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Percutaneous cryoablation for stage IV lung cancer: A retrospective analysis ☆

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ABSTRACT

The aim of this study was to investigate the therapeutic effect of cryoablation treatment and palliative treatment in stage IV lung cancer. Fifty-four patients were enrolled into the study. Thirty-one patients received cryoablation treatment (including intra- and extrapulmonary tumors), and 23 patients had palliative treatment (no cryoablation). Both the safety of the procedure and overall survival (OS) for stage IV lung cancer were assessed during a 6.5 year follow-up period. The OS of patients in both groups and the effects of treatment timing and frequency were compared. The OS in the cryoablation group was significantly longer than in the palliative group (median OS: 14 months vs. 7 months, $P = 0.0009$). The OS of those who received delayed cryoablation treatment was longer than that observed for those who received timely treatment (median OS: 18.5 months vs. 10 months, $P = 0.0485$), but this was not observed in those who received palliative treatment (median OS: 7 months vs. 7.5 months, $P = 0.9814$). Multiple treatments played an important role in improving the OS of patients who received cryoablation treatment (median OS: 18 months vs. 14 months, $P = 0.0376$). There was a significant difference between cryoablation and palliative treatment, in terms of OS. In addition, multiple cryoablation treatments may have an advantage over single treatments.

Introduction

Lung cancer is the most common cause of cancer-related death in adults [16]. In 2013, 228,190 new cases of lung cancer and 159,480 deaths from lung cancer are estimated in the United States [26]. The treatment of choice is surgical resection with lobectomy, but this is only suitable for localized, early-stage disease, with or without regional lymph node involvement [17,23]. Unfortunately, most patients have metastatic disease when diagnosis and are therefore not suitable for surgery [25]. Chemotherapy regimens are considered first line treatment for advanced and metastatic lung cancer [21]. However, these regimens are often associated with a decreased quality of life, without a significant improvement in prognosis.

Cryosurgery, which is widely accepted as a minimally invasive curative technique for solid tumors, such as prostate cancer, renal cell carcinoma and hepatocellular carcinoma [14,15], has emerged as a new therapy for lung cancer [12,18]. We were the first to report on the combination of cryosurgery and iodine-125 seed implantation, which eliminates residual tumor in advanced lung cancer [19]. In the report, at six months post-treatment, there was a complete remission rate of 93.4%, a partial remission rate of 70.1%, a stable disease rate of 7.4%, and a progressive disease rate of 5.7%. The 6-month and 12-month survival rates were 94.3% and 65.7%, respectively. In addition, Yamauchi et al. reported the successful use of percutaneous cryoablation for pulmonary metastases from colorectal cancer [32], and George et al. reported that cryosurgery was a safe method for the treatment of endobronchial malignancies with airway obstruction [2].

In this study, patients were divided into a cryoablation treatment group, in which patients received cryoablation for primary lung tumors and metastases, and a palliative treatment group, in which patients received conventional treatment without cryoablation. Our aim was to compare the effects of two therapeutic re-

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gimes on stage IV lung cancer, and to assess the influence of treatment timing and frequency on OS.

Patients and methods

Ethics

The study protocol received ethical approval from the Regional Ethics Committee at Guangzhou Fuda Cancer Hospital. Written informed consent was obtained from each participant in accordance with the Declaration of Helsinki.

Patient selection

This was a retrospective study of patients treated for metastatic lung tumors in our hospital between August 2004 and February 2011. Before hospitalization, 54 patients received a comprehensive evaluation, which included a consideration of whether the tumor was unresectable. The evaluations and decisions were multidisciplinary and included a radiologist, a surgeon and an oncologist from our hospital. Diagnoses were principally based on computed tomography (CT) imaging, and confirmed by a CT-guided needle biopsy. An 18-gauge Tru-cut (Baxter Inc, Deerfield, IL) biopsy needle was inserted percutaneously to obtain one or two cores of tissue from the intra- and extrapulmonary tumor. Patients received their final treatments in our hospital, and follow-up assessments continued for a period of 6.5 years.

