Original Research Paper

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ROBOT-ASSISTED RADIO FREQUENCY ABLATION OF PRIMARY AND SECONDARY LIVER TUMOURS: EARLY EXPERIENCE AT BIR, CHENNAI.

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ABSTRACT This study aimed to evaluate the technical success, radiationdose, 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, 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 completed in 15 patients with 32 lesions and confirmed on multiphasic contrast-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 scores 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.

KEYWORDS : Robot. Radiofrequency ablation .Microwave ablation. Liver tumor. CT-guided Interventional radiology

INTRODUCTION

CT-guided interventions are the effective procedure of choice to obtain diagnoses& treatment in patients with lesions suggestive of malignancy at imaging.Image-guidedthermalablationssu chasradiofre quencyablation (RFA) andmicrowaveablation have emergedasattr active minimally invasive interventional treatments of livermaligna ncies, as first-line therapy and in patients ineligible for surgery. Probes are percutaneously inserted into thetumor and a volume of tissue is devitalized either by heat (using radiofrequencyormicrowave). Accurate placement of the probe is critical to achievingnotonly technical success(for lesions high in thedomeor large lesions requiring multiple overlapping ablations), but also vital in ensuring adequate ablation margins to prevent local tumor recurrence [1]. Additionally, patient safety is compromised withimpreciseel ectrodeplacement, whichmayleadtomajor complications such as pleural and gastrointestinalperforations,lacerationofvesselswithbleeding, orthermalcollateral damage with bile duct stenosis, gastrointestinal inflammation and subsequent perforation[2]. Toimprovetrajectory planningandtargeting,surgicalnavigation systems have recently been adapted to the needs of interventionalradiology[3,4]. Thenavigation systems(commonlyknownas"robots")assistineitherplanningorplacing oftheneedles/probes,orallowtrackingthepositionofa surgical tool that is projected in real-time in the patient's correspondingcomp utedtomography(CT)images[5].TheaimoftheseCTcompatible robots is to increase the accuracy of needle or probe placementthroughthree-dimensional(3D)imagingandcomputerizedtrajectoryplanninginarbitr aryorientatedtracks,to improve the outcomes of interventional therapies. Further- more,inhighlyinaccessiblelesionst hatrequirem ultipleplane angulations, robotically assisted needle placement may improveaccesstothetargetbyallowingoff-axialpathsofneedle placement. Thegoalofourstudywastoevaluatethetechnicalsuccess, radiationdose,easeofuseandsafetyofanewcommercially available CT-guided robotic system, Maxio (Perfint Healthcare), in assisting treatment planning and tumor targeting for liver tumours ablative therapy.

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, radiationdose, safetyandper formanceleveloflivverradiofrequency 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 March2019, 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 participation after being thoroughly informed of the benefits and potential risks of the procedure. Atotalof15patients (32lesions) withprimaryorsecondary liver tumours were treated with thermal ablative therapy with the guidance of the robotic needle positioning system, Maxio (Perfint Healthcare), attached to a CTsystem (SOMATON Definition AS 16, Siemens Healthcare, Munich, Germany).Tenpatientshadnewandrecurrenthepatocellularcarcinoma(HCC),while fivepatientshadlivermetastases. Patients were treated with the Cool tip RFA system(Valley lab,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 × 23mm).

