CLINICAL GUIDELINE

CT-guided liver beacon transponder implantation

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Abstract
Objective: To investigate the method of CT-guided beacon transponder implantation and precautions after implantation for liver malignant tumor.
Methods: CT-guided beacon transponder implantation in three patients with liver malignancies was the first time in China. The operations were performed using Siemens’s 16-row large-aperture spiral CT and 17-G guide needles were using for percutaneous liver puncture.
Results: All three operations were successfully completed. During the operations, the beacon transponders were successfully implanted at predetermined targets next to the lesion in the liver parenchyma, and there was no obvious bleeding, pain or discomfort. All patients underwent localized CT examination on the fifth day after operations. Only one beacon transponder moved slightly, the remaining eight beacon transponders did not move, and the CT images did not have obvious metal artifacts. After the completion of radiotherapy in three patients, the follow-up CT examination showed no movement of the beacon transponders, and the liver lesions shrank well. However, 3.0 T MRI of the liver showed that the magnetic sensitive artifacts at beacon transponders were more obvious, which affected the observation of local liver tissue.
Conclusion: CT-guided liver beacon transponder implantation is safe and feasible. Beacon transponders may move in the liver parenchyma within a short period of time after implantation. Therefore, localized CT examination is recommended to be performed 4 days after the implantation. CT scans after beacon transponder implantation have no obvious metal artifacts. So CT is recommended for follow-up. However, magnetic resonance sensitive artifacts are more obvious when MRI is performed, which will affect the evaluation of local efficacy and detect new small lesions.

KEYWORDS
beacon transponder, CT-guided, implantation, liver malignant tumor

1 | INTRODUCTION

Liver malignant tumor is one of the most common malignant tumors worldwide, with an incidence rate of seventh and a mortality rate of third. Liver malignant tumor ranks fourth among common malignancies with the second highest mortality rate in China, and the number of morbidity and death accounts for more than half of the world. Therefore, the prevention and treatment of liver malignant tumor is particularly important. In the era of two-dimensional radiotherapy, the treatment of liver malignant tumor depends on
surgery and interventional treatment. The traditional view is that although liver malignant tumor cells are moderately sensitive to radiotherapy, normal liver cells are less tolerant to radiation, and radical dose of radiotherapy has a fatal blow to normal liver cells, so radiotherapy in the era of two-dimensional radiotherapy is rarely used for the treatment of liver malignancies. In recent years, with the rapid development of radiotherapy equipment and technology, stereotactic body radiation therapy (SBRT) characterized by large doses and few times has gradually been applied to the treatment of liver malignancies. As the liver changes position with breathing, how to irradiate the target lesion more accurately during radiotherapy has always been the focus and difficulty in the radiotherapy of liver malignancies in the era of precision radiotherapy.

Beacon transponder designed and developed by American Varian Corporation is a small electromagnetic marker. Before the radiotherapy, the beacon transponders are permanently implanted near the treatment target, which can provide accurate and reliable target positioning and continuous real-time target tracking for radiotherapy. From April 2019 to March 2020, the Department of Radiotherapy of Jiangsu Cancer Hospital took the lead in successfully conducting liver beacon transponder implantation in China. During the operation, three beacon transponders were percutaneously implanted into a preset target position next to the liver malignant tumor under the guidance of CT without significant complications. And during the radiotherapy, beacon transponders were used to accurately track the movement trajectory of liver malignant tumors, thereby achieving more accurate stereotactic radiotherapy.

2 | OBJECTS AND METHODS

2.1 | Objects

Liver malignant tumor was clearly diagnosed in three patients, and the tumor has recently progressed.

Example 1. Male, 44 years old, admitted to hospital for “7 years after interventional treatment for liver malignant tumor.” Auxiliary examination: MRI of the upper abdomen revealed a recurrence of the right posterior lobe lesion after interventional treatment.

Example 2. Female, 51 years old, admitted to hospital for “more than 3 months after concurrent chemoradiotherapy after sigmoid cancer surgery.” Auxiliary examination: MRI of the upper abdomen showed that the metastasis of the right anterior lobe of the liver was larger than before.

Example 3. Male, 83 years old, admitted to hospital for “more than 1 months after chemotherapy after right hemicolon cancer surgery.” Auxiliary examination: MRI of the upper abdomen showed that the metastases of the right liver were as large as before.

