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Comparison of fully automated and semi-automated biopsy needles for lung biopsy under CT fluoroscopic guidance

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Objective: The aim of this study was to compare two different automated biopsy needles, a fully automated biopsy needle (Monopty; Bard, Covington, GA) and a semi-automated biopsy needle (Temno; Bauer Medical, Clearwater, FL), for lung biopsy.
Methods: 50 consecutive percutaneous lung biopsies using the Monopty needle between June 2006 and January 2007 and 66 consecutive lung biopsies for 1 nodule in each session using the Temno needle between February 2007 and August 2008 were performed under CT fluoroscopic guidance followed by histopathological evaluation.
Results: In 42/50 lung biopsies performed with the Monopty needle and 54/66 lung biopsies performed with the Temno needle, the final diagnosis was confirmed by independent surgical pathological findings or clinical follow-up. Sufficient samples for histopathological evaluation were obtained in all 50 (100%) biopsies using the Monopty needle and in 55 (83.3%) of the 66 biopsies using the Temno needle ($p<0.01$). Accurate diagnosis was achieved in 41 (97.6%) of 42 biopsies using the Monopty needle and in 45 (83.3%) of 54 biopsies using the Temno needle ($p=0.04$). Biopsy-induced complications were pneumothorax, haemoptysis and haemothorax in 44.0%, 10.0% and 6.0% of biopsies, respectively, using the Monopty needle and in 48.3%, 8.3% and 3.3%, respectively, using the Temno needle.
Conclusion: There is a possibility that a fully automated biopsy needle such as the Monopty is more useful for CT scan-guided lung biopsy than semi-automated biopsy needles.

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CT scan-guided needle biopsy of lung nodules has become a well-established diagnostic technique [1]. Most CT scan-guided lung biopsies cited in earlier reports [2, 3] were performed with fine-needle aspiration for cytology and were useful in differentiating malignant from benign lesions. In addition, a tissue-core biopsy using a cutting needle, which enables histopathological evaluation of the samples obtained [4], has been implemented to enhance diagnostic ability. Owing to the development of the automated cutting needle, tissue-core biopsy can now be performed more easily and higher quality core specimens can be obtained for histopathological analysis [5–11].

There are two types of automated cutting needles: the fully automated biopsy needle and the semi-automated biopsy needle. Comparisons have been made of the use of these needles for autopsy [12] or breast tissue biopsy [13]. To our knowledge, no investigation has been carried out to compare these two types of automated cutting needles for lung biopsy. The aim of this study was to compare two different automated biopsy needles, a fully automated biopsy needle (Monopty; Bard, Covington, GA) and a semi-automated biopsy needle (Temno; Bauer Medical, Clearwater, FL), for use in CT scan-guided lung biopsy.

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Subjects and methods

Subjects

Between June 2006 and August 2008, 120 consecutive percutaneous lung biopsies were performed under CT fluoroscopic guidance at our institution. Among these biopsies, between June 2006 and January 2007, 50 consecutive lung biopsies were performed using an 18 gauge Monopty needle, and between February 2007 and August 2008, 70 consecutive lung biopsies were performed using an 18 gauge Temno needle. Among the 70 lung biopsies performed using the Temno needle, in 4 patients biopsies were performed for 2 nodules on the same day. In 14 patients in whom the Temno needle was used, repeat biopsies were carried out using the Monopty needle on the same day ($n=6$) or on another day ($n=8$) because specimens obtained by the Temno needle were, or were thought to be, inadequate for histopathological evaluations, although in 3 patients the specimens subsequently proved to be adequate for diagnosis.

Biopsy needle

The Monopty needle is a fully automated biopsy device that automatically triggers a rapid firing side-notch Tru-Cut-type biopsy needle. It uses a two-stage biopsy action. A spring action thrusts the inner trocar

forward, followed almost instantaneously by a similar forward thrust of the outer cutting cannula. The specimen is trapped in the side notch of the trocar when the cutting cannula is advanced.

The Temno needle is a semi-automated biopsy device that requires manual advancement of the trocar to expose the side notch. With pressure on its plunger, an automated biopsy action rapidly advances the cutting cannula over the specimen-containing side notch of the trocar.

