

KEYWORDS : Interventional Non-vascular, Oncology, Percutaneous, Localization, Ablation Procedures.

method. This clinical trial depicts the advantages of the automated CT guided planner in reducing the procedure time and radiation dose and

ensuring patient safety with high diagnostic accuracy, thus making it acceptable for the routine clinical practice.

# INTRODUCTION

CT-guided interventions are the effective procedure of choice to obtain diagnoses& treatment in patients with lesions suggestive of malignancy at imaging. CT-guided biopsy can be performed either with the step-and-shoot or the fluoroscopic technique: the step-andshoot approach is preferred in larger, non-moving lesions, while CTfluoroscopy is more advantageous when targeting smaller lesions and lesions that are susceptible to respiratory motion []. 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 CTfluoroscopy is significantly faster and more precise but significantly raises radiation dose to both operator and patient [, ]. Various assisting technologies have been proposed to increase the diagnostic accuracy and reduce the duration of CT-guided biopsies, including external laser targeting [] and augmented reality []. Dedicated interventional robotic systems that operate under imaging guidance also became available recently []. 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 [] and for clinical radiofrequency ablation of liver lesions []. The objective of this study was to evaluate the clinical performance of this system for CT-guided intervention of percutaneous lesion.

### BACKGROUND

- Imaging-guided biopsy procedures are usually challenging due to
  patients breathing, especially during local anesthesia procedure.
- This is an ongoing prospective study with 100 patients targeted in Barnard institute of radiology, RGGGH Chennai.
- This was an initial phase assessment of the efficacy involving 100
  patients underwent the CT-guided interventions utilizing the
  Robot-assisted Navigation system (Maxio, Perfint Healthcare).

### PURPOSE

To evaluate the new Robot-assisted Navigation System for CT-guided Lung procedures with the assessment of the accuracy of needle placement, radiation dose and performance level

## 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, 100 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.

## PRE-PROCEDURE

All procedures were performed by the radiologist on a 16-slice scanner (SIEMENS). An axial breath-hold scan (Detector configuration 16×1 mm, slice thickness 1 mm, reconstruction interval 1 mm) was acquired

in all cases prior to procedure, 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 structures and visceral organs (No-Go regions). Local anesthesia 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  $16 \times 1$  mm, slice thickness 1 mm, reconstruction interval 1 mm).

### **METHODS AND MATERIALS**

- All the procedures were performed under local anesthesia.
- The lesions were identified in the baseline plain CT scans.
- The targeted needle pathway was then planned in the provided software of the Robotic system.
- The primary end point was the satisfactory instrument position for the intended intervention.
- Patient demographics were captured.
- · Adequacy of needle tip placement was measured.
- Target parameters such as lesion size and depth from skin were noted.
- Planning time (time from baseline CT scan to local anesthesia needle insertion, including planning procedure in provided software) wasrecorded.
- Navigation time (time from local anesthesia needle insertion to interventional needle to target lesion) were recorded.
- The performance level was documented for each procedure on a five-point scale (5-1: excellent-poor).
- The total radiation doses were recorded and compared against 10
  patients with conventional CT-guided thoracic procedures and 10
  patients with CT fluoroscopy thoracic procedures.
- All procedures were performed by experienced interventional radiologist.

## **ROBOT-ASSISTED TECHNIQUE**

Positioning and docking of the robotic system were performed as previously described [], 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. 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. A disposable 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. Procedure was then performed similarly to the conventional approach.

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### **IMAGES FOR THIS SECTION:**



Fig. 1&2: Overall view of Robot-assisted Navigation system in the CT suite.



Fig. 3: Robot-assisted Navigation system for CT-guided percut ane ous lung procedures. Planning procedures in the provided software.



Fig. 4, 5&6: Robot-assisted Navigation system for CT-guided percutaneous lung procedures. Needle placement via the robotic arm at the location of planned pathway.



Fig. 7: Planning Software projected the needle pathway. The lung lesion was targeted for lung biopsy.



Fig. 8: Verification images after the biopsy needle insertion (Left: original planning pathway; Middle: Combined images; Right: The biopsy needle within the lesion). The biopsy needle position was almost the same as the original planning pathway.

## RESULTS

- 50 males and 50 female are patients in Robotic group.
- Average age was 67.1 years (range from 25 to 85).
- Most of the cases underwent CT guided tumor FNA and/or Biopsy.
- Very few had lung tumor thermal ablation, fiducial marker insertion and lung abscess drainage.
- Average lesion size was 3.0cm (range from 0.8 to 7.8cm).
- Lesion depth was 5.6cm on average (range from 2.8 to 9.5cm).
- All of the interventions met the primary end point of satisfactory instrument positioning.
- 6 cases required a second planning procedure for targeted needle pathway as these patients cannot achieve the same breath holding during the procedures.
- 1 case required a third planning procedure due to the above same reason.
- Average Planning time was 3mins and Navigation time was 7 mins.
- Performance levels were 4.69 on average.
- 10 cases complicated with minimal to small pneumothorax while only 3cases needed chest drain insertion.
- Robotic group: Radiation dose (Dose Linear Product) was 262.7mGycm on average (range from 83.7 to 512.7mGycm).
- Conventional CT-guidance group: Radiation dose (Dose Linear Product) was 645.4mGycm on average (range from 285.1 to 2043.5mGycm).



Graph1: Radiation dosage Conventional V/S Robotic group

### CONCLUSIONS

- Our experience demonstrated the effectiveness of the Robotassisted Navigation system for CT-guided percutaneous interventions (including FNA, Biopsy, RFA, abscess drainage) with a lower radiation dose compared with conventional CTguidance procedures and similar radiation dose compared with CT fluoroscopy procedures.
- No radiation exposure to the interventional radiologists as compared with CT fluoroscopy procedures.
- The average Planning and Navigation time were 10 minutes and 8 minutes respectively, which was relatively not time-consuming.
- Performance level was excellent. The planning software was easy to learn and the robotic device was easy to handle.
- The targeting success rate for a satisfactory intervention was 100%.
- Robot-assisted Navigation system is potentially valuable for more technically demanding procedures, like Irreversible Electro poration (IRE).

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