A NEW INDUCTIVE THERMOTHERAPY SYSTEM FOR MINIMAL INVASIVE SURGERY IN SPLENOMEGALY

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ABSTRACT

Splenomegaly is an enlargement of the spleen, which usually causes infectious mononucleosis and portal hypertension. In this study, a new inductive thermotherapy system for minimal invasive surgery (MIS) was reported for treatment of splenomegaly. It can generate a high-frequency alternating electromagnetic field to induce a localized temperature increase by inserting a two-part needle into the spleen. To prevent the overheating, a temperature feedback control system was developed such that the treatment can be operated at a safe and effective temperature. The relationship between the coagulation zone and the operating temperature/time was first explored. Then Lan-Yu pigs’ spleen under the ultrasonic guidance was heated by using the developed system. The experiments showed that the developed electromagnetic thermotherapy system can successfully cause the atrophy of the spleen, which is very promising for further clinical use.

KEY WORDS

splenomegaly, minimal invasive surgery, electromagnetic, thermotherapy

1. Introduction

Therapy has been used to treat a variety of diseases [1]. It is usually operated as raising the tissue temperature (usually higher than 42°C) in a short period of time and then maintaining it during the treatment. As a result of the high temperature, the apoptosis of cells can be induced. In recent years, minimal invasive surgery (MIS) has been developed to minimize the incision and blood loss and thus improve the recovery after surgery [2]. As a consequence, many surgery tools have been reported recently by combining thermotherapy and MIS to develop new treatment procedures for cancers or other diseases. Radiofrequency ablation (RFA) [3], microwave ablation [4], high-intensity focused ultrasound (HIFU) [5], laser-induced thermotherapy [6] and inductive thermotherapy [7] have been demonstrated in literature. For instance, RFA applies a high-frequency electrical current in a radiofrequency range (450 k to 500 kHz). When the current flows through the tissue, it generates a high temperature in the neighbourhood of the electrodes and then causes tissue ablation. Therefore, RFA has been applied for treatment of liver tumours and many other applications. However, it is well recognized that it is challenging to precisely control the operating temperature. For some specific applications requiring a high temperature for coagulation, it has difficulty to provide the required thermal energy. More importantly, RFA is relatively expensive, which may hinder their applications in resource-limited areas.

In this study, a new inductive thermotherapy system is used to generate a high-frequency electromagnetic field (30 kHz to 100 kHz) to induce a temperature increase through stainless steel needles. When magnetic materials are placed in the alternating magnetic field (AMF), the hysteresis loss results in an effective heating [8]. The AMF also causes an eddy current on the magnetic materials, thus generating heat [9]. The thermal energy is then transferred to the neighbourhood of the needles to cause the tissue ablation. The apparatus is designed as two-part needles for performing MIS. The upper part is made of a ceramic material designed to prevent damage to normal tissues and skins. Conversely, the lower part is made of stainless steel for generating a temperature high
enough to cause tissue ablation. In this work, the apparatus is inserted into the spleen under ultrasonic imaging guidance, and then heated under the AMF. During the surgery, the temperature of the needle is monitored by a temperature feedback control system such that a precise temperature can be accurately maintained. The high temperature causes tissue ablation, closes the vessels in the spleen, and finally makes the spleen atrophy. With this approach, a new MIS tool for splenomegaly can be realized.

2. Material and Methods

2.1 High-frequency electromagnetic induction machine

The high-frequency electromagnetic induction machine is commonly used in metal annealing processes. It can heat the metal to a high temperature (several hundred degrees) in a very short period of time without touching the object or transmitting electrical current into it. For this reason, it may useful in medical applications, i.e., surgery may be performed without opening the abdomen.

The high-frequency electromagnetic induction machine composes a power supply, a current amplifier, an 80-cm-long cord and a coil. The 80-cm-long cord connects the coil with the current amplifier. It allows the coil to move around such that the surgery can be operated in a more flexible way. The coil generates an AMF when a high-frequency alternating electrical current (30 kHz to 100 kHz) passing through it, which is generated by the current amplifier. It allows the coil to move around such that the surgery can be operated in a more flexible way. The coil generates an AMF when a high-frequency alternating electrical current (30 kHz to 100 kHz) passing through it, which is generated by the current amplifier. In MIS, the needle is placed underneath the coil. Therefore, AMF may decay along with the distance away from the center of the coil. Therefore, a large plane coil with an outer diameter of 15 cm is used to generate a magnetic field with a wider range to make sure the needle is within the effective magnetic field. For some applications such as organ resection surgery, the needles can be placed in the center of the smaller plane coil, which has an outer diameter of 8 cm.