Treatment planning and simulation

All the thermal ablation procedures were performed under general anesthesia. After intubation, the patients were wrappedinreusablei mmobilizerstominimizepatientmovement during the procedure. Following baseline CT with suspended expiration, the lesions were identified. All the patientshadnon-contrastedbase lineCTs,exc eptsixpatients whoselesionsweredifficulttolocalize.TheC Timageswere then reconstructed to 1 mm thickness and transferred to the Maxioworkstationforsimulationandtreatmentplanning.The application software allows 2D and 3D visualization ofthevolumetric data. Once the volume of interest (VOI) was identified, the tumor was segmented automatically by the softwaretoallowverification ofthetargetvolume.Thisisdisplayedinaxialcoronalandsagittalplanes,to gether witha3Dsegmentedimage.Anydeviationfromthetumor margins can be manually adjusted by either cropping or adding to the target volume. The target point (center of the tumor volume) was then defined by the radiologist on the treatment plan. The entry point (needle puncture site on the skinsurface)wasdetermined bytakingintoconsi derationany critical structures in the needle path. This was done by scrolling the axial images manually on the treatment plan andascertainingiftheneedlepathtraversesanycriticalstructures,astheso ftwareisnotabletoreconstructanobliquityto seetheentireneedlep athinoneimage.Ifcriticalorganswere involved,theentrypo intneededtobemodifiedtochangetheneedletrajectory.Theoperatortheni nputthechoiceofablation device (RFA or microwave), including the length ofthe probethatwasgoingtobeused.Theworkstationdetermined theorbitalandcraniocaudalangulationsaswellastheminimum length of the probe required to complete the ablation .The system allows up to six probes to be plannedatonetime.The plan was carefullycheckedby theradiologisttoavoidcriticalorgansor boneacrossthetrajectory priortoconfirmingtheplan.Ifthe margins were inadequate, the target point or the entry point could bemodified.

Robotic-assisted needle placement

Oncethetreatmentplanwasconfirmed,thepatientwaspositionedattheex actcoordinateasdeterminedinthetreatment plan. The patient's skin in the intended region was prepared for the procedure. The skin and liver capsule along the projected path of the ablation probe was infiltrated with 10mlof1%lignocaine.Theroboticarmwasthenactivated and moved automatically to the desired location. Once the roboticarmwascompletelyhaltedatitsposition,theradiologistplacedana ppropriatebush(aplasticneedleholder)that hadadiametermatchin gthediameteroftheablationprobeat the end-effectors of the arm. The function of a bush is to minimize deviation of the needle entry point from the treatmentplan,byguidin gtheneedlealongthe planned trajectory. The radiologist then inserted the ablation probe through the bushandgenerallydeployedtheprobecompletely(inonego) totheendo fthebushuponcompletionofthe insertion of the probe, the end effectors were detachedfrom 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 thetarget volume.Ablationtherapywasthenstarted.Formultiplelesions,theproces sofneedleinsertionwasrepeatedas determined by the treatment plan. The completeness of the ablation was determined by using multiphasic contrast- enhancedCTimmediatelyaftertheablation.

Patient respiratory motion control

Tooptimizetumorlocalization,thebaselineCT,CTfluoroscopycheckan dpost-ablationcontrast-enhancedCTwereall performedatthee ndexpirationofthepatient,withtheairway disconnectedfromthe ventilator.Tominimizeliverandhence ablation probe excursion between the end expiration (when needleplacementwascarriedout) andtheinspiration,thetidal volumesweresetatahighrespiratoryrat eandhighO_2level considered safe by the attending anesthetist. Muscle relaxants were used regularly (especially when doing multiple placements)tominimizespontaneousbreathingofthepatient sothatthe endexpiratoryphaseswereconsistent.Otherwise, thelosso fm uscleparalysiswouldimpairtheendtidalvolume and place the liver at a much lowerlevel

Data collection and analysis

Theorbitalandcraniocaudalangulationsoftheroboticarm 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. Deviationso fthetipfromthece nteroft hetargeted location were alsorecorded. The performance level of the overall procedures was assessedonafive-pointscale (referTable 1forthedescription of the scoring scheme) by the interventional radiologistfor each robotic-assisted thermal ablation. Any complications related to the use of the robot or the procedures were also recorded. TheCTfluoroscopicdose(DLP)receivedbythepatients during the probe placement and ablation was recorded. The totalCTdosefromthewholeprocedureincludingthemulti- phasic CT studies was also recorded. The doses were then compared with a random historical control group of 10 patients(20lesions) whohadliverradiofrequencyablationperformedbythesameradiologist, butwithoutusing theassistanceofarobotforprobeplacement.

