INTRODUCTION

Lung cancers, the most frequent and lethal of all tumors, continue to increase in prevalence (1, 2). Although lung cancer is best treated by surgical resection, a large number of patients cannot tolerate surgery due to advanced stage of disease, pulmonary insufficiency, co-morbidity, age, or poor physiological status (2, 3). In these patients, chemotherapy may be used, but may fail to control the disease or extend their survival. Patients who cannot tolerate surgery may also be more susceptible to adverse effects of chemotherapy or radiotherapy (4, 5). Alternative techniques such as radiofrequency ablation (RFA), ablation by laser, microwave, or percutaneous cryotherapy are well-tolerated and may have the potential to increase the survival of patients with inoperable lung cancer (6-9).

Percutaneous cryotherapy is most commonly applied for lesions to the prostate (10), kidney (11) and liver (12), but may also be effective with inoperable lung tumors (13-17). The mechanisms of percutaneous cryotherapy include osmotic breakdown by intracellular ice formation, cellular membrane disruption, and ischemia by microvascular injury at temperatures below -20°C to -30°C. Not only is percutaneous cryotherapy minimally invasive, easy to use, and amenable to real-time monitoring, but it also preserves collagenous architecture of the tissue (13, 17, 18). This enables us to achieve successful ablation without bronchial disruption or perforation, in contrast to hyperthermal techniques such as RFA. Also, percutaneous cryotherapy might offer the other advantage over other ablative techniques during the procedure that is the superior visibility of the ablation zone, i.e. ice ball, during freezing (19).
Until now, there has been no paper on the experience of using percutaneous cryotherapy for the treatment of inoperable lung malignancy in Korea. Although percutaneous cryotherapy for inoperable patient with lung cancer is feasible using recently developed probes measuring less than 1.5 mm in diameter for the tumors in other country (13-17), the effectiveness of percutaneous cryotherapy for lung cancer has not still been established through mid-term follow-up. Therefore, we evaluated the post procedural therapeutic efficacy for complete ablation of patients treated with percutaneous cryotherapy for the inoperable non-small cell lung cancer (NSCLC) and metastatic pulmonary nodules through mid-term follow-up.

MATERIALS AND METHODS

Patient Population

Between August of 2006 and July of 2009, CT-guided percutaneous cryotherapy was performed on 14 patients with inoperable NSCLC or pulmonary metastasis at our institution. These patients were followed until October of 2010 (range; 7-56 months, mean 27.6 ± 14 months) to evaluate the effectiveness of the treatment. The institutional review board of our hospital approved retrospective data review of this clinical result. Every patient signed an informed consent agreement prior to the study and the possible risks and complications associated with the procedure were fully explained.

To qualify for percutaneous cryotherapy, a patient with inoperable NSCLC and pulmonary metastasis had to meet the following requirements: A) a diagnosis of primary NSCLC or pulmonary metastasis was histologically proven using percutaneous needle lung biopsy or bronchoscopic biopsy; B) medical inoperability (stage I-II) due to medical contraindications or strong refusal of surgery; C) single metastatic nodule; D) the patient who was in stage III-IV wanted to reduce the volume of the primary tumor instead of radiation therapy and follow by adjuvant chemotherapy; and E) tumor size measures less than 2.5 cm in diameter.

During the course of conducting this study, new guidelines, the 7th Edition of TNM staging system in Lung Cancer of the International Association for the Study of Lung Cancer, were published and we adopted these guidelines from 2009; however, all of the patients enrolled in this study were diagnosed and staged prior to 2009, and our data remain based on the 6th edition guidelines.