Biopsy procedure

All procedures were performed after written informed consent was obtained from the patients. Our institution does not require institutional review board approval for retrospective review of previously collected data such as in the present study.

All patients had undergone diagnostic CT scans of the chest with 5 mm thick contiguous axial tomographic sections before undergoing biopsy. At the time of the biopsy, preliminary helical CT scan images (X Vigor Laudator; Toshiba Medical System, Tokyo, Japan) were obtained in 5 mm thick sections through the lesion. From a review of these preliminary images, the patient's position, level of the needle entry site and direction of the approach were planned to provide the most direct route for the biopsy, to traverse the least amount of aerated lung and to avoid bullae and fissures. The procedure was performed by one of six interventional radiologists who were experienced in CT scan-guided biopsy. A CT fluoroscopic imaging system was used for all CT scan-guided biopsy procedures. Details of CT fluoroscopy have been described elsewhere [14]. Imaging parameters during CT fluoroscopy included a CT beam width collimated to 3 mm, tube voltage with a 120 kV peak, current of 30–50 mA and scanning speed of 0.75 s per rotation (360°). An operator wearing a protective lead apron in the CT room was responsible for control of the CT fluoroscopic exposure via a foot pedal, assisted in table movement and gantry tilt, and directed the laser light beam via the control panel. The control panel was covered with a sterile transparent drape when a single operator performed the procedure. Alternatively, an assistant would help by adjusting the controls. An intermittent real-time CT fluoroscopic technique was preferred while advancing the biopsy needle using the I–I device (Hakko, Tokyo, Japan) that was developed to assist in precisely advancing the needle while avoiding irradiation to the operator's hands [15]. This technique was performed in a stepwise manner [16] with quick application of CT fluoroscopy to confirm the path of the needle while meticulous care was taken to minimise direct radiation to the operator's hands. Patients who could not cooperate with breath-holding underwent the procedure during usual respiration. After confirming that the needle tip had reached the lesion, a specimen was obtained and the needle was withdrawn. When the operator was uncertain as to whether the needle tip had reached the lesion or whether the specimen was insufficient, re-biopsy was performed. An on-site cytopathologist was not present during the procedure, and frozen-section analysis cannot be performed at the time of biopsy at our institution.

All biopsy procedures were performed under local anaesthesia. After the biopsy procedure, axial CT images were obtained during a single breath-hold through the level of the biopsy or, if necessary, through the whole chest using helical CT scanning to determine the presence of complications such as pneumothorax. While still on the scanner table, patients with a moderate or severe pneumothorax or with symptoms of pneumothorax underwent immediate manual aspiration of air from the pleural space by an 18 gauge intravenous catheter. When the pneumothorax did not decrease, or even increased despite manual aspiration, a chest tube was placed.

Specimens obtained by core biopsy were evaluated histologically. All histological evaluations were performed by experienced chest cytopathologists. They were required not only to classify obtained specimens as positive or negative for malignancy but also to identify specific cell types, if possible.

Investigated variables

The following dependent variables were retrospectively investigated: (1) technical success rate, (2) rate of success in obtaining sufficient samples for histopathological evaluation, (3) ability to determine whether the lesion was malignant (*i.e.* accuracy, sensitivity, specificity, positive predictive value, negative predictive value) and (4) rate of complications. Technical success was declared when it was confirmed that the target was hit or was penetrated with the needle as shown on the CT fluoroscopic image. The biopsy was deemed inadequate if specimens collected contained only blood or normal lung cells. Histological findings of percutaneous lung biopsy were compared with the final diagnosis obtained after needle biopsy by independent surgical pathology or clinical follow-up. Inadequate specimens obtained by percutaneous lung biopsies were defined as ''no malignancy'' in this study. Final diagnosis of a malignant lesion was accepted if the patient was treated for malignancy and the subsequent clinical course and response to therapy were appropriate. Final diagnosis of a benign lesion was accepted if one of the following three conditions was satisfied: (1) spontaneous resolution; (2) resolution after treatment for conditions other than cancer, such as antibiotic treatment; and (3) no change in lesion size for more than 24 months. As to complications, the incidence of pneumothorax, haemosputum and haemothorax was evaluated. Haemothorax was defined as a new pleural effusion after biopsy that was confirmed by CT performed immediately after biopsy. With regard to pneumothorax, the rates of administration of manual aspiration and tube placement were investigated.

