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대한영상의학회지

Analysis of Factors Affecting Local Tumor Progression of Colorectal Cancer Liver Metastasis after Radiofrequency Ablation
대장암 간전이의 고주파열치료 후 국소재발에 대한 분석

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Purpose: The purpose of this study was to evaluate the independent predictive factors for local tumor progression (LTP) of colorectal liver metastasis (CRLM) after radiofrequency ablation (RFA).

Materials and Methods: Patients with CRLM were included in the analysis if nodules were up to five in number, each nodule was ≤ 5 cm, and RFA was performed in our center from January 2006 to December 2015. Univariate and multivariate analyses to identify the predictors of LTP were performed by using a Cox proportional hazard model.

Results: Overall, 58 tumors from 38 patients were included in this study. LTP occurred in 14 tumors from 9 patients. The overall 1- and 3-year LTP rates were 23.5% and 29.4%, respectively. Multivariate analysis showed that tumor size > 2 cm and insufficient ablative margin were two independently significant adverse prognostic factors for LTP (p = 0.045 and 0.022, respectively). The 3-year LTP rates for 33 and 25 tumors with and without sufficient ablative margin were 4.5% and 61.2%, respectively. The difference was statistically significant (p < 0.001). The difference in the 3-year LTP rates according to the tumor size was not statistically significant (p = 0.791).

Conclusion: Insufficient ablative margin seems to be the most potent predictor of LTP after RFA of CRLM.

Index terms
Local Neoplasm Recurrence
Neoplasm Metastasis
Radiofrequency Thermal Ablation
Colorectal Neoplasm
Laparoscopy

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INTRODUCTION

Surgical resection is the only curative treatment in patients with colorectal liver metastasis (CRLM) (1-4). Unfortunately, only a minority of patients are amenable to surgery, and radiofrequency ablation (RFA) can be an effective alternative therapy for inoperable patients (1, 3, 5-8). However, compared to surgical resection, local tumor progression (LTP) of CRLM is usually more common after RFA, although excellent local tumor control has occasionally been reported for small metastatic nodules ≤ 3 cm in the literatures (1, 9-13).

The LTP rates for CRLM after RFA can differ according to the approach, and LTP tends to be more common after percutaneous approaches than after intraoperative approaches (1, 11, 14). Owing to the advantages that localization is technically easy even for tumors located in difficult areas and adjacent abdominal organs can be widely separated from the liver (15), acceptably low LTP rates may be expected for small metastatic nodules ≤ 3 cm after intraoperative RFA (16). On the other hand, the ablation size usually differs significantly according to the type of electrode, potentially leading to a difference in the LTP rates.

The purpose of this study was to evaluate the independent predictive factors for LTP of CRLM after RFA.

MATERIALS AND METHODS

Patient Selection

This is a retrospective study of patients in whom RFA was performed for CRLM nodules in our center, from January 2006 to December 2015. The inclusion criteria for this study were as follows: 1) patients who were ineligible for hepatic resection, or who declined surgical treatments, 2) patients who agreed to take RFA, and 3) single or multiple CRLM nodules up to five in number, each nodule ≤ 5 cm. Patients were excluded from the study if prior treatments were performed for metastatic liver nodules, or if prothrombin time ratios (i.e., normal time divided by the patient's time) were less than 40%, or the platelet counts were lower than 40000 per cubic millimeter ($40 \times 10^3/\mu L$).

For patients with CRLM, hepatic resection was considered with priority. If resection was not feasible because of the patient's co-morbidity, extrahepatic tumor involvement, small remnant liver volume expected after resection, poor performance, or patient's own decision, RFA was considered as an alternative treatment modality. With respect to RFA, percutaneous approach was considered first if technically feasible. When effective local tumor control was not feasible because of anatomical reasons or invisibility on ultrasound (US), and when severe comorbidities threatening the life expectancy of patients were not present, laparoscopic or open surgical RFA was considered with priority, and laparoscopic approaches were considered first, if possible.

Informed consent was obtained from all the patients after the nature of the procedures had been fully explained to them. The Institutional Review Board of our hospital approved the data collection and analysis for this study. The diagnosis of CRLM was proved histopathologically or clinicoradiologically. Radiological diagnosis was made based on contrast-enhanced dynamic computed tomography (CT) and/or dynamic magnetic resonance imaging (7). The primary end point was LTP of the metastatic liver nodules from the date of the initial treatment by RFA.