The following were exclusion criteria for surgery: (1) Multiple metastases; (2) Multiple lung cancers; (3) Central lung cancer infiltrating or blocking the main bronchus; (4) Patient refused surgery and chemotherapy, or sought for further treatment after chemotherapy failure in other hospitals; (5) Severe complications (for example, hypertension, hydrothorax and ascites); and (6) Advanced age. Inclusion criteria were as follows: (1) Karnofsky performance status (KPS) score $\geqslant 70$; (2) Platelet count $\geqslant 80 \times 10^9$/L, white blood cell count $\geqslant 3 \times 10^9$/L, neutrophil count $\geqslant 2 \times 10^9$/L, and hemoglobin $\geqslant 90$ g/L; (3) Prothrombin time international normalized ratio $\geqslant 1.5$; (4) Diameter of largest primary or metastatic tumor < 8 cm on preoperative CT; (5) Absence of level 3 hypertension, severe coronary disease, myelosupression, respiratory disease, brain metastasos and acute or chronic infection; (6) Primary and metastatic site of the tumor is isolated, not diffused; (7) Pulmonary functional compensation stage; (8) Normal baseline liver function and ascites < 1 L; (9) and Patient was deemed capable of cooperating during the procedure.

Patients with primary or metastatic tumors >8 cm in diameter received other treatments [3,31] by Dr. XH. P, and were not enrolled into the study. If the tumor had blocked the trachea or main bronchi, radiofrequency ablation through a bronchoscope was firstly performed to release obstruction, and then cryotherapy could be used to treat the tumor [5,20].

Percutaneous cryoablation and iodine-125 seed implantation

Cryoablations on lung, liver and bone were all performed under double row helical CT (Siemens Inc, Heusenstamm, Germany) [19]. Before cryoablation, patients received general or local anesthesia and were positioned for the procedure, irrespective of whether the tumor was central or peripheral. Dr. LZ.N and assistants (L.Z and F.M) performed all cryosurgeries. Based on the location of the tumor, the cryoprobes were inserted percutaneously via the scapular line, the posterior axillary line or the rib margin (Fig. 1). For tumors greater than 3 cm in long diameter, more than two 1.7 mm cryoprobes (Endocare Inc, Irvine, CA) were used. Double cycle of freeze/thaw procedure was used with an argon gas-based cryosurgical unit (Endocare Inc, Irvine, CA) [19]. Additional implantation of iodine-125 seeds for some patients occurred under the following conditions: centrally-located lung cancer that cannot be covered by cryolesion; a large mass, which cryoablation could not completely ablate; and local small lymph node metastases that is not suited for cryosurgery because of risks [19]. Iodine-125 seed (Syncor Pharmaceutica, Shanghai, China) implantation was performed under a 3D treatment planning system, either at the time of cryoablation or afterwards. The seeds (activity of a single seed 0.7 mCi, half-life three months) were implanted at the tumor borderline. The number of seeds deployed depended on the tumor size (matching dose approximately 120 Gy, usually $\leqslant$20 particles), with the seeds implanted at intervals of 0.5 cm. Metastases, for example to liver and bone, where practically feasible, also received cryoablation or iodine-125 seed implantation. Once cryoablation had been completed, 1 mL of fibrinogen and thrombin were injected into the sheath simultaneously. Patients were then observed in the intensive care unit for at least 6 h, and fasted for at least 24 h. Anti-infective therapies were administered for a few days.

Twenty-three patients refused cryoablation, for reasons that included cost, treatment concept and age, and therefore received palliative treatment [28], including chemotherapy, radiotherapy or targeted drug treatment. Overall, patients in this group accepted at least one palliative treatment.

Response evaluation and statistical analysis

Complications were recorded and classified in accordance with the Common Terminology Criteria of Adverse Events (CTCAE) v4.0 [1]. Three-six months after first treatment in our hospital, all patients returned for imaging examination, and response evaluation was performed on every ablated tumor according to RECIST guideline (version 1.1) [8]. If new recurrences or metastases were found, the patients will be suggested to receive cryosurgery again. The OS was calculated from the month when the patient was first diagnosed with stage IV lung cancer, and compared using the Kaplan–Meier test with long-rank analysis by GraphPad Software (San Diego, CA, United States). A significant difference was indicated by a P value <0.05.

Results

Clinical data

The basic clinical data of cryoablation and palliative treatment group were shown as Table 1, including the sex, nationality, age, pathologic type, metastatic sites, treatment protocol, et al.

