Development of Biliary Stent Compatible with Microwave Hyperthermia for Bile Duct Carcinoma

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Abstract: We have introduced a thermal treatment using an endoscope and a thin microwave antenna for treatment of bile duct carcinoma. In the bile duct carcinoma, stent placement is often utilized for palliative treatment of malignant bile duct obstruction due to enlarged tumors or abscesses in general. In addition, we have known that a metallic stent could shield electromagnetic energy. Therefore, in this paper, a new biliary metallic stent compatible with microwave hyperthermia will be introduced. It has several plastic stents in order to generate more effective and extensive heating regions around it. By comparisons of the SARs of the proposed and conventional metallic stent, we confirmed that the proposed biliary stent could generate extensive heating regions in the longitudinal direction up to 60 mm. Therefore, it is highly possible that the developed biliary stent would be useful for microwave hyperthermia for the bile duct carcinoma in situation that it has implanted in a bile duct.

Key Words: microwave hyperthermia, bile duct carcinoma, biliary stent, endoscopic coaxial probe, SAR (Specific Absorption Rate)

Introduction

Microwave hyperthermia is a thermal treatment for treating localized tumors. For carrying out intracavitary heating, an antenna is inserted into the tumor and microwave energy is radiated by the antenna directly to the target¹⁻². Thus, the tumor is heated effectively. Up to now, intracavitary heating techniques have been regarded as important for deep-seated carcinomas. The authors have been studying the microwave antenna with endoscope for thermal treatment of bile duct carcinomas⁴⁻⁷. The antenna is so thin and flexible that it can be inserted into the endoscope. This non-invasive treatment is effective for treating unresectable bile duct carcinoma. Therefore, it is expected to be useful for treating various types and scenes of carcinomas.

By the way, today, placement of self-expandable metallic stents is the standard of care for patients with malignant obstructive jaundice caused by bile duct carcinoma if their life expectancy is less than 3
months\(^4\),\(^5\). However, in less than 50% of patients with metallic stents, stent blockage develops within 6 to 8 months\(^6\) by explosive growth of cancer cells. Moreover, according to our previous study, we have known that the metallic stent would shield microwave energy from the antenna inserted into the metallic stent\(^7\). Therefore, the authors introduced the new biliary stent compatible with microwave hyperthermia of bile duct carcinoma involving the use of an endoscopic coaxial probe for intracavitary treatment. Fig. 1 shows the proposed treatment scheme. In this treatment, first, an endoscope is inserted noninvasively into the duodenum. Then, the probe is guided through an endoscope into the bile duct where the metallic stent is implanted. Finally, the target tumor around a biliary metallic stent is extensively heated by the microwave energy radiated from the probe. In this study, the proposed stent, which is composed of the metallic and plastic stents in order to leak microwave energy to outside of it, is introduced.

This paper describes the effectiveness and possibility of the newly developed biliary stent compatible with microwave hyperthermia. First, the results of calculation are described. In order to investigate heating characteristics around the newly developed biliary stent, we carried out numerical simulations using the Finite-Difference Time-Domain (FDTD) method. In this calculation, we confirmed that the proposed stent can generate extensively heating regions in the longitudinal direction up to 60 mm. This result means that the proposed stent is suitable for thermal therapy for invasive carcinoma, such as bile duct carcinoma. Next, the results of experiment using tissue-equivalent solid phantom are described. From results of experiment, the validity of calculations was confirmed. Therefore, it is highly possible that microwave hyperthermia using the developed biliary stent could be the curable treatment.

Materials and methods

Structure of the Biliary Stent

Fig. 2 shows the structure of the biliary stent models. There are two types of the biliary stent model. One is the conventional metallic stent in Fig. 2A. The other is the proposed stent in Fig. 2B. The proposed stent is composed of six metallic stents and

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**Fig. 1.** Microwave hyperthermia by use of biliary stent.

**Fig. 2.** Structure of biliary stent models.

A, conventional stent; B, proposed stent. Unit is mm.
five plastic stents of 2 mm in length. Taking account of previous study, we confirmed that the arrangement of plastic stents at regular intervals can generate extensive heating outside of the stent. Moreover, in case of the distance between plastic stents is narrowed to some extent, microwave energy cannot be radiated from plastic stents efficiently. Therefore, plastic stents (relative permittivity: 2.1) are arranged at regular intervals of 8 mm. The length and diameter of the stent that was determined taking account of the previous study⁹, are 60 mm and 5 mm, respectively. In order to adjust for the length of the stent, a metallic part at the bottom of the proposed stent is set 10 mm in length. Although the structure of stents is a mesh structure in general, a solid cylindrical structure is used in calculation, because the size of a mesh is small enough in comparison with the wave length of feeding electromagnetic wave.