The input voltage of the induction machine is 220V and the power consumption is 15kW. The output current can be amplified to 600A and the operation frequency is between 30–100 kHz, which depends on the size and geometry of the different coils. In this study, the operation frequency is set to be 45 kHz when the plane coil with an outer diameter of 15 cm is used.

In order to prevent overheating of the high-frequency induction machine and the coils, a water cooling system is developed. The water cooling system includes a pump, two fans and radiators. The water flows through the induction machine, the extension cord and the coil such that the machine can be operated safely. Figure 1 is a photograph of the developed system.

![Figure 1](image)

Figure 1, Photograph of the inductive electromagnetic thermotherapy system. The system includes a current amplifier, a power supply, a water cooling system, an extension cord, and a coil.

2.2 Feedback temperature control system

As mentioned above, temperature would rise substantially very rapidly. To avoid tissue overheating, a feedback temperature control system is adopted to perform in-vitro experiments and the spleen surgery at a safe constant temperature. It is composed of a thermocouple (R-type, InterTech Technology Inc., Taiwan) and a thermometer (DB1000B, Chino, Japan). The thermocouple is used to monitor the temperature on the needles and provide a feedback control signal to the control system.

The operation principle of the temperature feedback control system is described as follows. The thermocouple is first placed on the needles to monitor the temperature, and then the operating temperature T(x) is set in the thermometer. When the control system is turned on, the thermocouple begins to provide a feedback control signal to the thermometer. If the temperature is lower than the T(X), the control system turns on the power of the high-frequency induction machine. When the temperature is close to the T(X), the control system turns down the power automatically to slow down the heating rate. If the temperature is higher than the T(X), the system turns off the power to cool down the needles. With this approach, the temperature can be kept at an accurate valve during the surgery.
2.3 Two-part needle for MIS

The apparatus for MIS is a two-part needle. In this study, the needle is inserted to the target tissue by ultrasound imaging guidance. After insertion, the needle is heated by the AMF generated by inductive high-frequency electromagnetic thermotherapy system. During the treatment, the upper needle may touch the normal tissue. Only the bottom part of the needle (magnetic part) is inserted to the target tissue. If the whole needle is made of stainless steel, the normal tissue may be damaged by the high temperature. For this reason, the needle is designed in two parts.

Figure 2 shows a schematic diagram of the two-part needle. The two-part needle is composed of three sections. The first part is a hollow, outer needle which can be used to insert a thermocouple device or for injection of drugs into the target organ. The second part is an inner needle A, which can be inserted into the outer needle. It is used to strengthen the structure of the outer needle during insertion. The last part is an inner needle B which can be used to enhance the heating effect during the procedure. The structures of the outer needle and the inner needle B consist of two parts. The first part is made of ceramic, which cannot be heated under the AMF to prevent damage to the normal tissue. The second part is made of stainless steel, can be heated to a high temperature to treat the target tissue. Note that the inner needle A is not a two-part needle, which is made of stainless steel. Before the surgery, the outer needle with the inner needle A is inserted to the target tissue under ultrasound image guidance. After inserting, the inner needle A is removed from the outer needle and the inner needle B is inserted into the outer needle. Note that the dimension of the stainless steel part is determined by the size of the tissues, which determines the heating area. In the Lan-Yu Pig model, 2.0~3.0cm stainless steel needles are adopted. The outer diameters of the magnetic parts for the outer needle are 1.7mm. The outer diameter of the inner needle A and B are 0.8mm. The outer and inner diameters of the ceramic part are 1.8 mm and 1.1mm, respectively. The length of the ceramic part is 10cm. The total length of the two-part needle is 15cm. Figure 3 shows a photograph of the two-part needle.

I. The outer needle
Stainless steel  Ceramics

II. The inner needle A
Stainless steel

The position of the thermocouple

III. The inner needle B
Stainless steel  Non-magnetic material

Figure 2, Schematic diagram of the two-part needle including an outer needle, an inner needle A and an inner needle B.

2.4 Temperature measurement

Temperature is an important factor in this study. The temperature distributions of a single needle and two needles in the porcine liver under the AMF are measured. The needles are first inserted to the porcine liver. Then, the temperature feedback control system is used to maintain a temperature of 120°C. In the single-needle test, only one heating needle is used. Then a thermocouple is used to measure the temperature at a distance of 0.25, 0.5, 0.75 and 1cm, respectively away from the needle. In the double-needle test, two heating needles are used with a separation distance of 0.3 and 0.5 cm. The temperature is measured at different distances as mentioned previously. From the results, the optimal distance between each needle that yields the acceptable coagulation can be determined.

