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Robot-Assisted Navigation System For Percutaneous CT Guidedbiopsies With A Comparison of Conventional Manual Technique

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Abstract
Objective: *To evaluate the performance of a robotic system for CT-guided biopsy in comparison to the conventional manual technique.*
Materials and methods*: Patientsreferred for CT-guided biopsy were randomly assigned to two groups namely, Robot-Assisted Procedure (Group A) and Conventional Procedure (Group B). Procedure duration, dose length product (DLP), accuracyof the needle positioning, diagnostic performance of the biopsy and rate of complications were evaluated to assess the clinical performance of the robotic system as compared to the conventional technique.*
Results*:All biopsies were successfully performed. Procedure duration and radiation dose were significantly reduced in group A as compared to group B. Accuracy of theneedle positioning, diagnostic performance of the biopsy and rate of complications were similar in both groups.*
Conclusion*: Robot-assisted CT-guided biopsy can be performed safely, with high diagnostic accuracy thereby reducing procedure duration and radiation dose in comparison to the conventional manual technique.*
Key Points: *CT-guided biopsy is the main procedure in tumor diagnosis for various body organs.*
1 The robotic device facilitates percutaneous needle placement under CT guidance.
2 Robot-assisted CT-guided biopsy reduces procedure duration and radiation dose.
Keywords*:Robot,Biopsy, Cancer.CT-guidance. Interventional radiology*

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I. Introduction

CT-guided biopsy is the effective procedure of choice to obtain diagnoses in patients with lesions suggestive of malignancy at imaging [1–3]. Following the recent advances in targeted therapies, biopsy of unresectable lesions has also become necessary to assess genetic mutations in unresectable non-small cell cancers (NSCLC), with core biopsy usually being preferred to aspiration cytology owing to the larger specimens made available for molecular analysis [4]. CT-guided biopsy can be performed either with the step-and-shoot or the fluoroscopic technique: the step-and-shoot approach is preferred in larger, non-moving lesions, while CT-fluoroscopy is more advantageous when targeting smaller lesions and lesions that are susceptible to respiratory motion [5]. Both procedures have technical limitations that should be taken into consideration; in particular the step-and-shoot technique is based on the operator's subjective assessment of needle path and positioning and may result in increased procedure duration and complication rate, whereas CT-fluoroscopy is significantly faster and more precise but significantly raises radiation dose to both operator and patient [6, 7]. Various assisting technologies have been proposed to increase the diagnostic accuracy and reduce the duration of CT-guided biopsies, including external laser targeting [8] and augmented reality (i.e. with a live indirect view of anatomy by computer-generated video input) [9]. Dedicated interventional robotic systems that operate under imaging guidance also became available recently [10].

However, while these systems may theoretically represent an important step toward the automation of interventional procedures, clinical experience and comparative data with conventional techniques are still lacking or insufficient. The MAXIO (Perfint Healthcare Pvt. Ltd) is a FDA approved robotic positioning system that facilitates percutaneous needle placement during CT-guided interventional procedures and that has been successfully tested for CT-guided biopsy and ablation on phantoms [11] and for clinical radiofrequency ablation of liver lesions [12]. The objective of this study was to evaluate the clinical performance of this system for CT-guided biopsy of lesions in comparison with the conventional manual technique.

II. Materials And Methods

2.1 Patient population and study details

This was a comparative study done by receiving the approval of local institution review board. Between July 2016 and December2016, 75 patients with previously diagnosed suggestive of malignancy at CT imaging both were referred to the radiology department of our tertiary care hospital for the analysis. The patients were referred for CT-guided biopsy and randomly assigned to group A (robot-assisted procedure) or group B (conventional procedure). All enrolled patients gave their written informed consent to participation after beingthoroughly informed of the benefits and potential risks of the procedure.

Pre-procedure

All procedures were performed by theradiologist on a 128-slice scanner (Philips). An axial breath-hold scan (Detector configuration 128×1 mm, slice thickness 1 mm, reconstruction interval 1 mm) was acquired in all cases prior to biopsy, to confirm the presence and to assess the position of the target lesion. Patients were laid on a vacuum stabilization mattress and positioned to reduce the patient movement as well as to avoid critical structuresand visceral organs (No-Go regions).Localanesthesia was performed with lidocaine/lignocaine along the projected path of the biopsy needle into the soft tissues. In all cases, quick core biopsy end-cutting needle was used for tissue sampling. Targeting CT scans were acquired with a low-dose interventional protocol (Detector configuration 128×1 mm, slice thickness 1 mm, reconstruction interval 1 mm).