**Structure of coaxial probe**

Fig. 3 shows structure of the coaxial probe model. The probe is composed of a thin flexible coaxial cable which can be inserted into the endoscope. The diameter of the endoscopic coaxial probe and an outer conductor of the probe are set to be 2.4 mm and 1.6 mm, respectively. An inner conductor of the probe sticks away 3 mm from the tip of the cable. A feeding point is set at the end of the cable. In this treatment, whole of the probe is placed at the center of the stent, and the probe passes through the stent end approximately 1 mm. Therefore, whole of the probe does not contact to the stent. Thus this feeding method utilizing electromagnetic coupling is able to carry out in situation that the biliary stent has been covered with tissues or tumor due to restenosis.

**Calculation model**

The authors carried out numerical simulations to confirm the validity of experimental results. In this study, two types of the biliary stents and an endoscopic probe are introduced. Here, the operating frequency of the probe is 2.45 GHz, which is one of the industrial, scientific and medical (ISM) frequencies in Japan. In this section, we will describe the method of the numerical analysis for the heating characteristics around the biliary stent inside the biological tissue. By use of the FDTD method, the SAR (Specific Absorption Rate) around the biliary stent are calculated from following equation

\[
\text{SAR} = \frac{\sigma}{\rho} E^2 \quad [\text{W/kg}]
\]

where \(\sigma\) is the conductivity of the tissue [S/m], \(\rho\) is the density of the tissue [kg/m³], and \(E\) is the electric field (rms) [V/m]. The SAR takes a value proportional to the square of the electric field around the probe and is equivalent to the heating source generated by the electric field in the tissue. The SAR distribution is one of the most important characteristics for the heating.
Fig. 4 shows the FDTD calculation model for the biliary stent and the coaxial probe and observation plane. The stent model is placed in the bile duct filled with the bile, and the bile duct is in the muscle. Moreover, assuming restenosis due to tumors, the inside of the stent is filled with muscle from the view point of their electrical properties. A sinusoidal electric field was applied between the inner and outer conductors of the coaxial cable and then a steady-state analysis was carried out. The parameters used in the FDTD calculations are listed in Table I, and the properties of the biological tissues are listed in Table II. The cell size of $\Delta x$ and $\Delta y$ is 0.05 mm around the probe and the stent, and it increased gradually with distance from them. Further, in the calculations, nonreflective boundary condition of Mur 1st order is used outside of the muscle model.

![Fig. 4. FDTD space for the biliary stent and the coaxial probe. A, over view; B, top view. Unit is mm.](image)

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<th>Table I. Parameters for FDTD calculations.</th>
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<td>Cell size [mm] (minimum)</td>
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<td>Cell size [mm] (maximum)</td>
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<td>Time step [ps]</td>
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<td>Absorbing boundary condition</td>
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<th>Table II. Electrical properties of biological tissues. Relative permittivity and conductivity at 2.45 GHz were used in calculations.</th>
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<tr>
<td>Relative permittivity : $\varepsilon_r$</td>
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<tr>
<td>Inner dielectric</td>
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<td>Catheter</td>
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**Experimental procedure**

Fig. 5 shows the experimental system used in the experiment. Figs. 6A and B show trial manufactures of the biliary stent and the endoscopic coaxial probe we employed. First, the proposed and the conventional metallic stent for trial manufacture are put between the muscle-equivalent solid phantoms (Figs. 6C and D). Next, the probe passes through the stent end 1 mm and supplies it with microwave energy. Table III shows target and measured electrical properties of the phantom used for the probe at 2.45 GHz. The difference between target and measured value are less than 10%.

**Fig. 5.** Experimental system.

**Fig. 6.** Experimental setup. A, trial manufactures of stents; B, endoscopic coaxial probe; C, section of phantom; D, setup; E, observation plane. Unit is mm.

**Table III.** Electrical properties of the phantom at 2.45 GHz.

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<td></td>
<td>$\varepsilon_r$</td>
<td>$\sigma$ [Sm$^{-1}$]</td>
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<tr>
<td>Target</td>
<td>47.0</td>
<td>50.2</td>
<td>6.8</td>
<td>2.21</td>
<td>2.32</td>
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<td>Meas.</td>
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The diameter of the endoscopic probe is 2.4 mm. The probe is connected to microwave generator. The input power and the radiation time for the probe are set 50 W and 60 s, respectively. We measured the temperature rise distributions by an infrared camera and converted them into the SAR distributions (11). Fig. 6E shows the observation plane of experiments.