2.2 | Indications for liver beacon transponder implantation

① KPS ≥ 70; ② Clear diagnosis of liver malignancies; ③ Indications for SBRT; ④ No obvious liver puncture contraindications; ⑤ No

FIGURE 1 Beacon transponder and beacon transponder implantation
**FIGURE 2** Three beacon transponders are distributed in a triangle beside the liver tumor. A, Patient 1. B, Patient 2. C, Patient 3.

**FIGURE 3** Relevant pictures of patient 1 (A. Location of beacon transponders on CT on the day of operation; B, Beacon transponder position shown by CT 5 days after the operation; C, 3.0 T MRI showed magnetically sensitive artifacts 1 month after operation).
severe comorbidities; ⑥ No obvious abnormalities in coagulation function; ⑦ Evaluation of CT, MRI, and other imaging methods before operation confirmed that there is a feasible puncture path; ⑧ Patients and their families agreed to perform permanent liver Beacon Transponders implantation and signed informed consent.

2.3 | Contraindications for liver beacon transponder implantation

① KPS < 70; ② Coagulation dysfunction; ③ The patient has a mental disorder and cannot cooperate with surgery.

2.4 | Implementation process

2.4.1 | Preparation before operation

① Check the patient’s information and sign the informed consent form.
② The Siemens SOMATOM Definition 16-row large-aperture spiral CT machine was used for positioning. The three patients were scanned with the same scanning method, with a layer thickness and a layer distance of 5 mm. The tube voltage was 120 kV and the tube current was scanned by 350 mA. The soft tissue density algorithm is a window width of 40Hu and a window level of 300Hu. Determine the patient’s implantation site and design the needle insertion path. Use the surface catheter grid positioning method to determine the needle’s entry point. The needle’s entry path needs to avoid the ribs and liver’s large blood vessels and does not pass through liver tumors.
③ According to the location of the liver lesion, three beacon transponder implantation sites were initially set, and the sites should be close to the tumor. Three beacon transponders were arranged in a triangle and were distributed around the tumor as evenly as possible. The distance between each two beacon transponders was 1 to 7.5 cm, and the distance between the beacon transponders and the skin of the front abdominal wall was less than 19 cm.
④ Three beacon transponders were respectively filled into three guide needles in a sterile environment. The guide needles consist of a 17G outer needle and an internally detachable probe. After the

FIGURE 4 Relevant pictures of patient 2 (A, Locations of beacon transponder on CT on the day of operation; B, Beacon transponder position shown by CT 5 days after the operation; C, 3.0 T MRI showed magnetically sensitive artifacts 1 month after operation)
beacon was inserted into the guide pin, a matching clip needed to be installed. This clip was used to fix the probe to the needle base, and the clip must not be removed before releasing the beacon transponder to prevent the beacon transponder from falling off prematurely due to accident. Beacon transponder was placed in a sterile area for use after installation.

2.4.2 Beacon transponder implantation

① Disinfect the skin, lay a sterile surgical towel, and local anesthesia with 2% lidocaine hydrochloride.

② Under CT guidance, a No. 1 guide needle containing Beacon Transponder was inserted into the predesigned liver implantation site, and the needle insertion process was performed in stages.

③ After confirming that the tip of the guide needle was at or near the implantation point, fix the guide needle.

④ Repeat steps “②-③” in “②,” and insert the No. 2 and No. 3 guide needles, and confirm that the needle tips were in place (Figure 1).

⑤ Perform a CT scan to confirm that the three guide needle tips were in place, then remove the clips one by one, and retract the cannula while gently pushing the probe forward to make the beacon transponder in the guide needle fall off.

FIGURE 5 Relevant pictures of patient 3 (A. Locations of beacon transponder on CT on the day of operation; B, Beacon transponder position shown by CT 5 days after the operation; C, 3.0 T MRI showed magnetically sensitive artifacts 1 month after operation)
After the CT scan was performed again to confirm that the beacon transponder fell off at the target implantation point, the guide needles were pulled out one by one and placed in a sharps recycling waste box for disposal. Sterilize the skin injection point and cover with a sterile gauze.

2.4.3 | The work after implantation

1. Vital signs were routinely monitored for 3 hours after operation.
2. A localized CT was performed 4 days after the beacon transponders were implanted to ensure that the implanted beacon did not move.
3. Follow-up SBRT was performed according to the treatment plan.