IMAGES FOR THIS SECTION:

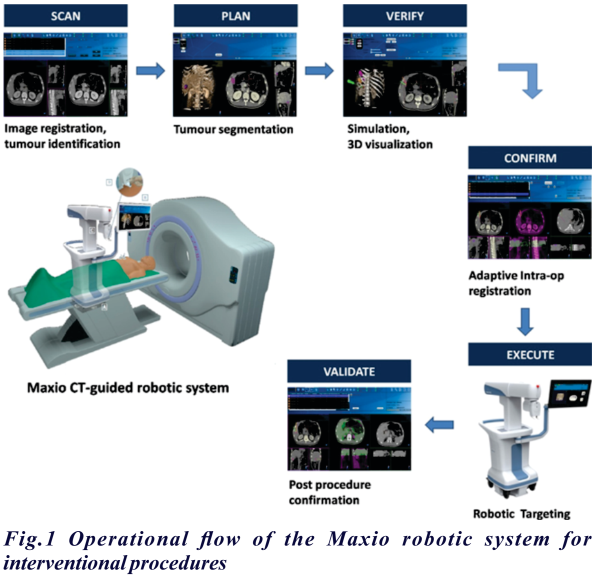

Fig.1 Operational flow of the Maxio robotic system for interventional procedures

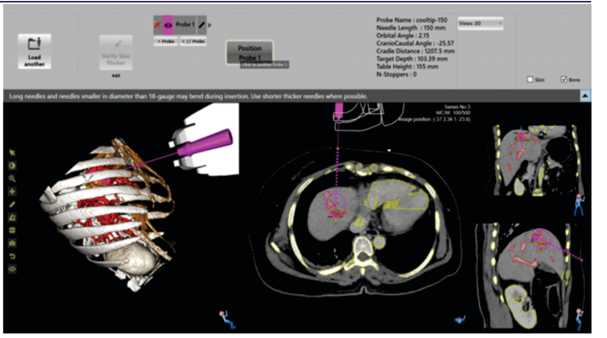

Fig. 2: Robot-assisted Navigation system for CT-guided percutaneous lungprocedures. Planning the procedure in the provided software.

Fig. 3: TheinterventionradiologistinsertedtheRFAprobetothetarget tumorthroughthebushlocatedattheend-effectoroftheroboticarm.

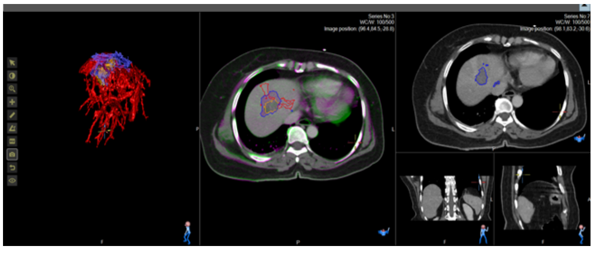

Fig. 4: Post verification image – post procedure confirmation .In the above case the probe was inserted in a single shot with accurate depth control to avoid damage to proximal structures, thus accurately helping tumor coverage from the tip of the probe.

RESULTS

Thermal ablation was successfully completed in 15patients with 32 lesions, and confirmed on multiphasic contrast enhanced CT. No complications related to either the use ofthe robot or the thermal ablation was noted in this study.However, there was a single case of residual disease after the ablation.Table1demonstrat espatientde mographyandtreatment protocols for all thepatients.

Thetotalnumberoflesionstreatedineachsessionranged from one to a maximum of four lesions (mean of 2±1). The deepestlesion was170mm,whiletheshallowestwas 39mm from the skin's surface. The diameter of from 5 to 49 mm.The lesions werealltargete dsuccessfullywiththeassistanceoftherobotic device. Readjustments of the probe were required in 6 of the15 patients,withonl yasinglerepositioningineachofthelesions. The average number of needle readjustment was 0.8±0.3(less than 1). Therewerenoca sesofneedlereinsertionsrequired.Themean performanceleve lratedfortherobotic-assistedablationprocedure was4.4±0.6.

The total DLP per patient for the entire robotic assisted thermalablationwas1438±436mGy.cm,whiletheCTfluoroscopicdosep erlesionwas342±268mGy.cm.Whencompared with historical data from our standardablation 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 601±387 mGy.cm.The total DLPand CT fluoroscopic dose perlesionwerer educedby17and35%,respectively.

