AN ORIGINAL STEREOTACTIC DEVICE FOR TRANSTHORACIC CT-GUIDED BIOPSY. AN EXPERIMENTAL STUDY

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REZUMAT

Obiective: Puncţiile transtoracice ghidate CT asistate de dispozitivul stereotactic sunt superioare din punct de vedere al acurateţii comparativ cu metoda free hand, ceea ce înseamnă mai puţine complicaţii. Rezultatele obţinute în acest studiu sunt superioare cu privire la serviciul de precizia comparativ cu metoda stereotactic hand, respectiv a fost atinsă într-un procent de 100%. Rezultatele obţinute în acest studiu sunt superioare cu privire la serviciul de precizia comparativ cu metoda stereotactic hand, respectiv a fost atinsă într-un procent de 100%. Rezultatele obţinute în acest studiu sunt superioare cu privire la serviciul de precizia comparativ cu metoda stereotactic hand, respectiv a fost atinsă într-un procent de 100%.

Concluzii: Punctele transtoracice ghidate CT asistate de dispozitivul stereotactic sunt superioare din punct de vedere al acurateţii comparativ cu metoda的手 free hand, ceea ce înseamnă mai puţine complicaţii. Rezultatele obţinute în acest studiu sunt superioare cu privire la serviciul de precizia comparativ cu metoda stereotactic hand, respectiv a fost atinsă într-un procent de 100%.

Cuvinte cheie: puncte ghidate tomografice, cost scăzut, dispozitiv stereotactic original, studiu experimental

ABSTRACT

Objective: Transthoracic CT guided fine needle biopsy is extremely valuable in establishing the diagnosis for mediastino-pulmonary masses, especially when the patient cannot undergo other types of surgical intervention, be it curative or diagnostic. Although minimally invasive, the method is sometimes followed by complications, among which pneumothorax and bleeding have been most frequently reported. These complications are directly linked to various factors, the most important of them being the accuracy with which the target is reached at the first attempt. Objective: In order to reduce the number of these complications, we made a study about a low cost stereotactical device that meets the criteria of accuracy required. Material and methods: The device is a pure mechanical concept. It has a system of columns-racks united by a guiding body, a goniometrical system to properly establish the attack angle for the target, a pusher rod with an ensemble of clamping/release system for the biopsy needle and a single-block base. We chose an experimental plant model in which we put radioopaque targets with sizes of 0.5 cm, 1 cm and 2 cm. We performed 20 procedures for each of the targets by means of the stereotactical device and the same number of procedures using the free hand method. Results: Using the stereotactical device, the targets with sizes greater than 1 cm were reached at the first attempt in a percentage of 100%. The target of 0.5 cm had a percentage of 65% of successful attempts, which means that it was touched for 13 times. By means of the free hand technique we obtained the following results: the 2 cm target was touched for 15 times (75%), the 1 cm target for 11 times (55%), while the 0.5 cm target presented the lowest rate of accuracy, that is 3 times (15%). Conclusions: The procedures of transthoracic CT guided fine needle biopsy assisted by our stereotactical device are superior in terms of accuracy, in comparison to the free hand technique, an aspect which involves fewer complications. The results we obtained using this device are comparable to those presented in international studies using more expensive and sophisticated devices.

Key Words: CT guided biopsy, low cost, original stereotactical device, experimental study

INTRODUCTION

Establishing the hystopathological diagnosis for mediastino-pulmonary masses is of great importance both for the selection of the surgical patients and for the pre-operative management of these patients. Moreover, in cases when the stage of the disease represents a contraindication for surgery, the precise hystopathological diagnosis is crucial for the oncological treatment of the patients. One of the most commonly used procedures for establishing the
diagnosis of mediastinopulmonary masses is CT guided fine needle biopsy/aspiration.\textsuperscript{1,2} The most frequent complications resulting from this procedure are pneumothorax, with a percentage of 8-64\%, and bleeding accompanied or not by hemoptysis, 2-26\%.\textsuperscript{3-8} The occurrence rate of these complications is a variable depending on several factors: the distance between the pleura and the mass, the size of the mass, the condition of the lung parenchyma, the number of procedure attempts in order to reach the target and the experience of the surgeon.\textsuperscript{3}

**OBJECTIVE**

In order to minimize these complication rates, we analysed all the variables described above. The only variable we can influence is the last one – avoiding the repetition of the procedure. Therefore, we propose a very easy to use, low cost stereotactical guidance device, which helps the surgeon introduce the needle with precision into the mediastinopulmonary mass, eliminating the risks of missing the target.

**MATERIAL AND METHODS**

There is a wide range of stereotactic devices for transthoracic biopsies presented in international studies, devices with very good performance (the average deviation from the target core is of 1-3 mm), but they are expensive technical solutions and present very high complexity, which makes them very difficult to operate.\textsuperscript{9-16} For exemplification, we reproduce some pictures of guidance devices imagined in various international studies.

A multicentric study performed in three prestigious universities, John Hopkins Baltimore (USA), Szeged University (Hungary), Denki University in Tokyo (Japan), presented a guidance device which had very good performance, but which required high budget and a specialized team. We exemplify some of the images of this study. (Figures 1,2)

![Figure 1. The schematics of the device attached to a computer tomograph device.](image1)

![Figure 2. The stereotactical device.](image2)

In another experimental study conducted in Germany, another model of the device is described, also having good performance, but, likewise, having the disadvantage of a very high cost and of complex manipulation. (Fig. 3)

![Figure 3. The Medarpa experimental system.](image3)

Given the data presented above, we imagined a very simple solution, at a low cost, but sufficiently precise to allow reaching a small size target, thus avoiding the repetition of the procedure which would increase the number of complications.

