

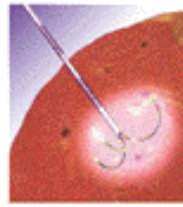
# The Tumor Registry

## General Concepts

The tumor registry treats patients and their ablated lesions somewhat separately. Some conclusions are drawn "per patient" e.g. hospitalization time whereas other parameters are related to every single lesion. To clarify the distinction between patient and lesion all sheets and webpages have either a patient or lesion logo.



patient



lesion

We collect information on the number of tumors per patient, the histology, the pre-ablation size of the lesion, the location (using segmental anatomy of the liver), the number of cycles required to ablate the lesion and whether or not the target temperature was maintained for at least 8 minutes. It may be helpful to have the "Patient Demographics" and "Individual Lesion" data sheets with you in the OR with to facilitate data collection.

The sheets may be useful in your own on-site record keeping. Once your center has a series of patients in the database you may also obtain summary information on your cases on our web site. All patient information will be kept in the strictest confidence, and the database link to the web site will be secured to allow access to summary information only to physicians participating in the data collection.

## Study Schedule

The proposed time points for CT scans and laboratory studies are 1 week preceding surgery, 1 week postoperatively and every 3 month after RF ablation. On post op day 1 the "routine patient" at our institution gets a blood draw but not a CT scan.

Therefore we created sheets to be used at the operation, for immediate postoperative data collection and for long-term follow up. Because operation and postoperative investigation is only one week apart, you might send both sheets together after the postoperative investigation is done. The quarterly long-term follow up sheets are identical, so please don't forget to indicate the month of follow up. If follow up data are overdue longer than a month, we might send a reminder preferably by e-mail.

## **Questionnaire design**

All sheets are designed to be as intuitive, understandable and easy to fill out as possible. We have tried to reduce the questions to a minimum and therefore **all fields are mandatory information and should be filled out!**

A more extensive study that will include data about liver function and hematologic parameters and a quality of life questionnaire is planned for the near future. Your input is welcome in designing the extended study.

## **Definition of terms used in the registry**

Most of the fields are self explanatory, however as with everything it is important to insure that we are speaking the same "language". The following glossary of terms may help.

***successful ablation:*** the apparent size of the lesion as measured in the CT (MRI) scans is larger on the first postoperative (1 week) scan indicating that the ablative process encompassed the entire lesion as well as a rim of surrounding normal liver tissue as a margin. Thereafter the size of the lesion should progressively decrease on each quarterly scan.

***ablation failure or local recurrence:*** a clear indication on the initial CT (MRI) scan that the lesion was not encompassed by the ablation process (no increase in size or clearly perfused areas within the lesion). On the quarterly follow-up scans any increase in size or the appearance of perfused tumor at any of the margins of the lesion indicates a local recurrence.

Ablation failures are subdivided into

***definite recurrence:*** there is an unequivocal local regrowth of a previously ablated lesion.

***suspect recurrence:*** the patient who develops multifocal disease within the liver and any of the new foci are adjacent to a zone of ablation

## **How patients with repeated RF Ablations are handled**

Many patients have recurrence or the appearance of new disease that is amenable to repeat treatment. If a patient is retreated it should be handled the same as a new patient. This means that you will generate a new operative data sheet and new immediate postoperative and quarterly follow up sheets using the new treatment date as the reference date. If there is a clear distinction of the new lesions treated and the old you may continue to enter data for both ablations. However if the distinction is unclear you should follow the new lesions and close out the data from the original ablation by referring it to the new date.

## **Fax and mailing address**

The Liver Tumor Ablation Program has its own fax number at (216) 445-7653.

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