Perioperative outcome

All 98 percutaneous cryoablations of intrapulmonary (31 primary lesions and 11 metastases) and extrapulmonary (56 lesions) lung cancers under CT monitoring were successfully performed in the first cryoablation. No severe complications, such as cardiac arrest, asthmatic attack and respiratory failure, pothological fracture, hepatic rupture and liver failure occurred post procedure. In the cryoablation group, adverse effects did occur: transient hemoptysis occurred in 19 sessions in 16 patients (51.6%); pneumothorax occurred in 17 sessions in 12 patients (38.7%), usually immediately after the completion of the procedure; and bradycardia, hypotension and fever occurred separately in three sessions in three patients (9.7%), in five sessions in four patients (12.9%) and in six sessions in six patients (19.3%), all of which resolved following appropriate treatment. In all cases, perioperative pain was controlled by loxoprofen, which was discontinued within one week.

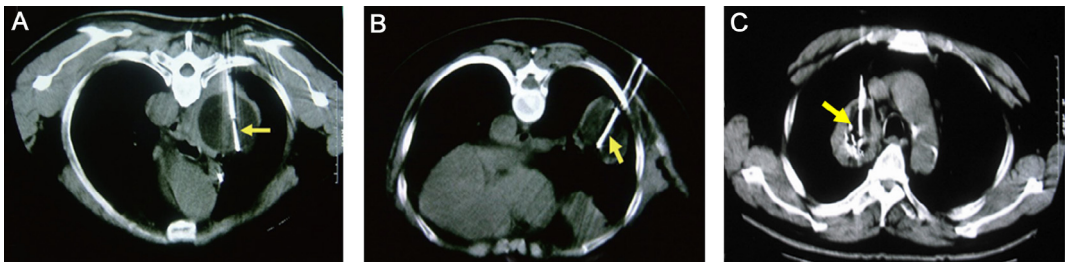

Fig. 1. Cryoprobe can approach to the lesions in different parts of lung. One cryoprobe (the arrow) is inserted into the lung tumor via the scapular line (A), the posterior axillary line (B) or the rib margin (C).

Table 1
Basic clinical data of cryoablation and palliative treatment group.

		Cryoablation group(31 patients)	Palliative treatment group (23 patients)
Sex	Male	13	8
	Female	18	15
Nationality	China	19	13
	Southeast Asia	9	5
	Middle East	3	5
Pathologic type	Adenocarcinoma	18	15
	Squamous cell carcinoma	13	8
Age (yr)	Average	59	56
	Range	36–81	31–74
Metastatic site	Bone	24 (43 lesions)	17 (29 lesions)
	Liver	7 (13 lesions)	4 (10 lesions)
	Lung	9 (11 lesions)	5 (8 lesions)
Treatment protocol	Cryoablation	31	0
	Chemotherapy	9 (other hospital)	23
	Surgery	3 (other hospital)	0
	Radiation	0	8

Some patients complained of a dull pain in the anterior chest soon after treatment, which was most likely due to damage to the intercostal nerves. The pain usually resolved within a few months. Nine patients (29%) in 16 sessions complained of a cough and blood-streaked sputum, which improved within three to five days without any treatment. Cryoablation of the 13 hepatic metastases was associated with the following side effects: mild liver hemorrhage, 2 (15%) patients (healed within 5 days after injection of hemostatic agents); transient thrombocytopenia within 1 week after cryoablation, 3 (23%) patients (all recovered naturally in a week); and liver abscess occurred 2 or 4 days after cryoablation, 2 patients (15%) (recovered after antibiotic and drainage treatment). There were no treatment-related deaths or conversions to chemotherapy. Within one week of cryoablation treatment, 11 patients experienced a $\geqslant$50% reduction in pain score, eight patients experienced a 50% decrease in analgesic consumption and 17 patients had a $\geqslant$20% increase in their KPS score.

Influence of therapy, treatment timing and treatment frequency on OS

The median OS for all patients was 10 months (95% CI: 12.70–14.02 months). In the cryoablation treatment group, approximately half of the patients received a combination of cryoablation and iodine-125 seed implantation treatment, with the remainder receiving cryoablation alone. There was no significant difference in survival between these subgroups (Supplement Fig. 1). In addition, there was no significant difference in survival between different pathological cell types (Supplement Fig. 2). The median OS of patients in the cryoablation group was 14 months, and that in the palliative group was 7 months, with a significant difference between the groups by long-rank test ($P < 0.001$, Fig. 2).

Overall, 14 patients received treatment within two months of diagnosis of stage IV lung cancer, and 17 patients received treatment within 2–29 months. The influence of treatment timing on the OS was assessed: in the cryoablation treatment group, the median OS of those who had treatment on time was 10 months, and when treatment was delayed, 18.5 months ($P = 0.0485$, Fig. 3A). For the palliative group, the median OS with treatment on time was 7.5 months, and with delayed treatment was 7 months ($P = 0.9814$, Fig. 3B).