Technique of Percutaneous Cryotherapy

All patients were admitted to the hospital at least one day before the treatment. Time from pre-procedural CT scans to the beginning of the procedure ranged from 4 to 49 days (mean, 20.2 days). Tumor size was obtained in 2 directions at the level that revealed the tumor most prominently. The technique of percutaneous cryotherapy was based on Galil’s 3rd generation percutaneous cryotherapy. The instruments we used (Seednet™, Galil Medical, Yokneam, Israel) included an argon and helium gas-based system, a 1.5-mm 17-gauge cryoprobe and a thermal sensor. The ice ball diameter refers to the outer 0°C margin that appears as low attenuation, but the diameter of the cytotoxic ice ball (temperature ≤ -20°C) is known to be as small as 2.5 × 3.5 cm (10). Patients were placed with feet toward the CT gantry, and CT was performed with breath held on expiration as used in the previous CT scan. This seemed to be critically important, because if the breath-hold duration (15 seconds) changes, the mass may shift in apparent location at the moment of cryoprobe insertion. After checking location of the mass, the procedure was performed. First, local anesthetics were injected at the insertion site of the cryoprobe. After checking to see that the cryoprobe was inserted precisely as planned from the CT scan, freezing was performed. The procedure consisted of 2 cycles of freezing for 20 minutes and thawing for 10 minutes. This protocol is optimized for maximal thawing of the iceball and cytotoxicity in the ablation zone. After confirming that the ice ball was sufficient in size, shown as a region of low attenuation with an envelope of ground glass opacity of a margin of 1 cm beyond the margin of the lesion on the CT scan, the cryoprobe was gently removed.

Image Analysis

All pre- and post-procedural CTs were performed using multi-detector CT (MDCT) scanners (Sensation 16, Enlargen, Siemens, Forchheim, Germany). A total of 120 mL of nonionic contrast material [(iopromide, 370 mg I/mL) Ultravist 370, Bayer Schering, Seoul, Korea] was administrated at a rate of 2 or 3 mL/sec using a power injector (CT 9000, Liebel-Flarsheim, Cincinnati, OH, USA). Imaging parameters were set at 120
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formed, while the patient was hospitalized for evaluation. Complications of percutaneous cryotherapy within 30 days were identified by follow-up CT scans.

Statistics

We evaluated changes of sizes in the completely and incomplete treated ablated lesions on follow-up CT scans. In addition, we evaluated therapeutic effectiveness on 1-year and last follow CT according to enhancement pattern (none or partial) of ablated lesion on immediately follow-up CT after cryoablation. Survival was calculated from the first day of treatment to the day of either death from any cause or censoring at the last follow-up date. The Kaplan-Meier method was used to calculate survival curves of the complete and incomplete treated ablation groups. The regular log-rank test was used to show the difference between survival curves. We evaluated complications after percutaneous cryotherapy using clinical reports and follow-up CT scans. All analyses were performed using SPSS 9.0 software (SPSS Inc., Chicago, IL, USA) or GraphPad (GraphPad Prism, San Diego, CA, USA).

RESULTS

We studied therapeutic effectiveness of percutaneous cryotherapy for 14 patients (7 men and 7 women; mean age 68.8 years, range 53-84 years). Ten of the 14 patients had primary lung cancers. Of these, 6 (60%) were adenocarcinoma and 4 (40%) were squamous cell carcinoma. Of our 14 patients, 3 (21.4%) patients had stage I, 3 (21.4%) patients had stage II, 2 (14.3%) patients had stage III, and 2 (14.3%) patients had stage IV cancer. Four (28.6%) of 14 patients had metastatic lung cancers that originated in the rectum. A central tumor was defined as any mass arising at or close (less than 2 cm) to the hilum and segmental bronchus. Two of 14 patients (14.3%) had central pulmonary nodules and the rest (85.7%) had peripheral pulmonary nodules. The MDCT images were obtained in a craniocaudal direction from clavicle to upper abdomen, using a 5-mm slice thickness. Follow-up CT scans were performed immediately after the second percutaneous cryotherapy cycle was completed and within 2-3 minutes following removal of the cryoprobe. Two experienced pulmonary radiologists compared the pre- and post-procedural CT images, and by consensus evaluated the effects of percutaneous cryotherapy on tumor size and complications.