3 | RESULTS

All patients successfully completed CT-guided liver beacon transponder implantation. Local anesthesia was given to the surface of the liver capsule by 5 ml of 2% lidocaine hydrochloride injection during the operation. The patient did not report pain. No complications such as bleeding and infection occurred.

In all cases, 3 beacon transponders were successfully implanted into the preset site next to the liver tumor during the operation. The operation time was about 30 minutes, of which the operation time was 30 minutes in case 1 and case 3, 35 minutes in case 2. On the fifth day after the beacon transponder implantation, a localized CT examination was performed. It was found that one of the three beacon transponders implanted in Example 1 moved slightly to the head side, about 7 mm from the original implantation point, and the remaining two beacon transponders did not move. None of the six beacon transponders from the patients in case 2 and case 3 moved compared to the day of implantation. Each patient's 3 beacon transponders were arranged in a triangle (Figure 2). There were no obvious metal artifacts in the CT image. Beacon transponders did not affect the observation of location and size of liver tumor, and the sketch of radiotherapy target area. A routine follow-up review 1 month after the end of radiotherapy revealed that the three beacon transponders implanted in the three patients did not move compared to the localized CT, and the CT images were still free of significant metal artifacts. However, the 3.0 T MRI examination of the liver showed that the magnetic sensitive artifacts at the beacon transponders were obvious and could reach about 1.7 cm around the beacon transponders. The liver tissue could not be observed within the scope of the artifacts, which affected the accurate measurement of the size of the original liver lesions. Liver tissue outside the range of artifacts could be displayed normally, and the patients had no obvious discomfort when MRI was performed (Figures 3, 4, and 5).

4 | CONCLUSION

CT-guided liver beacon transponder implantation is safe and feasible with short operation time and less pain for patients. Beacon transponders may have a small range of movement within a short period of time after implantation. Therefore, we recommend that CT be performed after the beacon transponders is fixed 4 days after implantation. CT scans of beacon transponders after implantation show no obvious metal artifacts, but magnetic sensitive artifacts at beacon transponders are obvious when MRI is performed, which will affect the evaluation of local efficacy and the discovery of new small lesions. Therefore, we recommend CT for follow-up and efficacy evaluation.

5 | DISCUSSION

Conventional radical treatments for liver malignancies include surgical resection, radiofrequency ablation, and liver transplantation. However, due to the size, location, number of tumor lesions, individualized differences in patients, and early symptoms are more insidious, most patients have lost the opportunity for surgical resection at the initial diagnosis.6-8 Although liver transplantation is currently considered to be the best treatment option for primary liver cancer, less than one-third of patients have liver transplantation conditions.9,10 Radiofrequency ablation should not be used in patients with lesions adjacent to the bile duct, large blood vessels, or under the liver capsule. And the maximum diameter of the lesion must not exceed 3 cm, the number of lesions per radiofrequency ablation cannot exceed 3.8 Therefore, most advanced liver malignancies cannot be treated radically, and their prognosis is poor.11-13 In the era of precision radiotherapy, radiotherapy is one of the main treatments for locally advanced, recurrent, and metastatic liver malignancies.14,15 Studies have shown that precision radiotherapy has potential effects in all stages of liver cancer treatment.16 The concept of the era of two-dimensional radiotherapy believes that normal liver tissues have poor tolerance to radiation, so the radiation dose and target area are limited; and the liver is affected by respiratory movement and has a large mobility, so it is difficult to accurately locate the lesion when radiotherapy is implemented. Therefore, radiotherapy was not routinely used for the treatment of liver malignancies.17 SBRT, which has made breakthrough progress in recent years is a new radiotherapy technology. It is a high-dose, low-fractionation radiotherapy technology guided by high-precision imaging methods. This technology can not only obtain a larger bioequivalent dose in the tumor area, but also protect surrounding normal tissues, and greatly shorten the treatment time, so the patient compliance is well. The efficacy of SBRT for liver malignant tumors is superior to local treatment options such as transcatheter arterial chemoembolization and radiofrequency ablation.18-20 The overall local control rate can reach 80% to 100%, and the 3-year survival rate can reach 54% to 70.0%;21-23 For patients with newly diagnosed and recurrent small liver cancer, a large number of recent studies have shown that the local control rate and overall survival rate of SBRT and radical surgery are similar.24-29 The main limitations of conventional SBRT for liver malignancies are dislocation of the treatment target caused by respiratory movement and acute radiation damage to the liver at low and medium levels. Therefore, how to make
SBRT with more accurate image guidance technology is the goal constantly pursued in the era of precision radiotherapy.