Results

Results of calculation

Fig. 7 shows the calculated SAR distributions around the conventional and proposed metallic stent. Here, observation plane is x-z outside of the stent. In conventional metallic stent, the lower SAR around the central part of the stent (40 < z < 70 mm) in comparison with SAR around both edges of the stent (10 < z < 30, 85 < z < 95 mm) is observed. This is due to the shielding effect by the metallic stent. Target carcinoma should locate at near or around the central part of the stent, thus this results means that the conventional metallic stent is unsuitable in this treatment. Besides, in the proposed metallic stent, the higher SAR region is appeared around the whole of the stent (30 < z < 90 mm). It is considered that the microwave energy can be leaked to outside from each plastic parts of the stent. From the above, we can say that the proposed stent could heat extensively around it, where target carcinoma should exist. However, these results show that undesirable hot spots from the lower part of the stent to the probe axis (10 < z < 30 mm) are observed in both cases. It will be improved as our further study.

Results of experiment

Fig. 8 shows the results of the measured SAR distributions around the stent put between the

![Fig. 7. Calculated SAR distributions. A, conventional stent; B, proposed stent. Unit is mm.](image)

![Fig. 8. Measured SAR distributions. A, conventional stent; B, proposed stent. Unit is mm.](image)
muscle-equivalent phantoms. Here, observation plane is the same as calculations. Figs. 8A and B show the SAR distribution around the conventional and the proposed metallic stent. In the conventional metallic stent, the lower SAR region around the central part of the stent (40 < z < 70 mm) than SAR regions at both edges of the stent (20 < z < 30 mm, 80 < z < 90 mm) is observed. Besides, in the proposed stent, the higher SAR region around whole of the proposed stent can be observed due to the microwave energy leaked to outside from each plastic parts of the stent. From these results, we confirmed that the proposed stent could generate extensive heating regions around it in the longitudinal direction up to 60 mm, as the validity of the calculated SAR distributions. In addition, we confirmed that undesirable hot spots from the lower part of the stent to the probe axis (10 < z < 30 mm) are observed in calculations and experiments. However, both SAR values at there are different from results of calculations. The reason for this can be found in thermal diffusion of the muscle-equivalent phantom, which is not considered in calculations. Therefore, SAR values obtained at undesirable hot spots in calculations are higher than those in experiments.

Discussion

The purpose of this work is to improve the longitudinal heating regions around the biliary stent. Moreover, this work is to decrease undesirable hot spots at the edge of the stent for intracavitary microwave heating. Fig. 9 shows the calculated SAR profiles in the longitudinal direction outside of the stent at a distance of 2.5 mm away from the centre axis of the coaxial probe (z-axis). The SARs were normalized to the maximum value for each configuration.

In the conventional metallic stent (Fig. 9A), the obvious peaks of the SAR profile at the edge

**Fig. 9.** Calculated SAR profiles in the longitudinal direction outside of conventional stent (A), and proposed stent (B). Shade, metallic part. Unit is mm.
of the stent ($z=30, 90$ mm) are observed. However, by comparing around the central part of the stent ($40 < z < 80$ mm) with near the edges of it ($10 < z < 30$ mm, $80 < z < 100$ mm), the much smaller SAR value is obtained in the former than SAR values in the latter due to shielding effect of the metallic stent against microwave energy propagating through into it. This result also means the conventional metallic stent could be unsuitable for effective heating of carcinoma located around it.

On the other hand, in the proposed metallic stent (Fig. 9B), the peak of the SAR profile is observed at the first plastic part from the tip of the probe ($z=80$ mm). In addition, the higher SAR values are appeared at the each plastic stents. We also confirmed that the SAR values at each plastic stents decrease with taking the distance from the tip of the probe because the SAR is dominant in the electric fields in inverse proportion to the distance. By comparing Fig. 9A with Fig. 9B, we can see that the SAR value at the undesirable hot spots ($z=30$ mm) are decreased by about $60\%$ in the proposed metallic stent. Specifically, the SAR value at one edge of the proposed stent becomes almost as same as it at the other edge of it. This phenomenon is considered that microwave energy radiated from the probe is distributed in each plastic stents of the proposed stent. Thus, we confirmed that SAR values around both edges of the proposed stent are lower than SAR values around there of the conventional metallic stent. In consequence, these results confirmed that the proposed metallic stent could generate mild microwave heating extensively outside of the stent. Moreover, there is possibility that the arrangement of the plastic stent in the proposed stent is able to control the heating characteristics around it.

Conclusions

In this paper, heating characteristics of the microwave hyperthermia for bile duct carcinoma by use of the proposed biliary stent fed by a thin endoscopic coaxial probe were introduced. As the results of investigations, we confirmed that the proposed stent is able to generate extensive heating regions in the longitudinal direction up to 60 mm. Therefore, it is highly possible that we can carry out microwave hyperthermia under the implantation of newly developed biliary stent. As further study, we intend to optimize the structure of the biliary stent in order to improve and control heating regions. Moreover, we have to do the animal experiment in order to investigate its usefulness under the blood flow.

Acknowledgments

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