Conventionalbiopsy technique

All conventional biopsies were performed with the step-and-shoot technique to assess needle positioning and angulation. The z-axis extension of targeting scans was limited to include only the needle and the target lesion. A minimum of two scans (before the pleura and into the lesion) was required to target lesions adjacent to the chest wall and a minimum of three scans (before the pleura, midway to the lesion, into the lesion) was required for deeper lesions. For liver a minimum of three scans (through the hepatic capsule, midway to the lesion, into the lesion) was required. Similarly, for kidney a minimum of three scans (through the renal capsule, midway to the lesion, into the lesion) was required. Additional scans and multiplanar reconstructions were performed in real time when necessary for needle adjustment. Once the needle tip was in position, biopsy was performed with a combination of aspiration and push/rotation movements.

Robot-assisted biopsy technique

Positioning and docking of the robotic system were performed as previously described [11], with the arm and planning console located to the side of the CT bed (left or right, depending on the required access) and firmly fixed to ground metal plates on the floor to ensure stability.Images were then transferred over a local area network to the MAXIO workstation for biopsy planning. Planning is done using the planning software. Planning the entry and the target region can be done either on single slice or across slices, based on the requirement of the physician.Each parameter was readily modifiable by the operator to avoid critical structures, such as the visceral organs, ribs and vessels. Once the plan was confirmed, the CT table was moved to the coordinates displayed on the workstation and the robotic arm was activated and positioned for biopsy execution. Adisposable bush was placed at the end effector of the robotic arm to guide needle insertion. Subsequently, the needle was manually inserted through the skin surface directly into the lesion in a single pass. After releasing the needle from the end effector, the robotic arm is pulled back and the needle positioning was confirmed with a further CT scan and adjustments were performed if required. Biopsy was then performed similarly to the conventional approach.

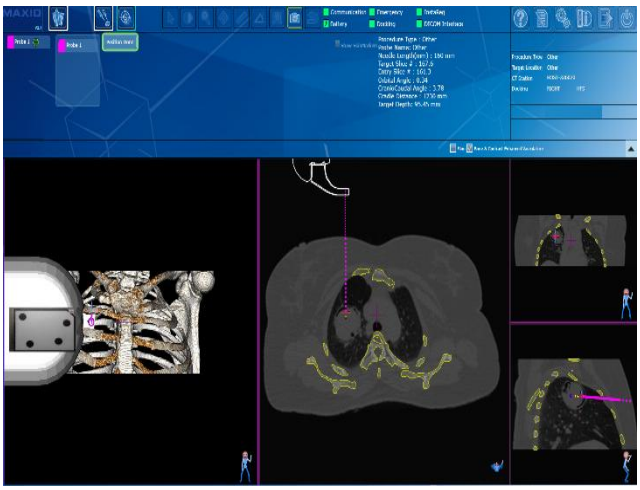

Fig. 1 Planning image of a lung biopsy.Planning Software projected the needle pathway. The lung lesion was targeted for lung biopsy

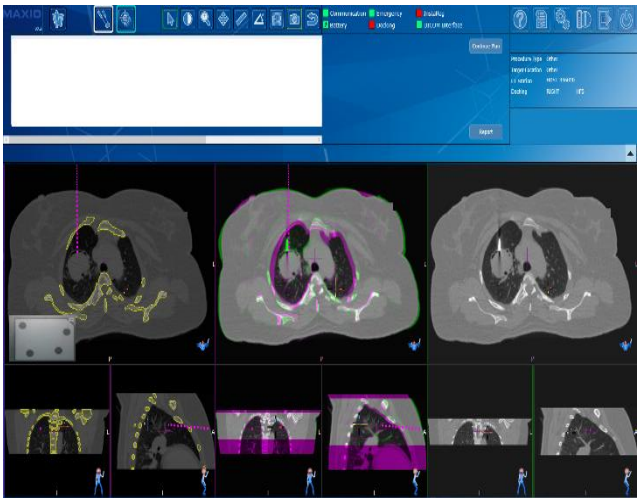

Fig. 2 Verification images after the biopsy needle insertion (Left: original planning image; Middle: overlaid image; Right: The biopsy needle within the lesion). The biopsy needle position was almost the same as the original planning pathway