The Varian Company in the US developed and designed the beacon transponder. Through minimally invasive interventional surgery, three beacon transponders that can emit signals of different frequencies were permanently implanted into the tissues adjacent to the tumor in patients. Used with the matching Calypso system, it can accurately determine the position of the patient’s treatment target. During radiotherapy, the Calypso system can identify and temporarily activate the implanted beacon transponders, causing it to temporarily emit a specific response signal. The Calypso system detects and judges the response signal to provide accurate and continuous treatment position. The beacon transponders, which originally used for prostate cancer have a large volume, up to 8.5 mm in length and 1.8 mm in diameter. It needs to be implanted through a 14G guide needle. Because the 14G guide needle is thicker, beacon transponders are rarely used for other organs. In 2019, Varian developed a new soft tissue beacon transponder with a length of 8.7 mm and a diameter of 1.3 mm (Figure 1). Compared with the previous beacon transponders used for prostate cancer implantation, it is smaller and can be implanted into soft tissue and organs with a 17G guide needle, and patients have less damage and a lower risk of bleeding during implantation. In April and May 2019, our center took the lead in completing two cases of liver beacon transponder implantation in China. When the liver tumor SBRT was performed 1 week after the implantation, the Calypso system and the beacon transponders responded to each other to monitor the position of the liver malignant tumor in real time. The application of this technology overcomes the off-target and damages caused by changes in the patient’s position during radiotherapy, and achieves the goal of accurate radiotherapy.

The determination of the beacon transponder implantation sites must meet the following three points: (1) three beacon transponders are distributed in a triangle and cannot be implanted in a straight line; (2) the distance between each two beacon transponders ranges from 1 to 7.5 cm; (3) the three beacon transponders should be less than 19 cm from the skin of the patient’s front abdominal wall. The insertion path of the guide needle needs to consider the safety and feasibility of the operation, try to avoid passing through the pleura, lungs, and diaphragm muscles, so as to reduce complications such as bleeding, pneumothorax, and implantation metastasis due to puncture of intrahepatic tumors. The optimal implantation sites should be about 1 cm from the tumor boundary, and not close to the liver capsule and large blood vessels. The distance between the two beacon transponders should not be too small, because during the operation, if the needle tip deviates from the predesigned target point due to factors such as the patient’s breathing movement or operator’s operating experience, the beacon transponder can still be released as long as it is within the allowed range, and does not affect subsequent Calypso system recognition and activation of beacon transponders. During the operation, we recommend releasing the beacon transponders after the tips of the three guide needles reach the target points, and pulling out the guide needles one by one to prevent complications such as bleeding during the needle removal process and affecting the release of the remaining beacon transponders. Because the first implanted guide needle can also play a certain fixing role, it can reduce the movement of the liver with breathing, which is conducive to the subsequent implantation of the accurate guide needles. Patients usually take a supine position during radiotherapy. The Calypso system requires three beacon transponders to be less than 19 cm from the skin of the patient’s front abdominal wall in order to activate the beacon transponders and detect the signal. Therefore, the design of the implantation site also needs to consider the distance of the beacon transponders from the front abdominal wall, especially when treating obese patients. Research in our center showed that on the fifth day after the beacon transponders was implanted, a local CT scan revealed that only one beacon transponder moved slightly, with a range of about 7 mm, and the remaining beacon transponders were not displaced. And 1 month after the end of radiotherapy, the beacon transponders of the two patients did not move significantly compared with the local CT. According to the experience of our center, it is recommended that the distance between each two beacon transponders is designed to be 2 to 6 cm, the distance between each beacon transponder and the front abdominal wall is less than 18 cm, and the localized CT examination is recommended to be performed 4 days after the implantation.