All dependent variables were compared between the Monopty group and the Temno group. Excluded from the analysis were biopsy procedures that were performed on the same day for 2 nodules in each of 4 patients using the Temno needle and the 14 biopsies that were performed using the Monopty needle after initial biopsies with the Temno needle. In summary, 116

biopsies (Monopty, n=50; Temno, n=66) were analysed. The ability to determine whether the lesion was malignant or benign was investigated for cases in which the final diagnosis could be obtained (n=96; Monopty, n=42; Temno, n=54). The rate of complications was investigated for patients who did not undergo an additional biopsy procedure with the Monopty needle on the same day as an initial biopsy was performed with the Temno needle (n=110; Monopty, n=50; Temno, n=60).

Statistical analysis

Patient characteristics as well as lung nodule characteristics in the Monopty and the Temno groups were compared using the χ^2 test or Fisher's exact test if the characteristics were qualitative and by the Wilcoxon rank-sum test if the characteristics were quantitative. All variables investigated were compared between the two groups using the χ^2 test or Fisher's exact test.

For statistical analysis, commercial software (JMP 5.1; SAS Japan, Tokyo, Japan) was used. A $p<0.05$ was considered to indicate a statistically significant difference for all analyses.

Results

The mean age, number of females, mean diameter of the lesion, mean depth as measured from the pleural surface to the edge of the mass, average number of punctures in a single biopsy procedure, and the rate of the presence of emphysema in each group are shown in Table 1. There was no significant difference between the two groups except for the number of punctures in a single biopsy procedure. The number of punctures in the Temno group was greater than in the Monopty group [2 (1–3) *vs* 1 (1–3)] ($p<0.01$). Table 2 shows the specific cell types of lesions obtained by percutaneous lung biopsy performed with each needle, and Table 3 shows the comparison between the two groups according to results of the final diagnosis. The rate of malignant lesions in the Temno group was higher than in the Monopty group [87% (47/54) *vs* 61.9% (26/42)] ($p<0.01$).

Table 4 shows the results of the analysis of the dependent variables that were investigated. The technical success rate and rate of each complication did not differ significantly between the Monopty group and the Temno group. However, sufficient samples for histopathological evaluation were obtained in all 50 (100%) of the 50 biopsies in the Monopty group and in 55 (83.3%) of the 66 biopsies in the Temno group ($p<0.01$), indicating a significantly lower rate of success in the Temno group than in the Monopty group. In the Temno group, the mean ($\pm$SD) size of the lesion in the 11 cases in which the samples obtained were insufficient was 13.3$\pm$7.4 mm (range 4–24 mm), whereas the mean size of the lesions in the other 55 cases in which adequate samples were obtained was 22.5$\pm$15.6 mm (range 7–80 mm) (p=0.06). With regard to the ability to determine whether the lesion was malignant, accuracy, sensitivity and negative predictive value were 97.6%, 96.2% and 94.1%, respectively, in the Monopty group and 83.3%, 80.9% and 43.8%, respectively, in the Temno group. The accuracy and negative predictive value in the Temno group were significantly lower than in the Monopty group (p=0.04 and $p<0.01$, respectively), and sensitivity in the Temno group tended to be lower than in the Monopty group (p=0.09). Moreover, adequate specimens for diagnosis were obtained in 14 biopsies using the Monopty needle after initial biopsies with the use of the Temno needle did not provide sufficient specimens for histopathological evaluations or were thought not to have yielded a sufficient specimen.