Technique and Equipment for Radiofrequency Ablation

Intraoperative RFA was performed under general anesthesia via a laparoscopic or open surgical approach. Percutaneous RFA was performed on inpatients under conscious sedation using a combination of intravenous fentanyl citrate (Fentanyl citrate®; Myoungmoon, Hwaseong, Korea) and midazolam (Midazolam; Bukwang, Ansan, Korea) (17). We selected the RFA device for each procedure depending on the size and location of the tumor. Multitined expandable electrodes, or internally cooled single or multiple electrodes (clustered or separable) were used as appropriate, according to the tumor size and location. All sonographic procedures were performed with a 3.5-MHz convex-array transducer (Sequoia; Siemens, Germany, or IU22, Philips, the Netherlands) by using a free-hand technique. Percutaneous RFA was performed under real-time sonographic guidance by an experienced radiologist with nine years of experience in US-guided ablation procedures at the start of this study.

The ablation procedure was terminated when the size of the ablation zone on US monitoring was large enough to measure at least 5 mm (18). Vital signs were monitored during the entire procedure.

Evaluation of Therapeutic Efficacy and Complications

CT examinations were performed with 8-slice, 16-slice, or 64-slice multidetector CT scanners. The number of tumors was determined on pretreatment CT imaging. The tumor size was determined as the maximal diameter of the nodule measured on the pre-ablation CT taken within one month from the ablation procedure. Retroperitoneal or axillary lymph node metastasis was diagnosed on pretreatment CT imaging as the cut-off value of 6 mm shortest diameter, assisted by the positive finding on the positron emission tomography CT scan (19, 20).

Ablative margin was estimated with visual inspections by two abdominal imaging radiologists on the axial and coronal scans of an immediate postprocedure or one-month follow-up CT.

An unablated residual tumor was judged to be present when an enhanced portion was seen within or around the original mass on the CT scan at the one-month follow-up. If no definite evidence of an unablated residual tumor was noted on the one-month follow-up CT, a 3-phase or 4-phase contrast-enhanced CT was performed at a three-month interval thereafter. LTP was judged to be present when there was appearance of tumor foci at the edge of the ablation zone, after at least one contrast-enhanced follow-up study had documented adequate ablation and absence of viable tissue in the target tumor and surrounding ablation margin on the follow-up CT scans (21). For these tumors, additional RFA or surgical resection was performed as appropriate.

Major complications were defined as those that might threaten the patient's life, lead to substantial morbidity and disability, or result in a lengthened hospital stay. All other complications were considered minor (21). Treatment mortality was defined as death within 30 days of RFA. Two abdominal radiologists with 18 and 8 years of experience, respectively, in liver imaging interpreted the CT images independently, without knowing whether the tumor showed local tumor recurrence on the follow-up CT images. Final decisions were reached by consensus.

Statistical Analysis

Patients lost to follow-up were censored at the date of the last observation. Survival periods were calculated from the time of RFA for CRLM. Various pretreatment variables at the time of the initial treatments were recorded, including patient age, sex, size of the tumor nodule (> 2 cm), number of tumors, serum carcinoembryonic antigen level, the presence of one or more severe comorbidities, lung or lymph node metastasis, and adjuvant systemic chemotherapy. With respect to the comparison of LTP rates according to the type of RF electrode, only the two most commonly used types of RF electrodes were included in the analysis, and the other less commonly used types were grouped as 'others'.

LTP rates were estimated by using the Kaplan-Meier method. For the 14 potential prognostic factors for LTP, univariate and multivariate analyses were performed using the Cox proportional hazard model. Parameters that proved to be significant or marginally significant in the univariate analysis (p-value < 0.1) were subsequently tested with the multivariate Cox proportional hazard model. Clinically relevant factors were also tested regardless of their statistical significance on the univariate analysis. p-values less than 0.05 were considered statistically significant in the multivariate analysis. The SPSS software package (version 10.0; SPSS Inc., Chicago, IL, USA) was used for the statistical analysis.

RESULTS

Patient Characteristics

From January 2006 to December 2015, RFA was performed in our center for 50 consecutive patients with 70 CRLM nodules. Among them, 38 patients with 58 tumors satisfied the inclusion criteria of this study. Among them, one patient was diagnosed histopathologically, and the other patients were diagnosed clinicoradiologically. All patients, except three, were male. Their ages ranged from 52 to 89 years [mean ± standard deviation (SD): 68.9–9.6 years]. The median follow-up period was 24 months (range: 4–61 months).