Table1 : Patient demography and treatment protocols of the robotic-assisted CT-guided thermal ablation for liver tumours (15 patients, 32 lesions)

ID	Age	Sex	Diagnosis	Baseline contrast-enhanced CT scan (Yes or No)	Sizeoflesion(Short Axis × LongAxis)		Depth of Lesion from the surface	Angulations (Degree)	
					Short axis (mm)	Long axis (mm)	(mm)	Orbital(+) Orbital(−)	cc(+)
1	84	M	Low rectal cancer post-anterior resection	Yes	21	21	78	45.7	
			with liver metastases at segments V,		20	21	119	45.8	0.0
			VI and VI		32	37	116	61.7	6.0
2	66	M	Colorectal liver metastases at segments	Yes	5	9	126	23.0	5.9
			VII, II, III and I		8	12	89	26.2	3.2
					16	24	43	20.3	0.0
					6	6	153	40.8	0.0
3	74	M	Colorectal liver metastases at	Yes	21	21	122	23.3	0.0
			segments III						
4	56	M	HCC at segment IVa	No	16	20	77	29.3	9.7
5	64	M	HCC at segments VI, VII and VIII	Yes	27	35	116	22.8	0.0
					23	29	152	44.7	0.4
					21	43	104	35.8	0.0
6	61	M	HCC post segmental hepatectomy,	No	11	13	112	22.5	0.0
			new lesions at segments IVb and VIII		13	14	81	49.4	0.0
					14	14	94	30.8	17.3
7	55	F	HCC at segment VII	Yes	35	43	141	8.6	6.5
8	46	F	Endometrial carcinoma with liver	No	22	30	170	9.0	0.0
			metastases at segment VII						
9	66	M	Colorectal liver metastases at segments	Yes	19	23	71	5.5	0.0
			V, VI, IIX, I and II		15	21	112	21.0	
					25	30	128	24.9	0.0
					21	22	53	30.6	0.0
					16	20	108	24.7	0.0
10	66	M	Recurrent multicentric HCC at	Yes	11	15	79	39.9	0.0
			segments III, VI and II		32	38	105	6.8	3.3
					10	11	128	1.8	0.0
11	61	F	Breast metastases to the liver at	No	12	12	39	2.1	0.0
			segments III, VI and VIII		20	23	86	35.2	0.0
					17	19	68	0.8	26.1
12	52	F	Multiple liver metastases from	No	20	23	52	8.6	0.0
			gastrointestinal stromal tumour		19	21	99	29.9	20.2
			at segments VII and V/VI						
13	80	F	Liver metastases at segments	No	13	14	117	25.6	0.0
			VII and III		12	14	126	0.0	36.8
					8	9	73	48.2	0.0
14	60	F	Liver metastases at segment IV	No	25	42	104	36.0	11.7
15	66	M	HCC at segment VI/VII	Yes	45	49	98	11.5	4.6

Table2: shows the comparison of patient radiation dose for robotic- assisted versus non-robotic assisted thermal ablation procedures.

	Robotic-assisted thermal ablation (n=15)	Non-robotic-assisted thermal ablation (n=10)	Dose reduction with robotic assistance (%)
Total DLP perpatient (mGy·cm)	1438±436	1721±768	17
CT fluoroscopic dose perlesion (DLP, mGy·cm)	342±268	601±387	35