**Technical conception**

The device was designed and crafted together with specialists from the Department of Mechatronics of the Polytechnic University of Timisoara and specialists of the Medical Equipment Division of Morhardt Gmbh Augsburg, Germany. The conception is purely mechanical and the ensemble has the following components: (Fig. 4)

- Two columns-racks positioned on the X-Y axes; (Fig. 5)
We opted for this concept with the purpose of eliminating the two drawbacks associated with the devices presented in other studies – high production and maintenance costs and the complexity of the device that makes it difficult to handle by the surgeon. On the other hand, our goal was to achieve the same level of performance.

To test the device, we chose a fruit – Citrus Maximus - as an experimental model, for various reasons: (Fig. 10)

- It has almost the same diameter as the normal
human adult/child thorax (12 - 27 cm);
- The peel is approximately 2.5 cm thick with a
density similar to the human soft parietal tissues;
- The core is 80% water and has compartments
with alveolate aspect, being architecturally the most
similar vegetable model to the human lung in terms of
consistency and structure;
- We can easily introduce inside it radioopaque
targets of different sizes;
- Due to its round shape, it can be easily rotated in
its holder, ensuring multiple attack angles and allowing
us to test the accuracy of the device in reaching the	
targets.

Figure 10. The fixation of the experimental model.

After making the device, we moved on to testing it. For this purpose, we used a 20 G biopsy needle with a length of 8 cm. Inside the plant we placed radioopaque targets with sizes of 0.5, 1 and 2 cm in diameter. (Fig. 11)

Figure 11. The visualisation of targets of 0.5, 1 and 2 cm.

After the tomographic scan of the fruit, we localised the target inside and randomly established the place of needle insertion by placing radioopaque markers on the surface of the model. (Fig. 12)

Figure 12. The radioopaque surface markers and the target.

The CT program calculated the attack angle of the target, then we proceeded to the fixation of the target onto the goniometrical system of the device. After attaching the needle to the fixation system we inserted it into the fruit by pushing the rod. (Fig. 13) We did this for all the 3 dimensions of the targets. We must mention that the results of the procedures assisted by our device are independent of the surgeon's experience.

Figure 13. Needle insertion.

RESULTS

Study of the experimental model
We performed 20 procedures of puncture for each of the three targets placed at 8 cm away from the needle insertion point. The targets with sizes of 1 and 2 cm were touched in all of the cases (100%), although there was an average deviation from the target's core of up to 0.4 cm, in comparison to the existing devices that recorded a deviation of up to 0.3 cm. (Fig. 14) At 8 cm distance from the insertion point, the deviation of our device did not lead to missing the target. For
the 0.5 cm target, 13 out of 20 attempts reached
the target which was at 8 cm away from the needle
insertion point (65%), reporting 7 failures. When we
reduced the distance between the insertion point and
the target by placing it closer to the surface of
the model, the number of successful attempts increased
proportionally with the reduced distance – 18 attempts
(90%) for a distance of 4 cm. (Fig. 15) For this situation
we recorded a 0.2 cm deviation from the target’s core
in comparison to other studies that reported 0.0 cm
deviation.

In order to compare our results, we performed
punctures on all the three targets situated at a distance
of 8 cm from the needle insertion point without using
the stereotactic device, by means of the free hand
method. For the objectivity of the study the free hand
procedures were conducted by a surgeon who had not
been made aware of the stereotactical device and the
results we obtained using it. The results were: the 2 cm
target was reached for 15 times (75%), the 1 cm target
was reached for 11 times (55%) and the 0.5 cm target
was reached less successfully, only for 3 times (15%) -
see Table 1.

<table>
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<th>Table 1. Comparative results for the two guided FNA methods.</th>
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<tr>
<td>Target with size 0.5 cm</td>
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<tr>
<td>Successful target approach using the stereotactical device (20 attempts)</td>
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<tr>
<td>Successful target approach using the free hand method (20 attempts)</td>
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DISCUSSIONS

From the point of view of its accuracy, the results
we obtained for targets larger than 1 cm by using the
device we designed are identical to the results reported
by international studies – 100% successful attempts.

When we compared the results of this technique
to the free hand method, we noticed that we obtained
a percentage of 100% versus 65% successful attempts,
which proves the usefulness of our device.

For the targets of 0.5 cm, the stereotactical assisted
procedures are clearly superior to the classical method
(65% successful attempts in comparison to 15%), but the
accuracy of our device is lower than the one reported by
other experimental studies. On the other hand, in our
experience which includes more than 2000 transthoracic
fine needle biopsies performed on patients with
mediastinopulmonary masses, less than 1% of these
cases had masses with dimensions under 1 cm, thus
the addressability of the device in this area is very low.

Another advantage of the device we proposed is
represented by its low production cost, approximately
20 times lower than in the case of the existing ones,
both as the fact that it is easy to use, being accesible
even to unexperienced surgeons.

We chose the vegetable experimental model over
human cadavers or living sleeping animals for the
following reasons:
- High costs;
- Human cadavers are not similar to living patients
due to different tissue density caused by preservation
solutions, and, consequently, the dehydration of the
tissues could interfere with the needle trajectory;
- The difficulty of introducing radioopaque targets
within the model.

CONCLUSIONS

The device we conceived and created is simple,
precise and very easy to manipulate, while its accuracy
is comparable to that presented by other similar devices for targets larger than 1 cm. It also has the advantage of a reasonably low production cost.

REFERENCES