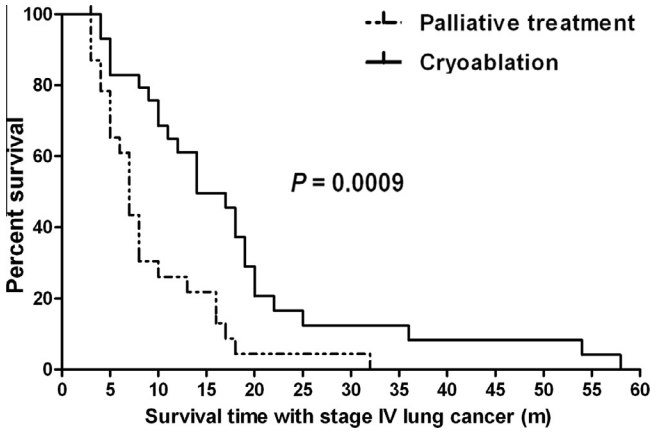

Fig. 2. OS of patients undergoing cryoablation or palliative treatment. All 54 patients had stage IV lung cancer and were followed up until February 2011. There were 31 patients in the cryoablation treatment group, and 23 patients in the palliative treatment group. The OS was obtained from the initial diagnosis of stage IV lung cancer in our hospital or from another center.

As a result of disease progression and individual patient needs, 19 patients (61%) received multiple cryoablation treatments when re-examined, other 13 patients (39%) gave up continued examination or treatment. In the cryoablation treatment group, the median

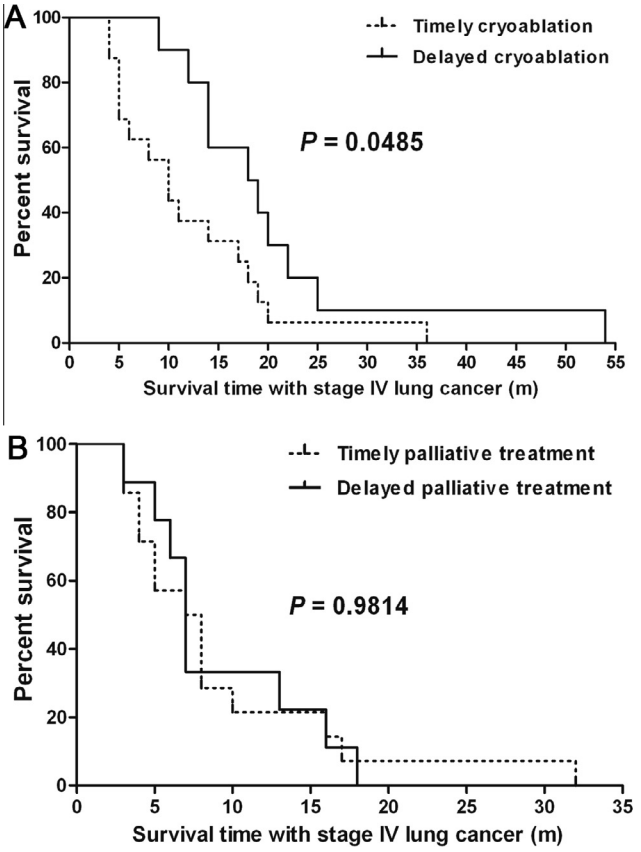

Fig. 3. OS of patients receiving timely or delayed treatment. (A) Comparison between patients in the cryoablation treatment group, 14 patients had treatment on time and 17 patients had delayed treatment. (B) Comparison between patients in the palliative treatment group, 14 patients had treatment on time and nine patients had delayed treatment.

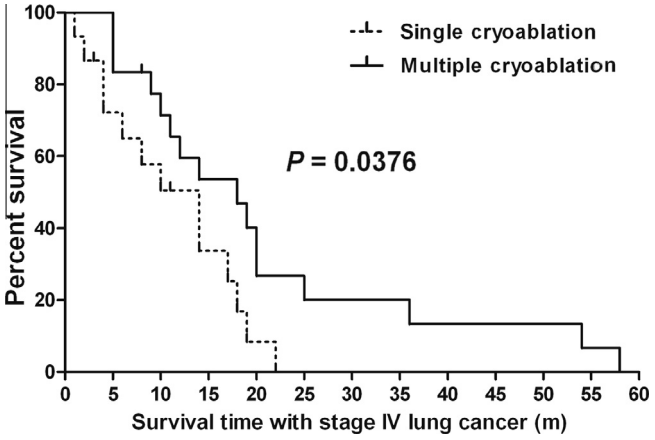

Fig. 4. OS of patients with different treatment frequencies. Comparison between patients in the cryoablation treatment group, 19 patients had multiple cryoablation treatments (two times, 12 patients; three times, five patients; and four times, one patient) and 13 patients had a single cryoablation treatment.