Technical success was evaluated by comparing the contrast-enhanced CT scans obtained within 24 hours after percutaneous cryotherapy with contrast-enhanced CT scans obtained before the procedure. Technical success was defined as how well the treatment was adherent to the protocol with complete coverage of the tumor. On follow-up, we evaluated the effectiveness of primary treatment and local tumor progression at 1 and 3 months post-procedurally, and every 6 months thereafter using contrast-enhanced CT. Technical success and primary effectiveness were defined according to the guidelines of Callstrom et al. (20) and Goldberg et al. (21).

Complete ablation was defined as the absence of enhancement of the ablated lesion on contrast-enhanced CT scans obtained within 24 hours after percutaneous cryotherapy, and in addition, a decrease in or no in size of the ablated lesion on contrast-enhanced CT at the last follow-up. Incomplete ablation was defined as enhancement at the lesion site on contrast-enhanced CT scans obtained within 24 hours after percutaneous cryotherapy, or an increase in size of the ablated lesion on the last follow-up contrast-enhanced CT.

We evaluated complications of percutaneous cryotherapy according to the classification system used by society of interventional radiology for grading complications and by the National Cancer Institute in the Common Terminology Criteria for Adverse Events (20). Complications within 24 hours were identified by follow-up CT scans, plain chest X-rays, vital signs and symptoms checked 6 times daily and one chemical study performed. We evaluated complications of percutaneous cryotherapy according to enhancement pattern (none or partial) of ablated lesion on immediately follow-up CT after cryoablation. Survival was calculated from the first day of treatment to the day of either death from any cause or censoring at the last follow-up date. The Kaplan-Meier method was used to calculate survival curves of the complete and incomplete treated ablation groups. The regular log-rank test was used to show the difference between survival curves. We evaluated complications after percutaneous cryotherapy using clinical reports and follow-up CT scans. All analyses were performed using SPSS 9.0 software (SPSS Inc., Chicago, IL, USA) or GraphPad (GraphPad Prism, San Diego, CA, USA).

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Comparing the contrast-enhanced CT scans obtained within 24 hours after percutaneous cryotherapy with contrast-enhanced CT scans,plain chest X-rays, vital signs and symptoms checked 6 times daily and one chemical study performed, while the patient was hospitalized for evaluation. Complications of percutaneous cryotherapy within 30 days were identified by follow-up CT scans.
Percutaneous Cryotherapy for Inoperable Lung Malignancy

Enhanced CT scans obtained before the procedure, the percutaneous cryotherapy was technically successful in all 14 patients (100%) (Table 1). Ten of 14 patients (71.4%) showed no enhancement of ablated zone on the contrast-enhanced CT scans obtained within 24 hours after percutaneous cryotherapy, and 4 of 14 patients (28.6%) showed a partial enhancement. All patients presented a low-attenuating ice ball without an enhancing portion on the contrast-enhanced CT scans obtained within 24 hours after percutaneous cryotherapy. On 1-year follow-up CT, 9 of 14 (64.3%) patients who had no enhancement on 24 hour CT, showed no enhancement of the ablated zone. Among them, 5 of these patients showed a decrease in tumor size in every follow-up scan; these 5 of the 14 patients (35.7%) were classified as complete ablation group (Fig. 1). The remaining 5 patients and 4 patients who had a partial enhanced ablated zone on the contrast-enhanced CT scans obtained within 24 hours after procedure increased an enhanced ablated zone and tumor size on 1-year follow-up CT. In total, 9 of the 14 were classified as incomplete ablation (64.3%) (Fig. 2).

The mean size of tumor before percutaneous cryotherapy in this study was 16.4 ± 6.9 mm. The mean tumor sizes before percutaneous cryotherapy in the complete and incomplete ablation groups were 13.2 ± 7.6 mm and 18.1 ± 6.2 mm, respectively. However, the mean lesion sizes in the complete and incomplete ablation groups on the last follow-up CT were 3.8 ± 2.7 mm and 33.7 ± 17.9 mm, respectively. Complete ablation was achieved in 100% of the nodules less than 5 mm, 50% of those less than 15 mm, 37.5% of those less than 20 mm, and 27.3% of those less than 25 mm.