The time and the temperature are crucial for the size of coagulation area and sealing the vessels. Therefore, four operating temperatures (60, 80, 100 and 120°C) for 1, 3 and 5 minutes are tested. After heating, the tissue is incised and the ablation zone is measured.

2.5 MIS in Lan-Yu pig’s spleen

In this study, MIS will be performed in spleens of Lan-Yu pigs. The two-part needle is first inserted to the pig’s spleen under ultrasonic guidance and then heated up to a specific temperature under the AMF. After heating, the needle is removed and ultrasound imaging is used to check the vessels in the spleen. After two weeks, the target tissue is removed for further histological
examinations and the animals are humanely sacrificed by an anesthesia overdose.

3. Results and Discussion

3.1 In vitro test

3.1.1 Heating effect of stainless steel needles

Hollow needles with different outer diameters and different lengths (1 and 3 cm) were heated under AMF for 3 minutes, and the final temperature was measured. The needles were heated in two different settings, including placed at the center of the coil to simulate the maximum heating, and 6 cm away from the coil to simulate the MIS animal model. The 6 cm is about the distance between the coil and the needle when it is inserted in the target tissue. First, the 1-cm needles with different outer diameters (0.4, 0.6, 0.8, 1.0, 1.2, 1.4, 1.6, 1.7 and 1.8 mm) were tested. Figure 4 shows the measured maximum temperature for different needles. The final temperature of all needles can be heated up to 200°C or even higher temperatures when placed at the center of the coil. However, the final temperature is only about 40°C or less when the needles are placed 6 cm away from the center of the coil. The heating effect is too low to coagulate the tissue in this case.

Similarly, the 3-cm needles with different outer diameters (0.4, 0.6, 0.8, 1.0, 1.2, 1.4, 1.6, 1.7 and 1.8 mm) were tested. Figure 5 shows the measured maximum temperature for different needles. The final temperature of all needles can be heated up to 350°C or even higher temperatures when the needles were placed at the center of the coil. If the needles were placed 6 cm away from the center of the coil, the temperature of the needles with outer diameter smaller than 1.4 mm was just raised to 70°C or less. However, the temperature of the needles with outer diameters of 1.6 mm is about 100°C. The temperature of the needles with outer diameters of 1.7 and 1.8 mm can rise to 110°C when the needles are placed 6 cm away from the center of the coil. From these results, both the outer diameter and the length are found to be important parameters. If the needle is placed far away from the coil, it is necessary to increase its outside diameter. In this study, the heating effect was almost the same for needles with an outer diameter of 1.7 and 1.8 mm. However, the smaller outer diameter causes less pain during the insertion. For this reason, hallow stainless steel needle with an outside diameter of 1.7 mm and 3 cm in length was chosen as the magnetic part of the two-part needle.

3.1.2 Temperature distribution in porcine liver

Temperature distribution is important when using two-part needle. Figure 6 shows the temperature distribution of the single needle which was inserted into a porcine liver under AMF for 5 minutes. Note that the needles are about 3 cm away from the coil. Then, the temperature feedback control system is used to maintain a temperature of 120°C. The upper measured point is close to the coil in the test. From the figure, the temperature of the middle point is higher than the upper measured point. The temperature of the upper point is about 120°C and the temperature of the middle point is about 140°C. It is due to the fact that the efficient mass of the middle part of the needle is higher than the mass of the upper part. The temperature distribution of the single needle is also shown in Figure 6. It can be clearly seen that the temperature declines to 80°C when the distance is 0.25 cm away from the needle.

Figure 7 shows the temperature distribution when two needles are used. Note that the distance between two
needles is 0.3 cm in this case. The setup temperature is 120°C. The temperature of the needle from the upper to the lower measured points are 120°C 140°C and 57°C, respectively. The temperature between the needles from the upper to the lower measured points are 100°C 120°C and 46°C, respectively. The temperature just declines 20°C between the two needles in this case.

Figure 8 shows the temperature distribution when these two needles are placed with a distance of 0.5 cm. The setup temperature is 120°C. The temperature of the needle from the upper to the lower measured points are 120°C 140°C and 58°C, respectively. The temperature between the needle from the upper to the lower measured points are 80°C 100°C and 42°C, respectively. The temperature between the two needles declines 40°C in this case. Therefore, the distance between each needle is designed to be 0.3 cm to coagulate the tissue efficiently and seal the vessels in the spleen.