Tumor size ranged from 0.5 to 3.7 cm (mean ± SD: 1.8–0.9 cm), while the median tumor size was 1.8 cm. Other baseline tumor characteristics per nodule are described in Table 1.

Local Tumor Progression Rates and the Predictive Factors

During follow-up, LTP occurred in 14 tumors from nine patients (Figs. 1, 2). Univariate analysis showed that minimal ablative margin of less than 5 mm was the only significant adverse prognostic factor for LTP (p = 0.003). Also, use of the internally cooled clustered electrode was not statistically significant (p = 0.091) (Table 2). Multivariate analysis showed that tumor size > 2 cm and insufficient ablative margin were two independently significant adverse prognostic factors for LTP (p = 0.045 and 0.022,

Table 1. A Comparison of the Baseline Characteristics Per Nodule

	n	%
Age (years) (< 75/≥ 75)	36/22	62.1/37.9
Gender (male/female)	53/5	91.4/8.6
Dominant liver tumor size (≤ 2 cm/> 2 cm)	47/11	81/19
No. of liver tumor (single/multiple)	28/30	48.3/51.7
Adjacent to large intrahepatic vessels > 3 mm (yes/no)	12/46	20.7/79.3
Presence of a liver dome nodule (yes/no)	11/47	19/81
Presence of a subcapsular tumor (yes/no)	34/24	58.6/41.4
Adjuvant chemotherapy (yes/no)	28/30	48.3/51.7
Synchronous lung metastasis (yes/no)	10/48	17.2/82.8
Synchronous lymph node invasion (yes no)	2/56	3.4/96.6
Serum level of CEA (≤10/>10 ng/mL)	32/26	55.2/44.8
Other malignancies (yes/no)	2/56	3.5/96.5
RF electrode type		
Internally cooled single	18	31
Internally cooled clustered	20	34.5
Multiple seperable	12	20.7
Expandable	6	10.3
Internally cooled wet	2	3.4
Ablative margin (≥ 0.5 cm/< 0.5 cm)	26/32	44.8/55.2
Primary TNM staging of colorectal cancer		
I	1	1.7
IIA	6	10.3
IIIA	2	3.4
IIIB	20	34.5
IVA	29	50