Six of 14 patients (42.9%) are still alive, including 2 of 3 patients in complete ablation (66.7%) and 4 of 8 patients in the incomplete-treatment ablation group (50%). The average follow-up period was 27.6 ± 14.1 months. The median survival of patients in the complete ablation group (n = 5) and the incomplete treated ablation group (n = 9) were 51.5 (range; 7-56 months) and 24 (range: 7-43 months) months, respectively (p = 0.048, log-rank = 3.90, 95% confidence intervals = 2.034 to 2.258).

One minor (7.1%) and 2 major (14.3%) complications occurred within 24 hours. However, there were no minor or major complications beyond 30 days. None of the patients developed extreme pain that needed to be controlled, pleural effusion, or cough. During the hospitalization, no patient showed significant changes in blood pressure, body temperature, heart rate, or respiratory rate, as compared to values before the procedure. One patient developed a small pneumothorax, which resolved spontaneously, as shown by chest X-ray. Two patients developed hemoptysis after the procedure. To minimize pulmonary hemorrhage, 20 mg of Vitamin K and 100 mg of anti-hemor-

### Table 1. Results of Therapy and Patient Survival after Percutaneous Cryotherapy for Non-Small Cell Lung Cancer

| N  | Age/Sex | Cell Type | Stage | Tumor Size before Treatment (mm) | Tumor Size on Last Follow-Up (mm) | Therapeutic Effectiveness | Survival (Months) | Complications |
|----|---------|-----------|-------|---------------------------------|-----------------------------------|--------------------------|------------------|---------------|
| 1  | 84/M    | Squamous  | I     | 24                              | 67                                | Incomplete               | 24               | None          |
| 2  | 59/F    | Squamous  | I     | 6                               | 8                                 | Incomplete               | 21               | Hemoptysis    |
| 3  | 79/M    | Adeno     | I     | 15                              | 5                                 | Complete                 | 7                | None          |
| 4  | 64/M    | Adeno     | II    | 25                              | 1                                 | Complete                 | 32               | Hemoptysis    |
| 5  | 77/F    | Squamous  | II    | 17                              | 34                                | Incomplete               | 21               | None          |
| 6  | 76/M    | Adeno     | II    | 12                              | 1                                 | Complete                 | 56               | None          |
| 7  | 72/F    | Adeno     | III   | 25                              | 44                                | Incomplete               | 34               | None          |
| 8  | 83/M    | Squamous  | III   | 24                              | 50                                | Incomplete               | 18               | None          |
| 9  | 53/M    | Adeno     | IV    | 12                              | 23                                | Incomplete               | 43               | None          |
| 10 | 59/F    | Adeno     | IV    | 20                              | 23                                | Incomplete               | 7                | Pneumothorax  |
| 11 | 61/F    | Adeno     | Meta  | 5                               | 5                                 | Complete                 | 47               | None          |
| 12 | 59/F    | Adeno     | Meta  | 18                              | 20                                | Incomplete               | 30               | None          |
| 13 | 79/F    | Squamous  | Meta  | 17                              | 34                                | Incomplete               | 21               | None          |
| 14 | 58/M    | Adeno     | Meta  | 9                               | 7                                 | Complete                 | 26               | None          |

Complete ablation was defined as the absence of ablated lesion enhancement on contrast-enhanced CT scans obtained within 24 hours after percutaneous cryotherapy, and in addition, a decrease in or no enhancement of the treated lesion on contrast-enhanced CT at the last follow-up. Incomplete treated was defined as enhancement at the lesion site on contrast-enhanced CT scans obtained within 24 hours after percutaneous cryotherapy, or an increase in size of the ablated lesion on the last follow-up contrast-enhanced CT.
the procedure-related death rates of RFA and microwave ablation have been reported as 5.6% (range 0-5.6%) (20) and 2% (one of 66) (9), respectively. Complications of these procedures include fistula and abscess formation, hemoptysis, and transient acute respiratory failure (20, 23-26), which we defined as major complications in the present study. However, none of our patients developed bronchial injury or fistula, although Niu et al. (22) reported one case of acute respiratory distress syndrome after percutaneous cryotherapy for a metastatic pulmonary nodule. A low incidence of major complications with percutaneous cryotherapy has been consistently reported (13, 21, 27).

