ABSTRACT

This study aimed to evaluate the technical success, radiation dose, safety and performance level of liverradiofrequency ablation using a computed tomography (CT)-guidedrobotic navigationsystem. All the procedures were done using MAXIO (Perfint healthcare Pvt Ltd.) machine using 16 slice CT scanners, under local anesthesia or IV sedation (general anesthesia) and aseptic precautions, under the supervision of trained radiologists. After marking the point of entry and target tumor, the path of the needle is confirmed on the planning software and the system calculates, coordinates angle & depth and positions the robotic arm. Radiofrequency ablation was successfully achieved in 15 patients with 32 lesions and confirmed on multiphasiccontrast-enhanced CT. MAXIO helps in precise placement of needle in complex angulated approaches. This method is more patient friendly and ensures maximum safety. Automated planning scans over manual planning in terms of technical difficulty, number of needle passes, time consumed, number of check scans and hence the patient's radiation dosage. This clinical trial depicts that therobotic-assisted planning and needle placement appears to be safe, with highaccuracy and a comparable radiation dose topatients. Thus making it acceptable for the routine clinical practice.


INTRODUCTION

CT-guided interventions are the effective procedure of choice to obtain tissue diagnosis&treatment in patients with lesions suggestive of malignancy at imaging-image-guided thermal ablation of primary liver tumors at radiofrequency ablation (RFA) and microwave ablation have emerged as attractive minimally invasive options for the treatment of liver malignancies, as first-line therapy and in patients ineligible for surgery. Probes are percutaneouslyinserted into thethorax and a volume of tissue is devitalized either by heat (using radiofrequency or microwave). Accurate placement of the probe is critical to achieving a high success rate and minimizing potential risks of the procedure. A totalfive patientshad liver metastases. Patients were treated with theCool tip RFA system (Valleylab,Boulder,Colorado,USA). Local anesthesia was performed with lidocaine/lignocaine and IV sedation was performed with Midazolam in the presence of anesthesiologist. All the lesions were less than 50 mm in maximum diameter (the average dimension of the tumor was 19 × 23 mm).

TREATMENTplanning and simulation

All the thermal ablation procedures were performed under general anesthesia. After intubation, the patients were wrapped in reassureablemobilizerstominimize patientmovement during the procedure. After intubation, the patients were wrapped in reassureablemobilizerstominimize patientmovement during the procedure. All the lesions were less than 50 mm in maximum diameter (the average dimension of the tumor was 19 × 23 mm).

BACKGROUND

• Imaging-guided RFA procedures are usually challenging due to patients breathing, especially during local anesthesia procedure.
• This is an ongoing prospective study with 25 patients targeted in Barnard institute of radiology, RGGGH Chennai.
• This was an initial phase assessment of the efficacy involving 15 patients underwent the CT-guided interventions utilizing the Robot-assisted Navigation system (Maxio, Perfint Healthcare).

Purpose

To evaluate the technical success, radiodose, safety&technical success of CT-guided thermal ablation using a computed tomography (CT)-guidedrobotic navigationsystem

MATERIALS AND METHODS

Patient population and study details

This study was done by receiving the approval of local institution review board. Between March 2018 and March 2019, 25 patients with previously diagnosed suggestive of malignancy at CT imaging both were referred to the radiology department of our hospital for the analysis. All enrolled patients gave their written informed consent to participate after being thoroughly informed of the benefits and potential risks of the procedure. A totalfive patientshad liver metastases. Patients were treated with the Cool tip RFA system (Valleylab,Boulder,Colorado,USA). Local anesthesia was performed with lidocaine/lignocaine and IV sedation was performed with Midazolam in the presence of anesthesiologist. All the lesions were less than 50 mm in maximum diameter (the average dimension of the tumor was 19 × 23 mm).

