available at https://apm.amegroups.com/article/view/10.21037/apm-24-45/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://apm.amegroups.com/article/view/10.21037/apm-24-45/coif). K.D. serves as an unpaid editorial board member of *Annals of Palliative Medicine* from February 2024 to January 2026. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by The Ottawa Health Science Network - Research Ethics Board (OHSN-REB 20150361-01H), and annual reapproval was obtained for as long as the trial was open. Written consent was obtained from all participating eligible patients.

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