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 physicianexperience. Additionally,thepresenceofvulnerable anatomy(suchasbowel, nervesorvesselsinproximitytothe target) intheneedle pathh aslowtoleranceforerrorsinneedle placement. With conventional techniques, challenging tumortargeting frequently mandates multiple needle adjustments and intra-procedural imaging, which can prolongprocedure duration as well as increase patient radiation exposure and proceduralrisk[6,7]. Recentad vances inrob otic allyguided interventionshavebeensuccessfulinassistingplacementof needlesorrelatedinstrumentsforsurgeryandinterventional procedures[8–13].Forsmalltumours,suchasHCCthatare<3cm,RFAhas been shown to achieve results comparable to surgicalr esection.However,itsefficacyisreducedforlargertumours[14, 15]. This may in part be attributable to the complexity of multi-probe placement (simultaneous or sequential), which ispronetohumanerror, aswellasthegreaterheatsinkeffect with larger, more perfused tumours. Accurate probe placement is thus critical for successful large volume composite ablation and a tumor free margin [1,16].Navigational software and robotic assistance may offera tailoredsolutio ntophysiciansconfrontingatechnicallychallengingbiopsyorablationtar get.The robot used in this study was a CT-compatible 3D tumortargetingandneedlepositioningsystemforinterventional radiol ogy 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 and processing of the 3D data to the robot's workstation can be complex and time consuming and occupy a lot of space in the operationroom. Devicesthataretimeconsumingintermsofpre-arrangement andusageareeconomicallyunattractive andar ether eforenot likely to be used in daily routine. In contrast, the Maxio requires minimal effort to be mounted and registered to the CT device using the InstaReg™ technology. The system is motorized and can be operated by one person. These features reduced the complexity of the robotic-guided procedure.Wefoundtheov erallsatisfac tionwit htheperformance ofthesystemtobehigh. Furthermore, theplann ingsoftware on the Maxio system allows the segmentation of thetumor and subsequent selection of the ablation probe (RFA) with the pre-determined ablation volumes to be overlaid on the target tumor. 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 adifferent probe selected.Aswaspreviouslyreported[3],thegreatercontrolandease ofneedleplacementoutsidetheboreoftheCTgantrywithout exposure to CT fluoroscopy dose was again a tremendous benefit. This is especially helpful in patients who are large, aswellasforthelesi onsthatre quiremorelateralaccessofthe needle. Eventhoughnoneo fthepatientsinthisstudyrequired placementof multiplep robessimultaneously,webelievethis systemwillb etrulybenefici alwhenmultipleprobes/needles are necessary for the treatment, e.g., Cool-tip RFA needles withaswitch ingcontr oller. Additionally, robotic-assistedinterventionswouldbeusefulforthose whodonothave access to CT fluoroscopy during theprocedures. Although our study showed no significant differences of patient radiation dose between robotic-assisted andconventionalthe rmalablation, thismayber elatedtotheexpertiseof theoperatorinth isstudy. Previouss tudiesnotedthedecreased accuracy of inexperienced operators when placement of the needles was performed manually under the guidance of CT fluoroscopy [21, 22]. Certain impreciseness during manual needleinsertionisunavoidable.

A critical part of the capability of the Maxio system is in ensuringaccurateco-registrationoftheplanningdatasetswith livervolumeatthetimeofneedleinsertion,asthesystemis 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 intubationandmusclerelaxantsattheendofexpiration,with theairwaydisconnectedfromventilator-producedconsistent positing.Themusclerelaxantswereusedregularly,especially whendoingmultipleplacements.Otherwise,thelossofmuscleparalysis wouldimpairtheendtidalvolumeandplacethe liveratam uchlowerlevel.ThebaselineCT,needleplacement andpost-procedur eCTacquisitionswereallperformedatthe endofexpir ationonce theventilatorwasdisconnected.Others have suggested that anaesthetic man oeuvres, such as high frequency jetventilat iontored ucerespiratorymotion,significantlyreduceradiationdose[23].However ,thesesystemsare expensivean drequireagrea terskillset. Additionally,weused low tidal volumes with high respiratory rate and high O_2 to minimizeliver excursio nandneedlemovementinthecranio-caudaldirection.

Theuseofrobotstoassistinthermalablationmayrequirea majorchange tothecurrentworkflow,withadditionalstepsto the procedure. These include docking the robotic system, importingth eimage sfromtheCTconsoleintotheworkstation, segmenting the tumor, planning the entry and target points, inputting theleng thoftheneedle,andfinallysending the information to the robotic arm. Thus, there would be a needtoredefinet herole sofdiff erentm embersofthemedical teamwithuse ofrobot icassist edthermal ablation.Acomprehensive work flow chart, with staff being well trained in operating the robot, also needs to beestablished.

CONCLUSION

The system showed good accuracy for percutaneous needle placement for ablative therapy, with a radiation dose comparable tothe historicalcontrols.Eventhoughthes epreliminarydataw ere promising, the study was not randomized. A randomized controlledstudywi thalargersamplesizecomparingrobotic andnon-robotic-assistedtherma lablationneedstobecarried out to determine theoutcomes. This clinical trial depicts that therobotic-assistedplanning andneedleplacem entappearstobesafe,withhighaccuracy and a comparable radiation dose topatients.Thus making it acceptable for the routine clinical practice.

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