Robotic-assisted needle placement

One patient had previously unconfirmed the patient was positioned at thehepatic axiscoordinatesandextraneousity determined at the CT scan. The patient's skin in the intended region was prepared for the procedure. The patient's skin in the intended region was prepared for the procedure.
interventional procedures

but without using the assistance of a robot for probe placement. who had liver radiofrequency ablation performed by the same radiologist, a random historical control group of 10 patients (20 lesions) was also recorded. The doses were then compared with a total CT dose from the whole procedure including the multiphasic CT also recorded. The CT fluoroscopic dose (DLP) received by the patients during the probe placement and ablation was recorded. The complications related to the use of the robot or the procedures were assessed on a 1-5 point scale (refer Table 1 for the description of the scoring scheme) by the interventional radiologist for each robotic-assisted thermal ablation. Any deviations from the treatment plan, by guiding the needle along the planned trajectory. The radiologist then inserted the ablation probe through the bush and generally deployed the probe completely (in one go) to the heathust upon completion of the insertion of the probe, the end effectors of the robotic arm were detached from the probe and the robotic arm was returned to its original position. A CT fluoroscopy check examination was performed to ascertain the location of the ablation probe within the target volume. Ablation therapy was then started. Formultiple lesions, the process of needle insertion was repeated as determined by the treatment plan. The completeness of the ablation was determined by using multiphasic contrast-enhanced CT immediately after the ablation.

Patient respiratory motion control

To minimize tumor localization, the baseline CT, CT fluoroscopy check, and post-ablation contrast-enhanced CT were all performed at the expiration of the patient, with the airway disconnected from the ventilator. To minimize liver movement, the ablation probe excursion between the end expiration (when needle placement was carried out) and the end inspiration, the tidal volumes were set at a high respiratory rate. The end expiratory phase was considered safe by the attending anesthetist. Muscle relaxants were used regularly (especially when doing multiple placements) to minimize spontaneous breathing of the patient, so that the end expiratory phases were otherwise. Otherwise, the lossof muscle paralysis would impair the end tidal volume and place the liver at a much lower level.

Data collection and analysis

The orbital and craniocaudal angulations of the robotic arm were recorded for each lesion targeted in all patients. The numbers of adjustment of the needle to achieve satisfactory positioning within the desired tumor volume were documented. Deviations from the target location were also recorded. The performance level of the overall procedures was assessed on a five-point scale (refer Table 1 for the description of the scoring scheme) by the interventional radiologist for each robotic-assisted thermal ablation. Any complications related to the use of the robot or the procedures were also recorded. The CT fluoroscopic dose (DLP) received by the patients during the probe placement and ablation was recorded. The total CT fluoroscopic dose (DLP) received by the patients during the whole procedure including the multiphasic CT studies was also recorded. The doses were then compared with a random historical control group of 10 patients (20 lesions) who had liver radiofrequency ablation performed by the same interventional radiologist, but without using the assistance of a robot for probe placement.

RESULTS

Thermal ablation was successfully completed in 15 patients with 32 lesions, and confirmed on multiphasic contrast enhanced CT. No complications related to either the use of the robot or the thermal ablation was noted in this study. However, there was a single case of residual disease after the ablation. Table 1 demonstrates the patient demographic and treatment protocols for all the patients.

Thetotal number of lesions treated in each session ranged from one to a maximum of four lesions (mean of 2±1). The deepest lesion was 170mm, while the shallowest was 39mm from the skin's surface. The diameter of from 5 to 49 mm. The lesions were all targeted successfully with the assistance of the robotic device. Realignments of the probe were required in 6 of the 15 patients, without yasingle repositioning in each of the lesions. The average number of needle readjustment was 0.8±0.3 (less than 1). Therewerenorcono complications related to either the use of the robot or the thermal ablation was noted in this study. However, there was a single case of residual disease after the ablation. Table 1 demonstrates the patient demographic and treatment protocols for all the patients.

The total DLP per patient for the entire robotic assisted thermal ablation was 1438±436 mGy.cm, while the CT fluoroscopic dose per lesion was 34±268 mGy.cm. When compared with historical data from our standard ablation procedure without the assistance of the robotic device, the total DLP per patient (n=10) was 1721±768 mGy.cm, while the CT fluoroscopic dose per lesion was 1721±768 mGy.cm. When compared with historical data from our standard ablation procedure without the assistance of the robotic device, the total DLP per patient (n=10) was 1721±768 mGy.cm, while the CT fluoroscopic dose per lesion was 34±268 mGy.cm. The total DLP and CT fluoroscopic dose per lesion were reduced by 17 and 35%, respectively.