Discussion

CT scan-guided lung biopsy is widely accepted as the principal method for evaluating lung nodules. Currently, the automated cutting needle in tissue-core biopsy is considered to be useful for obtaining specimens of lung nodules for histological evaluation [17]. There are numerous automated cutting needles, and comparisons of performance of various automated biopsy needles have been made [12, 13, 18–20]. Hopper et al [12] evaluated 20 different automated biopsy needles for use in fresh autopsy cases and reported that performance of the semi-automated biopsy needles, including the Temno needle, was worse than that of the fully automated biopsy needles, including the Monopty needle. In a comparison of seven large-core biopsy needles for yield of breast tissue, Krebs et al [13] noted that the Temno needle obtained smaller volumes of tissue than the Monopty needle, although the difference in volume was not significant. Although evaluations of

Table 1. Baseline characteristics of patients and tumours

	Monopty (n = 50)	Temno (n = 66)	Statistical test	p-value[a]
Age, years (range)[b]	63.0$\pm$13.1 (33–90)	67.1$\pm$10.7 (42–84)	Wilcoxon test	0.09
Female, no. (%)	24 (48.0)	26 (39.4)	χ^2 test	0.35
Size of lesion, mm, (range)[b]	17.6$\pm$14.6 (4–67)	21.0$\pm$14.9 (4–80)	Wilcoxon test	0.05
Depth of lesion, mm, (range)[b]	20.9$\pm$19.0 (0–73)	23.7$\pm$18.3 (0–72)	Wilcoxon test	0.36
Punctures, no., (range)[c]	1 (1–3)	2 (1–3)	Fisher's exact test	<0.01
Emphysema, no. (%)	13 (26.0)	23 (34.9)	χ^2 test	0.31

[a]$p<0.05$ was considered to indicate a statistically significant difference.
[b]Data are the means$\pm$standard deviation.
[c]Data are the median.

Table 2. Characterisation of specific cell types obtained by percutaneous lung biopsy

Diagnosed specific cell type	Monopty (*n*)	Temno (*n*)
Malignancy	27	42
Primary lung cancer		
Adenocarcinoma	10	19
Bronchioalveolar carcinoma	1	3
Squamous cell carcinoma	3	2
Small cell carcinoma	0	3
Large cell carcinoma	0	2
Non-small cell carcinoma	2	2
Acinar cell carcinoma	1	0
Metastatic lung cancer	8	10
Others		
Desmoplastic mesothelioma	0	1
Metaplastic thymoma	1	0
Malignancy	1	0
No malignancy	23	24
Granuloma	3	2
Sarcoidosis	0	1
Tuberculoma	0	1
Pneumonia	8	3
Fungal infection	1	1
Chronic organising pneumonia	1	0
Inflammatory and necrotic nodule	1	0
Abscess	2	0
Fibrosis	5	4
Nodular lymphoid hyperplasia	1	0
Epithelial proliferation	1	0
Necrotic lesion	0	1
Lung tissue	0	2
Inadequate sample	0	9
Total	50	66

the abilities of different types of biopsy needles have been reported as noted above, a comparison between a fully automated biopsy needle and semi-automated biopsy needle for CT scan-guided lung biopsy has not been reported.

There are many reports of lung biopsy performed by automated cutting needles [5–11, 21–24]. The rate of success in obtaining an adequate specimen and accuracy of this method to diagnose malignancy were reported to be 90–100% [5, 7, 9, 21, 23] and 64–95% [5–10, 21, 23], respectively. Hayashi et al [9], in a review of 52 biopsies for lung nodules smaller than 3 cm by the Temno needle, reported that both the rate of success in obtaining sufficient samples for frozen-section diagnosis and the accuracy were 90% (47/52 cases). In the five cases in which samples were insufficient, the lesion was 1.8 cm or smaller. The first samples were sufficient in 44 of the 47 (84%) cases. On the other hand, among previous reports of evaluations of automated cutting needles for lung biopsy, to our knowledge none has evaluated the Monopty needle.

The most common complication of CT scan-guided lung biopsy is pneumothorax, with a frequency ranging from 17.9% [25] to 54.3% [7, 25, 26–32]. Haemoptysis is also well known as a biopsy-induced complication, with a frequency ranging from 2.0% [32] to 10.1% [6].