**DISCUSSION**

The safety of percutaneous cryotherapy for treating lung cancer was established before we began this study. The technique is minimally invasive, easy to use, allows real-time monitoring, and allows direct approach to the central tumor. In the treatment of 644 patients with lung cancer using percutaneous cryotherapy, Niu et al. (22) reported only minor complications, which were controlled by conventional methods, and a procedure-related death rate of only 0.46% (3 of 644). In comparison, the procedure-related death rates of RFA and microwave ablation have been reported as 5.6% (range 0-5.6%) (20) and 2% (one of 66) (9), respectively. Complications of these procedures include fistula and abscess formation, hemoptysis, and transient acute respiratory failure (20, 23-26), which we defined as major complications in the present study. However, none of our patients developed bronchial injury or fistula, although Niu et al. (22) reported one case of acute respiratory distress syndrome after percutaneous cryotherapy for a metastatic pulmonary nodule. A low incidence of major complications with percutaneous cryotherapy has been consistently reported (13, 21, 27). Airway integrity may be preserved in percutaneous cryotherapy by low cellularity of the bronchus and associated tissues, such as nerve sheaths, collagen, cartilage, and fat, which are rel-

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Fig. 1. A 76-year-old male with NSCLC in right lower lobe shows complete ablation after percutaneous cryotherapy. He had undergone right bilobectomy (RUL and RML) for lung cancer and had a single metastatic nodule in the right lower lobe on follow-up CT.

A, B. Axial scans from mediastinal (A) and lung settings (B) show a 12-mm metastatic nodule (arrow) in right lower lobe.

C. Percutaneous cryotherapy was performed on patient in prone position.

D, E. (D) Follow-up CT shows decrease in nodule size with pleural thickening at 1 month and (E) at the 12-month follow-up image.

F. After 55 months of follow-up, only the pleural thickening remains.

Note.—NSCLC = non-small cell lung cancer, RML = right middle lobe, RUL = right upper lobe
are very wide from 3.8% to 59% (7, 8, 20), and from 9% to 32% (13, 15, 16), respectively.

It seems obvious that the size of tumor will critically influence the short- and long-term results of any ablative technique (6). As a tumor incompletely ablated in the initial procedure is likely to recur, it is important to know the optimal tumor size for complete ablation. As we compared the data for RFA and microwave ablation in the literature, we found that the optimal nodule size for complete ablation by percutaneous cryotherapy was smaller. Most investigators (6, 29) report a nodule size limit of about 3 cm for RFA and microwave in patients with lung cancer (9, 29, 30). In an animal model of cancer in pulmonary parenchyma, microwave ablation was achieved for nodules of a mean diameter that was 25% larger than that is for RFA (3.32 ±

Fig. 2. A 77-year-old female with NSCLC in left lower lung showing unsuccessfully treated ablation after percutaneous cryotherapy. A. Axial scan from mediastinal setting shows a 17-mm mass (white arrow) in the left lower lung.
B. Percutaneous cryotherapy was performed with patient in prone position.
C, D. Immediate follow-up CT with mediastinal setting (C) shows non-enhanced ice ball (white arrow) with peripheral rim enhancement (black arrow). Lung setting (D) shows peripheral ground glass opacity (arrow).
E, F. Three months later, ablated lesion in left lower lung had decreased markedly but (F) the ablated lesion re-grews at the 12-month follow-up. Note.—NSCLC = non-small cell lung cancer