Fig. 1: Operational flow of the Maxio robotic system for interventional procedures.
Table 1: Patient demographics and treatment protocols of the robotic-assisted CT-guided thermal ablation for liver tumours (15 patients, 32 lesions)

<table>
<thead>
<tr>
<th>ID</th>
<th>Age</th>
<th>Sex</th>
<th>Diagnosis</th>
<th>Baseline contrast-enhanced CT scan (Yes or No)</th>
<th>Size of lesion(short Axis × Long Axis) (mm)</th>
<th>Depth of lesion from the surface (mm)</th>
<th>Angulations (Degree)</th>
<th>Orbital(+/-)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>84</td>
<td>M</td>
<td>Low rectal cancer post-anterior resection</td>
<td>Yes</td>
<td>21 × 21</td>
<td>78</td>
<td>45.7</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>66</td>
<td>M</td>
<td>Colorectal liver metastases at segments VII, II, III and I</td>
<td>Yes</td>
<td>9 × 5</td>
<td>126</td>
<td>25.0</td>
<td>3.2</td>
</tr>
<tr>
<td>3</td>
<td>74</td>
<td>M</td>
<td>Colorectal liver metastases at segments III</td>
<td>Yes</td>
<td>21 × 21</td>
<td>122</td>
<td>23.3</td>
<td>0.0</td>
</tr>
<tr>
<td>4</td>
<td>56</td>
<td>M</td>
<td>HCC at segment IVa</td>
<td>No</td>
<td>16 × 20</td>
<td>77</td>
<td>29.3</td>
<td>9.7</td>
</tr>
<tr>
<td>5</td>
<td>64</td>
<td>M</td>
<td>HCC at segments VI, VII and VIII</td>
<td>Yes</td>
<td>27 × 35</td>
<td>116</td>
<td>22.8</td>
<td>0.0</td>
</tr>
<tr>
<td>6</td>
<td>61</td>
<td>M</td>
<td>HCC post segmental hepatectomy, new lesions at segments IVb and VIII</td>
<td>No</td>
<td>13 × 14</td>
<td>81</td>
<td>49.4</td>
<td>0.0</td>
</tr>
<tr>
<td>7</td>
<td>55</td>
<td>F</td>
<td>HCC at segment VII</td>
<td>Yes</td>
<td>35 × 43</td>
<td>141</td>
<td>8.6</td>
<td>6.5</td>
</tr>
<tr>
<td>8</td>
<td>46</td>
<td>F</td>
<td>Endometrial carcinoma with liver metastases at segment VII</td>
<td>No</td>
<td>22 × 30</td>
<td>170</td>
<td>9.0</td>
<td>0.0</td>
</tr>
<tr>
<td>9</td>
<td>66</td>
<td>M</td>
<td>Colorectal liver metastases at segments V, VI, IX, I and II</td>
<td>Yes</td>
<td>19 × 23</td>
<td>71</td>
<td>5.5</td>
<td>0.0</td>
</tr>
<tr>
<td>10</td>
<td>66</td>
<td>M</td>
<td>Recurrent multicentric HCC at segments III, VI and II</td>
<td>Yes</td>
<td>32 × 38</td>
<td>105</td>
<td>6.8</td>
<td>3.3</td>
</tr>
<tr>
<td>11</td>
<td>61</td>
<td>F</td>
<td>Breast metastases to the liver</td>
<td>No</td>
<td>12 × 25</td>
<td>129</td>
<td>2.1</td>
<td>0.0</td>
</tr>
<tr>
<td>12</td>
<td>52</td>
<td>F</td>
<td>Multiple liver metastases from gastrointestinal tumour</td>
<td>No</td>
<td>20 × 25</td>
<td>86</td>
<td>35.2</td>
<td>0.0</td>
</tr>
<tr>
<td>13</td>
<td>80</td>
<td>F</td>
<td>Liver metastases at segments VII and VIII</td>
<td>No</td>
<td>17 × 21</td>
<td>99</td>
<td>29.9</td>
<td>20.2</td>
</tr>
<tr>
<td>14</td>
<td>60</td>
<td>F</td>
<td>Liver metastases at segment IV</td>
<td>No</td>
<td>25 × 42</td>
<td>104</td>
<td>36.0</td>
<td>11.7</td>
</tr>
<tr>
<td>15</td>
<td>66</td>
<td>M</td>
<td>HCC at segment VI/VII</td>
<td>Yes</td>
<td>45 × 49</td>
<td>98</td>
<td>11.5</td>
<td>4.6</td>
</tr>
</tbody>
</table>

Table 2: shows the comparison of patient radiation dose for robotic-assisted versus non-robotic assisted thermal ablation procedures.