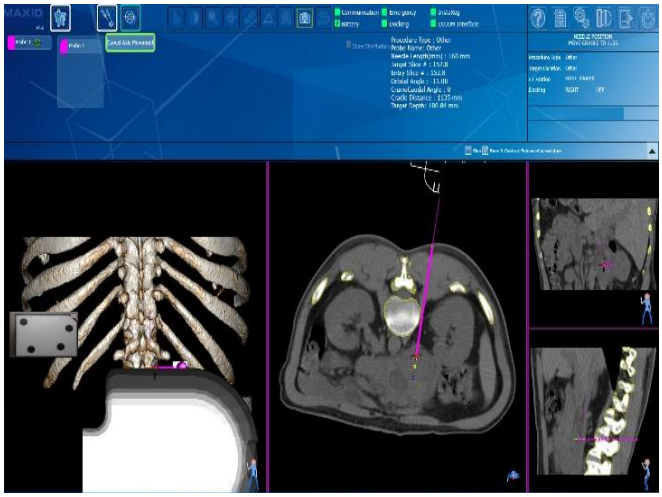

Fig. 3

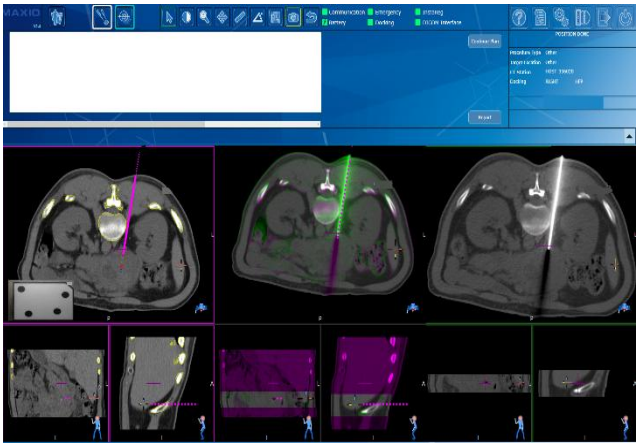

Fig. 4

Fig. 3&4 Biopsy planning on the MAXIO workstation. The entry point on the skin and target lesion are determined by the operator. The angulations and insertion path of the needle are automatically calculated by the workstation and displayed in real time

III. Data Analysis

To statistically substantiate the significant differences of clinical and technical performance, between the conventional biopsy approach and the robot-assisted technique, the following parameters were evaluated in the two groups:

1 Procedure duration (including planning time) and doselength product (DLP) were compared.
2 Number of needle adjustments was compared.
3 Orbital and craniocaudal angular deviations at the entry & targetfrom the needle path were calculated indegreesfor robot-assisted biopsies.
4 Diagnostic performance of the biopsy procedure wasevaluated qualitatively.
5 The rate of complications in the two groups was evaluated.

IV. Results

All biopsies were successfully performed under CT guidance in both groups. In group A procedure duration was significantly shorter($p=0.001$) when compared to group A. DLP was lower-both the total DLP and DLP of check scan verification, and just occasional needle adjustments were required as compared to group B. The RMS (i,e) orbital(transversal on the x-axis) and craniocaudal (longitudinal on the z-axis) angular deviationsfrom the projected needle path in robot-assisted biopsies were $1.2\pm1.01°$. The diagnostic performance of CT-guided biopsies was similar in the two groups. The rate of complications was significantly lesser in group A when compared to group B, with just 2% of complication in robot assisted procedure and 11% in conventional procedure. Full results of the assessment of the clinical and technical performance of the two groups are given in Table 1.