3.1.3 Coagulation test

In the coagulation test, a single needle (OD: 1.7mm, 3 cm long) is inserted into the porcine liver and heated under AMF. After heating, the porcine liver is incised and the ablation zone is measured. Figures 9 to figure 13 show the ablation zone of the porcine liver at the setup temperature of 60, 80, 100, 120 and 150°C for 1, 3 and 5 minutes, respectively. Figure 9 shows that the porcine liver tissue is not coagulated at 60°C for 1, 3, or 5 minutes. It indicates that this temperature is not high enough for coagulation. When the temperature is maintained at 80°C, the ablation zones are 30 mm × 6 mm, 30 mm × 8 mm and 31mm × 9 mm for 1, 3, and 5 minutes, respectively (Figure 10). Apparently, this temperature is good enough to generate coagulation. As the operation time increases, the ablation zone increases accordingly. When the temperature is maintained at 100°C, the coagulation zones are 33 mm × 7 mm, 32 mm × 8 mm and 33 mm × 10 mm for 1, 3, and 5 minutes, respectively (Figure 11). The ablation zone is found to be wider when the temperature is 100°C for 3 or 5 minutes, and the needle begins to adhere onto the tissue. Similarly, when the temperature is maintained at 120°C, the coagulation zones are 30 mm × 10 mm, 32 mm × 11 mm and 36 mm × 12 mm for 1, 3 and 5 minutes, respectively (Figure 12). Finally, The ablation zones for 150°C are found to be 31mm × 9 mm, 34 mm × 11 mm and 37 mm × 14 mm for 1, 3 and 5 minutes, respectively (Figure 13). The ablation zone is widest when the temperature is set up at 120°C or 150°C, which generate very similar effect. However, the porcine liver was found to be dry and a small area was even burned. The burned black tissue reduces the heat conduction and reduces the ablation zone. Therefore, 120°C and 5 minutes are chosen as the optimal coagulation temperature and time for MIS.

Figure 6, Temperature distribution of the single needle. The temperature declines to 80°C when the distance is 0.25 cm away from the needle. The setup temperature is 120°C.

Figure 7, Temperature distribution when two needles with a separation distance of 0.3 cm are used. The setup temperature is 120°C. The temperature decreases 20°C at the middle of the two needles.

Figure 8, Temperature distribution when the two needles with a separation distance of 0.5 cm are used. The setup temperature is 120°C. The temperature decreases 50°C at the middle of the two needles.
Figure 9, Incised surfaces of a porcine liver heated at 60°C for 1, 3, and 5 minutes. There is no coagulation observed for these three cases.

Figure 10, Incised surfaces of a porcine liver heated at 80°C.

Figure 11, Incised surfaces of a porcine liver heated at 100°C.

Figure 12, Incised surfaces of a porcine liver heated at 120°C.

Figure 13, Incised surfaces of a porcine liver heated at 150°C.

3.2 MIS in spleen

In this study, the ultrasonic guidance was used to monitor the needle inserting, spleen and blood flow. Figure 14 shows the ultrasonic guiding image before the heating. It can be found that the needle was inserted to the spleen and placed near a vessel. The red plots indicate the artery and the blue plots represent the vein. After the inserting, the AMF was used to heat up the needle to 120°C for 5 minutes. After the heating, the spleen was again scanned under the ultrasonic guidance. Figure 15 shows the ultrasonic guiding image after the heating. It can be found that the blood flow was blocked due to coagulation caused by the two-part needle. The vessels were successfully closed under the high temperature.

The abdomen of the Lan-Yu Pig was incised right after the heating, which is shown in Figure 16. The ablation zone was observed with a size of 8 mm×12 mm. Figure 17 shows the spleen two weeks after the surgery when the abdomen of the Lan-Yu pig was incised again. Compared to Figure 16, atrophy of the spleen can be clearly observed. Before the surgery, the volume of the pig’s spleen is about 220 cm³. After two weeks, the volume of the pig’s spleen is measured to be about 189 cm³. The percentage of the atrophy is about 14%.

In this experiment, the vessels in the spleen were closed under the inductive thermotherapy system by using a single two-part needle to reduce the blood flow and make the spleen atrophy. To increase the percentage of the spleen atrophy, two or more needles may be used. From the result, the developed system and apparatus can successfully treat the splenomegaly.
4. Conclusions

This study has demonstrated a new treatment method for minimal invasive surgery for splenomegaly. An inductive electromagnetic thermotherapy system was developed as a safe, efficient and useful medical equipment. In the in-vitro test, the heating effect of the two-part needles with different outer diameters was explored under the alternating magnetic field. The temperature distribution was measured in the porcine liver. The coagulation temperature and time were optimized to coagulate tissue and blood efficiently. In the in-vivo test, the vessels can be successfully closed in the spleen and the spleen atrophy without any complications can be achieved. In the future, we would like to extend it to more biomedical applications.

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