**DISCUSSION**

Percutaneous CT-guided intervention is an effective method for image-guided biopsy and tumor ablation. However, the accuracy of CT-guided needle or probe placement, which is critical for good diagnostic yield, is highly dependent upon the physician’s experience. Additionally, the presence of vulnerable anatomy (such as bowel, nerves, or vessels in proximity to the target) in the needle path may slow tolerance for errors in needle placement. With conventional techniques, challenging tumortargeting frequently mandates multiple needle adjustments and intra-procedural imaging, which can prolong procedure duration as well as increase patient radiation exposure and procedural risk.[6,7] Recent advances in robotic technology procedures[8–13] have shown to achieve results comparable to surgical resection. However, its efficacy is reduced for larger tumours.[14, 15]. This may in part be attributable to the complexity of multi-probe placement (simultaneous or sequential), which is prone to human error, as well as the greaterheatsink effect with larger, more perfused tumours. Accurate probe placement is thus critical for successful large volume composite ablation and a tumour free margin.[1,16]. Navigational software and robotic assistance may offer a tailored solution to the physician confronting a technically challenging biopsyor ablation target.
The robot used in this study was a CT-compatible 3D tumortargeting and needle positioning system for interventional radiology procedures.

Localization and navigation systems performed with optical or magnetic localization spheres require multiple skin markers to be broadly placed prior to imaging.[20]. In addition, pre-procedure import of the 3D data to the robot’s workstation can be complex and time consuming and occupy a lot of space in the operation room. Devices that require time consuming interregistration and asusagereconomically unattractive and either are not used or used in daily routine. In contrast, the Maxio X system requires minimal effort to be mounted and registered to the CT device and can be operated by one person. These features reduced the complexity of the robotic-guided procedure. Wefoundthat robotic-assisted thermal ablation (RFA) has shown to achieve results comparable to surgical resection. However, its efficacy is reduced for larger tumours.[14, 15]. This
adequacy of the ablation can be checked in all three planes to determine successful ablation. If this is found to be inadequate, the tip of ablation needle can be repositioned or another different probe selected. As was previously reported [3], the greater control of the needle placement outside the bore of the CT gantry without exposure to CT fluoroscopy dose was again a tremendous benefit. This is especially helpful in patients who are large, as well as for those who have claustrophobia. Access to CT fluoroscopy during the procedures. Although our study showed no significant differences in the placement of multiple robotic-assisted needle placement, a recent study demonstrated that robotic-assisted needle placement is more accurate than manual needle placement [21, 22]. Certain imprecisions during manual needle placement are unavoidable.

A critical part of the capability of the Maxio system is in ensuring accurate registration of the planning datasets with the liver volume through the needling system. The system still not able to compensate for movements of the target region, especially those caused by respiration, since the planned trajectory is based on a static acquired 3D data set. This co-registration in our practice was achieved by performing all procedures under general anesthesia with intubation and muscle relaxants at the end of expiration, with the airway disconnected from the ventilator, producing consistent positioning. The muscle relaxants were used regularly, especially when multiple needle placements are necessary for the treatment, e.g., when multiple probes/needles are necessary for the treatment, e.g., when multiple probed/needles are necessary for the treatment, e.g., when multiple probed/needles are necessary for the treatment.

CONCLUSION

The system showed good accuracy for percutaneous needle placement for ablative therapy, with a radiation dose comparable to the historical controls. Even though the preliminary data were promising, the study was not randomized. A randomized controlled trial is needed to assess the robotic-assisted device for navigation and intervention on the beating heart.

REFERENCES