CEA = carcinoembryonic antigen, RF = radiofrequency

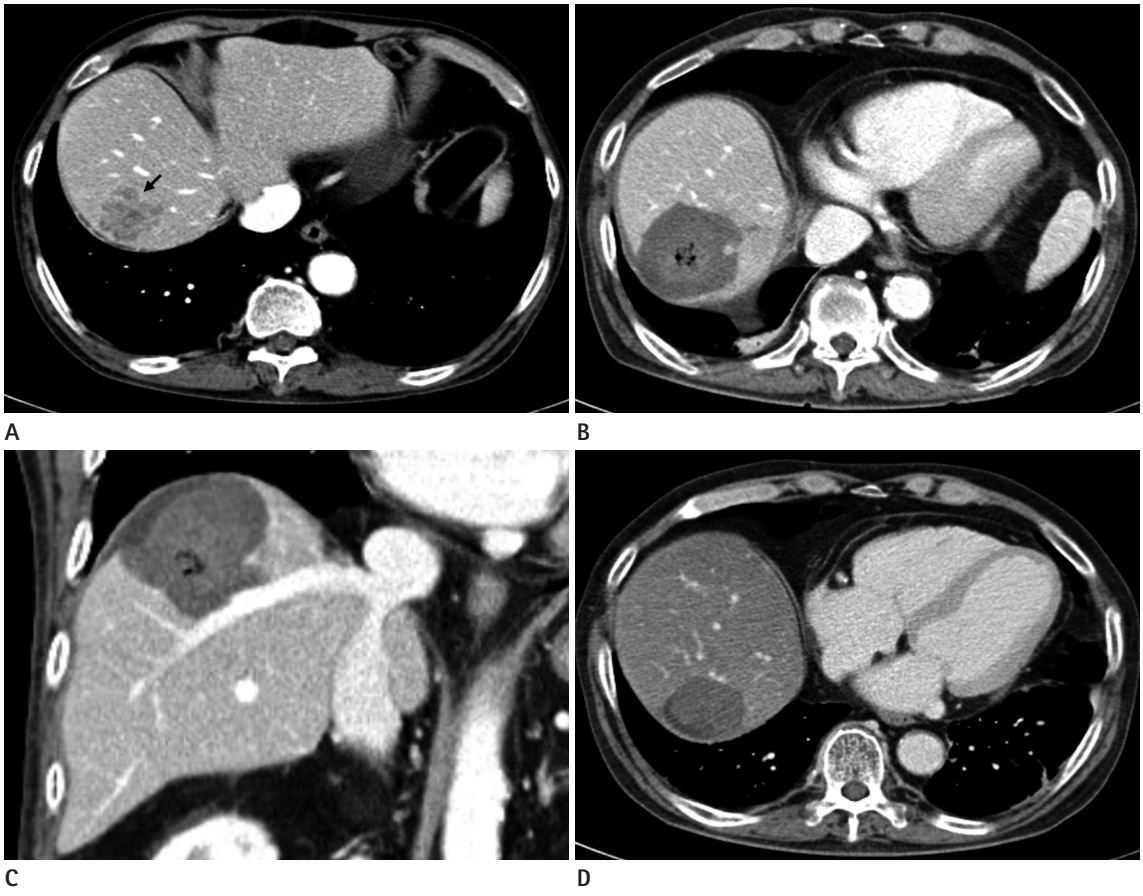

Fig. 1. A 68-year-old male patient with rectosigmoid colon cancer.
A. A 3.6 cm sized hypodense nodule with peripheral rim enhancement (black arrow) is newly detected in the right lobe of the liver on initial abdomen CT, suggesting liver metastasis.
B, C. Eight days after intraoperative RFA using multiple separable electrodes, follow-up axial **(B)** and coronal **(C)** CT show a 5.8 cm hypodense ablation zone with a sufficient ablative margin surrounding the ablation index tumor.
D. Nine months after intraoperative RFA, the ablation zone is markedly decreased in size without evidence of local recurrence.
RFA = radiofrequency ablation

Fig. 2. A 77-year-old male patient with rectal cancer.
A. A 1.9 cm sized, hypodense nodule with peripheral rim enhancement (black arrow) is newly detected in the left lobe of the liver on follow-up abdomen CT, suggesting liver metastasis.
B. Percutaneous RFA was conducted using an internally cooled single electrode. White arrow indicates the ablation index tumor.
C. A CT image taken five months after RFA shows that the previous ablation zone is markedly increased in extent, and multiple liver metastases are newly developed in the other sites.
RFA = radiofrequency ablation

respectively). Also, the percutaneous approach was not statistically significant (p = 0.455) (Table 3).

The overall 1-, 2-, and 3-year LTP rates were 23.5%, 29.4%, and 29.4%, respectively. The 1-, 2-, and 3-year LTP rates of tumors with sufficient ablative margin were 4.5%, 4.5%, and 4.5%, while the LTP rates of tumors with insufficient ablative margin were 39.0%, 61.2%, and 61.2%, respectively. The difference was statistically significant (p <0.001). For tumors less than or equal to 2 cm, the 1-, 2-, and 3-year LTP rates were 24.3%, 28.1%, and 28.1%, respectively. For tumors greater than 2 cm, the 1-, 2-, and 3-year LTP rates were 18.4%, 32.0%, and 32.0%, respectively. The 2- and 3-year LTP rates for tumors greater than 2 cm were slightly higher than those for smaller tumors, but the difference was not statistically significant (p = 0.791).

Among the tumors treated with percutaneous (n = 38) and intraoperative (n = 20) RFA, a sufficient ablative margin was secured in 14 (36.8%) and 19 (95.0%) tumors, respectively. The mean diameters of tumors treated with intraoperative or percutaneous RFA were similar, 1.8 ± 1.2 cm vs. 1.6 ± 0.6 cm (p = 0.249). For percutaneous RFA, the 1-, 2-, and 3-year LTP rates were 33.1%, 37.9%, and 37.9%, respectively. In contrast, the 1-, 2-, and 3-year LTP rates for intraoperative RFA were 6.7%, 14.4%, and 14.4%, respectively. The difference according to the approach was statistically significant (p = 0.033) (Fig. 3).