Image-guided percutaneous puncture is a safe, accurate, and widely used diagnosis and treatment technique, which is generally carried out in medical centers at all levels and has an important role in the diagnosis, treatment, and prevention of liver diseases. Commonly used image guidance methods are type-B ultrasonic and CT. Type-B ultrasonic guidance has no radiation damage, can monitor the angle, direction and depth of the puncture needle in real time, and can avoid important blood vessels; its disadvantage is that the puncture path is easily affected by the lungs, intestinal gasses and rib bone structure. CT guidance can accurately show the spatial location of the lesions and the relationship between the lesions and the intrahepatic blood vessels, especially for the liver lesions near the top of the Mediastinum, which are better than type-B ultrasonic; its disadvantage is that there is radiation, and the intrahepatic blood vessels cannot be avoided in real time. CT guidance was used in two cases in our center for the following three reasons: (1) Intrahepatic lesions were near the top of the mediastinum, the CT images showed clearer and were not disturbed by lung gas; (2) The choice of implantation site and the design of the needle path refer to the patient’s existing MRI image. The MRI image and the CT image have the same tomographic anatomy relationship, and the CT image can more clearly and intuitively display the spatial position and distance of the three beacon transponders through 3D reconstruction. It is beneficial for the consultation between doctors and physicists; (3) Immediate CT images after beacon transponder implantation and localized CT images 4 days later can be compared to determine whether the beacon transponder is displaced. We recommend choosing a large-aperture CT machine, because the length of the guide needle is 20 cm, and the needle needs to be inserted step by step in order to improve safety during puncture. Large-aperture CT can effectively
avoid the pollution caused by the external guide needles touching the CT frame. Each medical center can also choose type-B ultrasonic guidance according to the conditions and operator’s habits.

A 16-18G needle is commonly used for liver puncture, and its outer diameter is 1.2 to 1.6 mm. The overall incidence of image-guided liver puncture-related complications was 5.90%, including pain, bleeding, biliary peritonitis, hypotension, peripheral organ damage, and possible needle way tumor implantation and metastasis. Pain is the most common complication, but the symptom is mild. Generally, no special treatment is needed or the pain can be eliminated after simple symptomatic treatment. The secondary most common major complication is bleeding, with an incidence of less than 3.4%. Mueller M et al. conducted a study of 1961 cases and reported the incidence of liver puncture with 18G puncture needle guided by type-B ultrasonic. The incidence of bleeding was 1.2%, and the incidence of bleeding that needed to be treated was 0.5%. The results of research by Howlett DC et al. showed that the incidence of micro-bleeding under the guidance of type-B ultrasonic was 0.4% to 5.3%, and those without severe bleeding did not need special treatment. The results of research by Caturelli E et al. showed that the incidence of liver puncture bleeding was only 0.13%, and the amount of bleeding was small, and no blood transfusion or surgery was needed. In addition, although tumor implantation and metastasis along the needle path after puncture is not common, puncture times should be as few as possible to reduce the risk of tumor implantation and metastasis. Other complications are rare. A large number of studies have shown that liver puncture is safe and feasible when the puncture needle is of a size above 16G. Currently, the most common complication of beacon transponder implantation is bleeding. Other rare complications that may exist include pneumothorax, pain, and infection. The use of beacon transponder implantation to assist liver malignant tumors for SBRT is the first time in China. The two cases of beacon transponder implantation in our center all use matching 17G guide needles and the operation time is about 30 minutes. There was no bleeding during and after the operations, and no complications such as infection and pneumothorax occurred. In summary, liver beacon transponder implantation is safe and feasible.

Beacon Transponder implantation also has disadvantages. When the two patients reviewed 1 month after the end of radiotherapy, 3.0 T MRI of the liver showed that the magnetic sensitive artifacts at Beacon Transponders were large, and the artifacts could reach about 1.7 cm around the beacons. The liver tissues within the scope of the artifacts could not be observed, and affecting the efficacy assess and discover new small lesions. Therefore, we recommend enhanced CT for follow-up review of patients with beacon transponder implantation.

The application of CT-guided beacon transponder implantation under the guidance of 17G guide needle in SBRT provides a safe and feasible accurate solution for the treatment of liver malignancies, which is expected to improve the local control rate of patients and reduce the normal liver tissue damage outside the target area. The disadvantage is that there are magnetically sensitive artifacts around beacon transponders during the follow-up MRI examination, which interfere with the judgment of curative effect. Beacon transponder implantation-assisted SBRT is safe and feasible and worth promoting, but it needs to increase the number of cases and conduct multicenter clinical research to further verify its clinical value.

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