参考資料3

平成２０年４月９日

厚生労働省医政局研究開発振興課長　殿

岡山大学大学院医歯薬学総合研究科
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胸部悪性腫瘍のラジオ波焼灼療法に係る健康危険情報への対応について

平成２０年４月９日に厚生労働省健康機器管理調整官あて通報を行った標記情報について、対応状況を以下のとおり報告します。

１．危険情報の入手日及び入手方法
平成２０年３月１３日
FDA のホームページより

２．健康危険情報の内容
平成１９年１２月１１日に FDA より、肺腫瘍に対するラジオ波焼灼療法における死亡例が報告されたことから、米国内において当該療法を行う場合には承認された臨床試験に登録することを推奨する旨が推奨された。

３．健康危険情報入手後の対応
①院内における情報伝達等対応状況について
平成２０年３月に院内における臨床研究に関する倫理審査委員会において、肺腫瘍に対するラジオ波焼灼療法についての臨床研究開始前の審議を行ったところであり、FDA において上記のような注意喚起がなされている旨を説明文書に記載し、被験者から同意を取得する際には十分説明を行うことで、当該臨床研究を実施することが承認された。（承認証を添付）

②協力医療機関への情報伝達等対応状況について

本研究の協力医療機関については２７施設あり、平成２０年３月１３日に全ての医療機関に対して情報提供を行っており、各医療機関においても臨床試験実施前の倫理審査委員会で当該情報も含めた形で審議することとしている。なお、各医療機関における倫理審査委員会については、平成２０年５月３０日までに審議が実施される予定である。

（２７施設の名称については別添（エクセルファイル）のとおり。）

４．その他

①当該情報と同様の事例の発生状況について（協力医療機関を含む）

現在までに、当院及び協力医療機関において事例はない。

参考資料3

審 査 結 果 通 知 書

平成２０年３月２４日

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受付番号　531

課 題 名　肺悪性腫瘍に対する経皮的ラジオ波凝固療法についての第Ⅱ相臨床試験

研究者名　大学院医歯薬学総合研究科　教授　金 澤　右

貴殿から申請のありました上記課題に係る実施計画について，平成２０年３月２４日開催の委員会において審査し，下記のとおり結論を得ましたので，通知します。

記

判定	条件付承認 指摘のあった事項を修正し，確認を受けること

FDA Public Health Notification: Deaths reported following Radio Frequency Ablation of Lung Tumors

Issued : December 11, 2007

Dear Healthcare Practitioner:

This is to alert you to reports of deaths associated with the use of radio frequency (RF) ablation devices during lung tumor ablation.

Public health concerns

FDA has received reports of patient deaths associated with lung tumor ablation using RF ablation devices, and similar reports have appeared in the literature.1,2,3,4 Patient selection, subsequent treatment, and technical use of the RF device, including placement and operation, may have contributed to the fatalities.

Regulatory status of the devices

FDA has cleared many RF ablation devices as tools for **general** ablation of soft tissue by thermal coagulation necrosis. These devices have also been cleared for certain specific indications, including partial or complete ablation of non-resectable liver lesions and palliation of pain associated with metastatic lesions involving bone. It is important to note that they have **not** been cleared specifically for lung tumor ablation. Manufacturers of ablation devices cannot legally market them for use in lung tumor ablation because clinical data establishing their safety and effectiveness for this purpose have not been submitted to the agency. This includes promoting their safety and effectiveness in training programs.

Recommendations

- Use special caution when operating RF ablation devices, adhering strictly to information contained in the labeled operating instructions, Operators Manual, the Manufacturer's Instructions for Use and any training provided.
- If you wish to use an RF ablation device to treat patients with lung tumors, you should consider enrolling them in an approved clinical study, where training is available. Clinical trial information can be found at www.clinicaltrials.gov. Enter the search terms "ablation lung tumor."

Reporting to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of an RF ablation device, you should follow the reporting procedure

established by your facility.

Reporting adverse events is everyone's responsibility, even if the procedure involves off-label usage of medical devices.

To report your experience regarding the devices in this Notification, please use MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at http://www.fda.gov/medwatch/report.htm.

Getting More Information

For the most recent information on adverse events due to lung tumor ablation please check the MAUDE database

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm?searchoptions=1

Enter the Event Type – Death and Product Code – GEI for all reported deaths caused by electrosurgical, cutting and coagulation devices and accessories for various indications. To determine which of these adverse events may be related to lung tumor ablation, please read the detailed adverse event description.

The level of evidence required to obtain FDA clearance for general claims as compared to a specific claim related to general and specific indications of use of a device can be found in FDA's published industry guidance: Guidance for Industry: General/Specific Intended Use – November 4, 1998 (http://www.fda.gov/cdrh/modact/genspec.pdf)

The FDA cleared indications for use of a particular RF ablation device can be found in the FDA 510(k) database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. The Product Code for these devices, GEI, includes electrosurgical, cutting and coagulation devices and accessories for various indications. Each cleared device will be associated with a specific 510(k) number, as will the indication for use that FDA has cleared for each cleared device. The database is updated as new products are cleared. FDA requires medical device manufacturers to provide sufficient data to demonstrate that the device is safe and effective for each stated indication. FDA will clear each device for the stated indication once they have reviewed this data and the appropriate training programs for these indications are available from the manufacturer.

In February 2003, FDA's General and Plastic Surgery Devices Advisory Committee's met and discussed the subject of thermal ablation of lung tumors. Concerns were raised about the safety and adverse event reporting associated with RF Ablation of lung tumors. To read a transcript of the FDA Panel's deliberations, please refer to FDA Panel meeting Emphysema and Ablation devices Clinical Issues Discussion Session, February 28, 2003. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=385

If you have questions about this notification, please contact Ann Ferriter, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by Fax at 240-276-3356, or by e-mail at phann@cdrh.fda.gov. You may also leave a voicemail message at 240-276-3357 and we will return your call as soon as possible.

FDA medical device Public Health Notifications are available on the Internet at http://www.fda.gov/cdrh/safety.html. You can also be notified through email on the day the

safety notification is released by subscribing to our list server. To subscribe, visit: http://service.govdelivery.com/service/subscribe.html?code=USFDACDRH_10.

Sincerely yours,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm, MDR numbers 1717344-2007-00212, 1717344-2007-00213, 17344-2007-00214, 1717344-2007-00215, and 1717344-2007-00216

[2] Simon C, Dupuy D. Pulmonary Radiofrequency Ablation: Long Term Safety and Efficacy in 153 Patients. Radiology. 2007; 243: 268-275

[3] Lee J, Jin G, Goldberg N, et al. Percutaneous Radiofrequency Ablation for Inoperable Non-Small Cell Lung Cancer and Metastases: Preliminary Report. Radiology. 2004; 230: 125-134.

[4] Steinke K, Sewell P, Dupuy D, Morris D. Pulmonary Radiofrequency Ablation-an international study. Anticancer Res. 2004; 24(1): 339-343.

Updated December 11, 2007