OS of patients who had a single treatment was 14 months, and that following multiple treatments was 18 months, which was significantly longer than single treatments($P = 0.0376$, Fig. 4).

Discussion

For most patients with stage IV lung cancer, the tumor is unresectable. Radiofrequency ablation, chemotherapy and other palliative therapies are options for patients with metastatic disease [8,9]. Along with advances in cryosurgery and imaging, percutaneous cryoablation has been increasingly successful for the treatment of lung cancer [2,11,16,33]. As the volume of primary and metastatic tumors can be large, and adhesions to other organs and tissues and invasive growth are often present, percutaneous cryoablation cannot guarantee complete ablation, and a combination with brachytherapy may be a better supplement [6,7,10,27]. Studies have also demonstrated that cryotherapy can increase the efficacy of radiotherapy because the residual tumor around the cryolesion exhibits a high metabolism and an enhanced vascularization, and cooled cells show more radiosensitivity[4,29]. Moreover, this supplement can be carried out in the "restricted area" of the ablation on tumor growth control, reduces or avoids injury of physical vessels and normal tissue, thus decreases the likelihood of complications, and improves quality of life. However, whether this combined approach can extend OS remains unclear.

In our study, the OS of patients who received cryoablation treatment was significantly longer than that observed in the palliative group ($P < 0.001$), with a seven month extension of the median OS (7 months versus 14 months, respectively). The survival time of palliative group was similar with the former reports [24], and this result fully explain the advantages of comprehensive cryosurgery in the effectiveness of treatment. We found that patients with delayed cryoablation treatment had a better OS ($P < 0.05$) in the cryoablation group, with a 8.5 month extension of the median OS (10 months versus 18.5 months, respectively), but this was not observed in the palliative group ($P = 0.9814$). We therefore re-analyzed the data and found that 80% of patients in the cryoablation group and 14% of patients in the palliative group who had delayed treatment, had received chemotherapy prior to admission. Therefore, chemotherapy which was performed before comprehensive cryosurgery might explain the extension in OS observed. It appears that if chemotherapy is delivered early in stage IV lung cancer, it may change systemic disease into a more localized one, which would clearly benefit survival [28]. As for the frequency of cryoablation treatment, multiple treatments were associated with a survival advantage in the cryoablation group (median survival: 14 months vs. 18 months, $P = 0.0376$). As demonstrated in our study, in order to achieve an optimal therapeutic effect, early chemotherapy, cryoablation and multiple treatments are all important.

With regard to complications associated with cryoablation treatment, cardiac arrest, asthmatic attack, and respiratory failure were seldom observed in our study. Other minor complications, such as pneumothorax, hemoptysis, hypotension, bradycardia and fever were acceptable and resolved with treatment [13,16,22]. A broad range (11.8–61.7%) for the incidence of pneumothorax following percutaneous cryoablation of lung tumors has been reported [11,30,32]. In our study, the incidences of pneumothorax and hemoptysis were 38.9% and 51.6%, respectively, which were consistent with anticipated rates [34]. Other minor complications included a decrease in the platelet count, which returned to normal within two weeks after symptomatic treatment. By effectively reducing tumor load and with careful postoperative monitoring, physical strength and energy status of patients in both groups clearly improved, and pain levels also decreased significantly.

This study presents our initial experience, with a small number of patients. Hence, extrapolation of the results to clinical practice needs to be undertaken cautiously. In addition, this is not a definitive study for assessing the effects of chemotherapy on OS, the effectiveness of combined treatment for newly diagnosed stage IV lung cancer, or for determining whether cryoablation treatment is as effective as surgery. In conclusion, percutaneous cryoablation treatment may have a useful role in the management of stage IV

lung cancer, for tumors less than 8 cm in diameter, where surgery and chemotherapy are not appropriate options. To further enhance the OS of these patients, close postoperative monitoring and multiple treatments may be needed for recurrent tumors.

Disclosure

The author declares no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.cryobiol.2013.06.005.

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