Table 2. Univariate Analysis of Prognostic Factors for the Local Tumor Progression of Colorectal Liver Metastasis after RF Ablation Per Nodule

	Hazard Ratio	Standard Error	*p*-Value
Age ≥ 70 years old	0.584 (0.161–2.111)	0.656	0.412
Male gender	24.111 (0.013–43445.559)	3.825	0.405
Tumor size > 2 cm	1.169 (0.364–3.756)	0.596	0.793
Multiple tumors	1.785 (0.613–5.202)	0.546	0.288
Adjacent to large intrahepatic vessels > 3 mm in the diameter	0.399 (0.052–3.077)	1.042	0.378
Presence of a dome nodule	0.572 (0.128–2.559)	0.764	0.465
Presence of a subcapsular tumor	0.607 (0.212–1.740)	0.537	0.353
Adjuvant chemotherapy	0.942 (0.321–2.769)	0.550	0.914
Synchronous lung metastasis	1.474 (0.461–4.710)	0.593	0.513
Synchronous lymph node invasion	0.048 (0.000–149409.647)	7.632	0.690
Serum level of CEA >10 ng/mL	2.693 (0.901–8.052)	0.559	0.076
Presence of other malignancies	2.319 (0.301–17.880)	1.042	0.420
Intraoperative approach	0.228 (0.051–1.023)	0.765	0.054
RF electrode type			0.235
Internally cooled single	1 (reference group)	-	-
Internally cooled clustered	0.261 (0.055-1.240)	0.795	0.091
Others	0.678 (0.202-2.274)	0.618	0.529
Ablative margin ≥ 0.5 cm	0.102 (0.023-0.458)	0.767	0.003*

*Statistically significant.
CEA = carcinoembryonic antigen, RF = radiofrequency

Table 3. Multivariate Analysis of Prognostic Factors for the Local Tumor Progression of Colorectal Liver Metastasis after RF Ablation Per Nodule

	Hazard Ratio	Standard Error	*p*-Value
Tumor size > 2 cm	10.363 (1.405–76.44)	1.020	0.022*
Serum level of CEA >10 ng/mL	2.260 (0.681–7.502)	0.612	0.183
Intraoperative approach	0.435 (0.049–3.864)	1.114	0.455
RF electrode type			0.304
Internally cooled single	1 (reference group)	-	-
Internally cooled clustered	0.129 (0.012–1.404)	1.217	0.093
Others	0.592 (0.160–2.191)	0.667	0.433
Ablative margin ≥ 0.5 cm	0.105 (0.011–0.955)	1.128	0.045*

*Statistically significant.
CEA = carcinoembryonic antigen, RF = radiofrequency

Complications

In none of the patients, the ablation procedure was stopped because of severe pain. Twenty-one patients died during follow-up. Side effects after the ablation procedures included mild abdominal pain and intermittent fever in eight patients and one patient, respectively, but no major complication occurred.

DISCUSSION

In this study, we attempted to clarify the prognostic factors for LTP of CRLM after RFA. The finding that tumor size > 2 cm was statistically significant was largely in accordance with the results from a previous study which showed that tumor size of less than 3 cm and ablative margins greater than 5 mm were essential for effective local tumor control (18). More importantly, this study suggests that a 5 mm ablative margin may suffice for RFA of CRLM, in particular for tumors 2 cm or smaller. Further large scale studies are necessary to evaluate the minimal required ablative margins according to the tumor diameter of CRLM.

In general, the reported LTP rates after open surgical RFA for small nodules ≤ 3 cm were known to be lower than the LTP rates after percutaneous or laparoscopic RFA, which are usually less than 10% (13, 22). This can be explained by the more versatile directions and clear visualization of tumor margin in operative RFA (13). These LTP rates for small CRLM less than 3 cm after open surgical RFA were reported to be similar to those obtained by more invasive treatment such as conventional liver surgery (13). There is still ongoing controversy on whether open surgical RFA may replace surgical resection for these small CRLM nodules (15).