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of report should have many more patients with near complete strength and validity of the conclusions. We know that this type we started with a small cohort of patients compromises the value of an already very small study population. The fact that patients with metastases to lung in such a small study limited the small sample size. Mixing patients with NSCLC and pa
able median survival in patients with unresectable lung cancer. Based on these results, cryoablation may be obtained reason complete ablation group was 45.0 ± 12.1 months, while that of study, the survival time after percutaneous cryotherapy for the nodule survival rates following RFA in unresectable primary lung cancer was 59.4%, and the cancer-specific survival rate was 82.6%. However, the survival rate after percutaneous cryotherapy in patients with lung cancer is low and variable. In our study, the survival time after percutaneous cryotherapy for the complete ablation group was 45.0 ± 12.1 months, while that of the incomplete treated ablation group was 25.1 ± 17.7 months. Based on these results, cryoablation may be obtained reasonable median survival in patients with unresectable lung cancer.

Our study presents several limitations, related primarily to the small sample size. Mixing patients with NSCLC and pa
ents with metastases to lung in such a small study limited the value of an already very small study population. The fact that we started with a small cohort of patients compromises the strength and validity of the conclusions. We know that this type of report should have many more patients with near complete follow-up in all. Hence, in the future, a large multicenter trial may be needed to fully evaluate the use of percutaneous cryotherapy in patients with inoperable lung cancer. Second, since we planned our study to determine the maximal size that can be ablated completely for an intermediate term of follow-up, we set the nodule size limit at 2.5 cm or less. Thus, we were not able to evaluate the use of percutaneous cryotherapy for tumors larger than 2.5 cm. The use of a single cryoprobe in all cases, even for nodules up to 25 mm in size might be problematic, especially since we used the “ice seed” which creates the smallest ice ball of all the available Galil ice probe applicators. We recommend Ice Sphere or Ice Rod applicators if an operator want to obtain optimal margins on the larger nodules. Furthermore, if more probes are used to treat the lesion, tumors larger than 2.5 cm could be ablated using percutaneous cryotherapy in the future.

In conclusion, percutaneous cryotherapy may be a safe, effective therapeutic method for inoperable patients with malignant pulmonary nodules. Although the results of percutaneous cryotherapy in our study were not satisfied compared with others thermal ablation techniques, percutaneous cryotherapy could be performed safely in patients with inoperable patient with lung malignancy and may extend their survival period. Further study is needed to justify optimizing conditions for this treatment, such as probe selection and number of probes.

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수술이 불가능한 폐암의 냉각 소작술

박은혜1 · 진공용1 · 한영민1 · 이용철2 · 권근상3

목적: 수술이 불가능한 환자에서 악성 폐결절에 대한 냉각 소작술 후 치료 효과에 대해 알아보고자 하였다.

대상과 방법: 본 연구는 2006년 8월에서 2009년 7월까지 수술이 불가능한 폐암으로 냉각 소작술을 받았던 14명의 환자들(남자 7명, 여자 7명, 평균나이 68.8세) 대상으로 하였다. 전산화단층촬영을 이용한 추적검사로 치료 효과가 완전 소작인지 불완전 소작인지 알아보았다. 또한, 냉각 소작술을 받은 환자의 생존기간은 Kaplan-Meier method를 통해 평가하였다. 냉각 소작술 후 합병증에 대해 알아보았다.

결과: 14명 중 5명(35.7%)이 완전 소작 그리고 9명(64.3%)이 불완전 소작이 되었다. 치료 전후 최종 CT 추적검사에서의 완전 소작 군의 결절의 평균 크기는 13.2 ± 7.6 mm에서 3.8 ± 2.7 mm로 감소하였고, 불완전 소작 군은 18.1 ± 6.2 mm에서 33.7 ± 17.9 mm로 증가하였다. 평균 생존기간은 완전 소작 군은 51.5개월, 불완전 소작 군은 24개월이었다. 냉각 소작술 후 1명에서 기흉이 생겼으나 자연 치유되었고, 2명에서 객혈이 생겼으나 1일 내에 치료되었다.

결론: 수술이 불가능한 환자에서 악성 폐결절에 대한 냉각 소작은 안전하고, 효과적인 치료방법이다.

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