V. Discussion

Image-guided interventional techniques currently represent a fundamental tool in diagnosis and treatment of oncologic pathologies. Among the various guiding modalities, CT is the method of choice owing to its excellent spatial and contrast resolution for the visualization of structures that safely allows biopsy in thoracic, abdomen and pelvic region, percutaneous tube placement and ablation of tumors. The conventional technique for CT-guided interventional procedures requires a trial-and-error method with the step-and-shoot approach, or the application of a real-time fluoroscopic monitoring to visualize and modify the path of needles and percutaneous probes. Even if the clinical performance of conventional approaches is highly reliable in expert hands [4–7], these methods present well-known technical limitations and their successful application depends significantly on operators' manual skill and experience. In order to reduce such operator dependence, several assisting devices have been developed and tested in clinical practice, including external laser [8] or optical [14] targeting systems that project and/or guide the needle path onto the skin surface, electro-magnetic tracking with image fusionand augmented reality system under infrared guidance that display a real-time simulation of needle movements [9]. Preliminary reports are encouraging, but it should be noted that the success of these technologies is highly dependent on the integration between the assisting software/hardware, the CT system and the operator, with increased complexity and costs as compared to conventional techniques.
Moreover, with the approaches mentioned above the dependence on operator experience is reduced but not eliminated, not mentioning the need for adequate training. On the other hand, the use of medical robots for surgical or imaging-guided procedures allows extremely accurate tool guidance with stable access, leading to increased precision, accuracy and reproducibility in a variety of applications, including percutaneous ablations, biopsies, orthopedic fixture placement, hollow viscera or solid organ access [10]. While earlier robots required extensiveinstallation, and were often cumbersome to operate, being time consuming and economically disadvantageous, more recent systems, such as the MAXIO, require minimal effort to be mounted and registered to the imagingdevice [11], reducing the complexity of the procedure. Also, the fully automated movement of the robotic arm represents a relevant advantage that removes the need for manual or joy-stick adjustments in the pretreatment phase that are necessary with other devicesand may further complicate the clinical workflow. From a clinical point of view, our study demonstrated in a large patient population that the presented robotic system facilitates CT-guided biopsies, with results that are substantially in line with previous reports on biopsies in phantoms [11] and clinical radiofrequency ablation of liver lesions [12]. It should be considered that, apart from these two preliminary studies performed with the same robotic platform, there is no literature evidence of large clinical series of robot-assisted CT-guided interventions, hence,an indirect comparison with the performance of different robotic devices is currently impossible. In our single-center experience, the precision in lesion targeting, the diagnostic performance of the biopsy sampling and the rate of complications in the robot-assisted procedures were comparable to those of conventional biopsies, with accurate needle positioning and very few adjustments required even in lesions as small as 15 mm, but the use of the robot significantly reduced procedure duration and radiation dose in comparison to the unassisted technique. This observation is particularly relevant, since in our study all procedures were performed by an

operator with previous experience in CT-guidedbiopsies and, notwithstanding this expertise,significant reduction of procedure duration and radiation dose were in any case obtained in robot-assisted procedures as compared to the conventional technique. In this regard, future work should aim to evaluate when and how operators with different levels of experience may benefit from robot assistance in daily clinical routine, and assess potentialdifferences in the clinical performance of robot-assisted procedures between expert and non-expert radiologists.Moreover, even if a dedicated cost-analysis is currently unavailable, it could be speculated that the use of interventional robotic systems will be probably even more beneficial in clinical settings in which financial resources or time for appropriate training of interventional radiologists is lacking, pushing less expert, non-interventional operators to perform simple imaging-guided procedures.Eve if these preliminary results are encouraging, this study has some limitations. First, the sample size was not determined in advance with a power analysis to increase the relevance of the statistical evaluation. Moreover, a statistical sub analysis based on the anatomic characteristics of the target lesions (size, distance and position) was not performed; hence we cannot provide clustered data on system performance for the biopsy of smaller and hardly accessible lesions, which should be the ideal target for robot-assisted procedures. Last, the homogeneity of the organs and the corresponding lesion taken for the comparison study was not assessed. Notwithstanding these limitations, the results of our study demonstrate that robot-assisted CT-guided biopsy is a safe and accurate interventional technique that can reduce procedure duration and radiation dose in comparison to the conventional manual approach even in expert hands. Further studies are needed to confirm these data and to evaluate the performance of robot-assisted interventional procedures in other clinical scenarios.

Table 1 Full results of the assessment of the clinical and technical performance of the two groups

Procedure duration (min)	11.7±2.60 (range 8–20)	24.65±10.8 (range 15–61)	0.001
DLP (mGy)- Total	536.13±135.7 (range 267–780)	647.31±346.18 (range 254–2056)	0.001
DLP (mGy)- Check scan	134.4±76.11 (range 65-297)	342.22±196.8 (range 73-995)	0.002
Number of check scan	1.02±0.64 (range1-2)	3.34±2.88 (range 1-14)	0.001
Number of needle adjustments	0.31±0.65 (range 0–1) less than 1	3.25±2.69 (range 0–13)	0.002
RMS	1.21±1.02	5.45±2.03	0.003
Complications (%)	1	8	0.002

Values are expressed as average±standard deviation

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