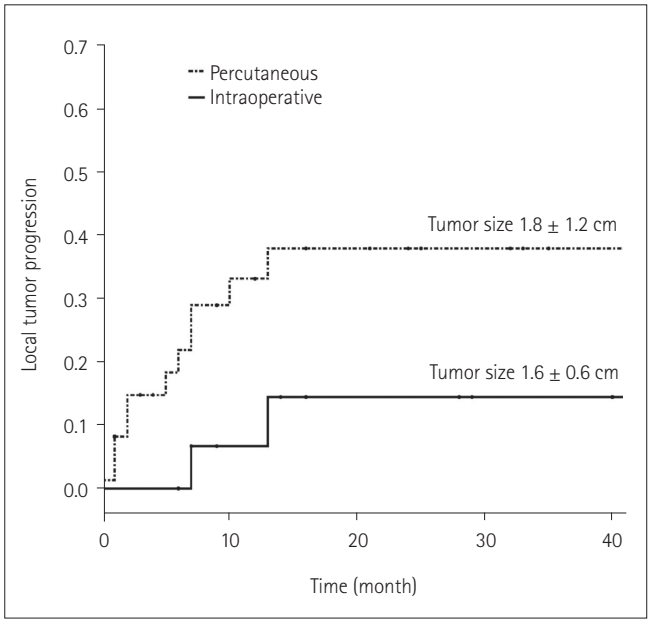

Fig. 3. A comparison of the LTP rates for colorectal liver metastasis between the patients, confined to the subgroup, undergoing percutaneous and intraoperative RFA. The 3-year LTP rates after RFA using the intraoperative or percutaneous approach are significantly different; 14.4% vs. 37.9%, with statistical significance (p = 0.033). LTP = local tumor progression, RFA = radiofrequency ablation

In this study, we could not compare the LTP rates between the open surgical and laparoscopic approaches because of the small number of patients. The 3-year LTP rate for 20 tumors treated with an intraoperative approach was 14.4%, which was comparable to the results reported in the literature. Notably, this reasonably low LTP rate may be explained by the fact that a sufficient ablative margin was obtained in most tumors treated with intraoperative RFA, including both open surgical and laparoscopic approaches (15). In this study, the 3-year LTP rate for tumors with sufficient ablative margin was only 4.5%.

The limitations of this study are as follows: first, this was a retrospective analysis, and it may be difficult to derive a strong conclusion. However, the independently significant adverse prognostic factors for LTP largely coincided with those reported in the literature (22). Second, not all tumors were diagnosed histopathologically. Third, all ablation procedures were performed by a single interventional radiologist in a medical center, and this may limit the generalization of the results of this study. Finally, evaluation of the ablative margin based on visual inspection may be less accurate than that performed by using a dedicated 3D software (23).

In conclusion, favorable outcomes in local tumor control can be expected after RFA of CRLM when the tumor size is less than or equal to 2 cm and a sufficient ablative margin is secured. Although the operative approach has a tendency to show a lower LTP rate than the percutaneous approach, the result did not reach statistical significance. Further large-scale prospective controlled studies are required.

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대장암 간전이의 고주파열치료 후 국소재발에 대한 분석

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목적: 대장암 간전이의 고주파 열치료 후 국소재발에 영향을 주는 요인을 알아보았다.

대상과 방법: 2006년 1월에서 2015년 12월까지 각 각 5 cm 이하, 다섯 개 이하의 대장암 간전이에 대해 본원에서 고주파 열치료를 시행한 환자군을 대상으로 콕스비례위험 모형을 사용하여 일변량분석과 다변량분석을 통해 국소재발과 연관된 인자를 알아보았다.

결과: 총 38명의 환자에서 58개의 종양이 분석에 포함되었고, 그 중 9명의 환자에서 14개의 종양이 재발하였다. 전체 1년과 3년 국소재발률은 23.5%와 29.4%였다. 다변량분석 시행 결과, 종양 크기가 2 cm 초과한 경우와 최소한의 안전역이 5 mm 미만인 경우가 나쁜 예후 인자로 통계학적으로 의미가 있었다(p = 0.045 및 0.022). 충분한 안전역을 가지고 치료했던 33개의 종양의 3년 국소 재발률은 4.5%였던 반면, 충분하지 않은 안전역을 가지고 치료했던 25개의 종양의 3년 국소 재발률은 61.2%였고, 두 군 간의 차이는 통계적으로 유의하였다(p<0.001). 종양 크기에 따른 국소 재발률은 통계학적으로 유의하지 않았다(p = 0.791).

결론: 본 연구에서는 5 mm 미만의 불충분한 안전역이 대장암 간전이의 고주파 열치료 후 국소재발을 높이는 가장 강력한 인자였다.

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