In the present study, the rate of success in obtaining sufficient samples for histopathological evaluation and the accuracy and negative predictive value using the Temno needle were significantly worse than with the Monopty needle. These results are similar to those of investigations for autopsy or breast tissue [12, 13]. The rate of success in obtaining sufficient samples in the Temno group (83.3%) was slightly lower than in the report by Hayashi et al (90%) [9]. The fact that frozen-section analysis cannot be performed at the time of biopsy in our study might have influenced this result, since the rate of success in diagnosis of the first sample in the report by Hayashi et al [9] was similar to ours (84%). Moreover, in cases in which samples were insufficient, the size of the lesion tended to be small in both the present study and the previous study [9]. We presume that one of the reasons for failure to obtain sufficient samples is that the nodule migrates slightly at the moment of manual advancement of the trocar because of looseness of lung tissue around the nodule and low thrust of the trocar in lung biopsy using the Temno needle.

In our study, the most frequent complication was pneumothorax in both groups (Monopty group, 44.0%; Temno group, 48.3%), which is similar to those in previous reports [7, 25, 26–32]. Also, the complication rates did not differ significantly between procedures using these two needles and were similar to those in previous reports of lung biopsy.

There are some limitations to this study. This was a non-randomised retrospective and observational study with a small number of subjects. There are differences in the distribution of characteristics of nodules in that the Monopty group included more benign lesions. Also, the numbers of both subjects and lesions were too small to attempt multivariate analysis to adjust for baseline characteristics of patients and tumours. However, we believe that our study is important for interventional radiologists in the thoracic field because some of the information presented here has never, or only seldom, been seen before. Previous reports have mentioned the need to determine the specific cell type in benign lesions as well as in malignant lesions [21]. Otherwise, for example, a diagnosis of simply ''negative for malignancy'' would indicate the necessity for long-term follow-up or biopsy with another procedure [7]. In the present study, the specific cell type could be characterised in 96% (26/27) of malignant lesions and 100% (23/23) of benign lesions that were evaluated histologically in the Monopty group and in 100% (42/42) of malignant lesions and 54% (13/24) of benign lesions in the Temno group. Moreover, the specific cell type was determined in 14 biopsies using the Monopty needle after initial biopsies with the Temno needle did not provide sufficient specimens for

Table 3. Tumours in which the final diagnosis was obtained

Final diagnosis	Monopty ($n=42$)	Temno ($n=54$)	Statistical test	*p*-value[a]
Benign, no. (%)	16 (38.1)	7 (13.0)		
Malignant, no. (%)	26 (61.9)	47 (87.0)	χ^2 test	<0.01

[a]$p<0.05$ was considered to indicate a statistically significant difference.

Table 4. Statistical comparison of variables between the Monopty and Temno groups

	Monopty[a]	Temno[a]	Analysis	*p*-value[b]
Technical success rate	100 (50/50)	98.5 (65/66)	Fisher's exact test	0.99
Sufficient sample	100 (50/50)	83.3 (55/66)	Fisher's exact test	<0.01
Accuracy	97.6 (41/42)	83.3 (45/54)	Fisher's exact test	0.04
Sensitivity	96.2 (25/26)	80.9 (38/47)	Fisher's exact test	0.09
Specificity	100 (16/16)	100 (7/7)	NA	NA
Positive predictive value	100 (25/25)	100 (38/38)	NA	NA
Negative predictive value	94.1 (16/17)	43.8 (7/16)	Fisher's exact test	<0.01
Pneumothorax	44.0 (22/50)	48.3 (29/60)	χ^2 test	0.65
Manual aspiration	10.0 (5/50)	8.3 (5/60)	Fisher's exact test	0.99
Tube placement	10.0 (5/50)	3.3 (2/60)	Fisher's exact test	0.24
Haemosputum	10.0 (5/50)	8.3 (5/60)	Fisher's exact test	0.99
Haemothorax	6.0 (3/50)[c]	3.3 (2/60)	Fisher's exact test	0.66

NA, not available.
[a]Values are given as the percentage (%) and numbers are in parentheses.
[b]$p<0.05$ was considered to indicate a statistically significant difference.
[c]One patient required tube placement for drainage.

histopathological evaluations or were thought not to have yielded a sufficient specimen.

From the results of our study, there is a possibility that a fully automated biopsy needle such as the Monopty is more useful for CT scan-guided lung biopsy than semi-automated biopsy needles.

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