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The Diagnostic Efficiency of the Use of Non-Standard Surgical Instruments in Mediastinoscopy

Kemal Karapınar, Merve Özbek, Yunus Seyrek, Cemal Aker, Ali Murat Akçıl, Levent Cansever, Mehmet Ali Bedirhan

University of Health Sciences Turkey, Yedikule Chest Diseases and Thoracic Surgery Training and Research Hospital, Clinic of Thoracic Surgery, İstanbul, Turkey

ABSTRACT

Introduction: Mediastinoscopy is an effective diagnostic method used in the diagnosing of benign granulomatous diseases and for lung cancer staging. However, the success of this method is directly proportional to the amount of pathological material taken. This study aimed to compare the diagnostic efficiency of the diagnostic superiority of the use of standard surgical instruments (SSI) and non-standard surgical instruments (NSSI) in mediastinoscopy in patients with mediastinal lymph nodes, which are thought to be pathological, according to different diseases.

Methods: One hundred and seven patients who underwent mediastinoscopy were divided into two groups according to the use of SSI (n=89) and NSSI (n=18). Analysis was made of age, gender, pre-diagnosis, fluorodeoxyglucose-positron emission tomography and substance uptake values of the groups, pathology if endobronchial ultrasound-transbronchial needle aspiration (EBUS-TBNA) had been performed, operation notes (use of video mediastinoscope, use of SSI or NSSI, sampled mediastinal lymph node stations), complications and pathology results analyzed.

Results: The use of NSSI was found to be statistically significantly higher in patients with previous EBUS-TBNA (p=0.013), in operations in which a single mediastinal station was sampled (p=0.004), and in cases where the pathological diagnosis was tuberculosis (TB) (p<0.001). A tissue with diagnostic value was sampled in all patients who needed NSSI were used in mediastinoscopy, no complications were observed, and TB was diagnosed at a rate of 60% (p=0.013).

Conclusion: The use of NSSI, such as long and thin mediastinoscopy aspirator and forceps, endoscopic scissors, injection needles, and endoclip in addition to SSI in mediastinoscopy increase the success of diagnosing TB.

Keywords: Mediastinoscopy, non-standard surgical instruments, invasive staging, tuberculosis

Introduction

Mediastinoscopy (Med) is a surgical method used to obtain sufficient samples from lymph nodes or masses located in the superior middle mediastinum (1). For many years, this surgical method has been widely used for the invasive staging of lung cancer (LC), and the diagnosis of lymphoma (Lym) or granulomatous diseases (GD) (2,3).

Low-dose computed tomography (CT) is of great importance in screening for LC in patients at risk (4). Fluorodeoxyglucose-positron emission tomography (FDG-PET) has 80% sensitivity and 88% specificity in the staging of LC, but has been repted to show increased false positivity in granulomatous, inflammatory, and infectious diseases (5). The specificity of PET increases and sensitivity decreases as the lymph node progresses (6). In sampling with endobronchial ultrasound-transbronchial needle aspiration (EBUS-TBNA), the diagnosis of L or GD may still not be as successful as LC (3). Although lymph nodes can be seen with EBUS, a high density of cells can be sampled with needle aspiration in LC, while sufficient cells may not be aspirated with needles due to the low tissue density, especially in GDs (7,8). The thickness and hardness of the pathological tissue may even hinder the biopsy. Mediastinoscopy is an effective diagnostic method in the diagnosing of benign GDs and for LC staging. However, the success of this method is directly correlated with the amount of pathological material harvested. A factor negatively affecting the success of the method may be the presence of encapsulated mediastinal lymph nodes or mass at a depth that standard surgical instruments (SSI) cannot reach and are hard to sample. Therefore, the additional use of surgical instruments originally designed for other operation types [non-standard surgical instruments: (NSSI)] may be considered to improve the sampling success in mediastinoscopy. Blunt dissection with Med aspirator with or without a video mediastinoscope and punch biopsy with Med forceps is performed as standards in mediastinoscopy. Lazzaro and LoCicero (9) stated that endoscopic scissors, endodissectors and, when necessary, endoclips were additionally used

Address for Correspondence: Kemal Karapınar MD, University of Health Sciences Turkey, Yedikule Chest Diseases and Thoracic Surgery Training and Research Hospital, Clinic of Thoracic Surgery, İstanbul, Turkey
Phone: +90 212 409 02 00 **E-mail:** kemalkarapinar55@gmail.com **ORCID ID:** orcid.org/0000-0002-0035-5325

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during mediastinal lymph node sampling. In this definition, it is stated that the endodissector is used for tamponage during hemorrhage, while clips are used to stop subcarinal bronchial artery hemorrhage.

The study aimed to compare the efficacy of the use of NSSI in addition to SSI to increase the amount of tissue harvested from lymph nodes regarding diagnostic value for various diseases.

First Null Hypothesis to be Tested

Using NSSI in addition to SSI during Med does not improve the diagnostic efficiency in patients with mediastinal lymph nodes that are thought to be pathological.

Second Null Hypothesis to be Tested

Using NSSI in addition to SSI during Med does not improve the diagnostic efficiency for reactive hyperplasia, malignancy, sarcoidosis, or tuberculosis (TB) in patients with mediastinal lymph nodes that are thought to be pathological.

Methods

A retrospective scan was made of the files of patients who had undergone Med operations in the thoracic surgery clinic of our hospital between December 2019-2020, and those with complete surgical notes were included in the study. Files were excluded if the data were incomplete with respect to the use of videomediastinoscope, SSI, NSSI, specification of the sampled mediastinal lymph node stations, complication development and the amount of the material taken. The evaluation was made of 107 patients who underwent Med, with respect to age, gender, pre-diagnosis, FDG-PET and substance uptake values (SUV), EBUS-TBNA if present, pathology, surgery notes (use of videomediastinoscope, use of SSI or NSSI, sampled mediastinal lymph node stations), complications, and pathology results. The 107 patients included in the study were separated into those where SSI was used during Med [control group, (n=89), group A] and those where NSSI was also used [study group, (n=18), group B]. Approval for the study was granted by the Clinical Research Ethics Committee of University of Health Sciences Turkey, Yedikule Chest Diseases and Thoracic Surgery Training and Research Hospital (approval number: 2020-59, date: 17.12.2020).

Mediastinoscopy Procedure Using the SSI

Cervical Med was performed using either a standard mediastinoscope (Figure 1A) or a videomediastinoscope (Figure 2A) based on the surgeon's preference. Standard Med aspirator (Figure 1B) for lymph node dissection and standard Med forceps (Figure 1C) for lymph node sampling was sufficient to reach the tissue in the targeted area (station). The tissue was usually released with the aspirator and sampling was performed with forceps, based on the surgeon's experience. If necessary, the same process was repeated at other stations.

Mediastinoscopy Procedure Using NSSI

Cervical Med; videomediastinoscopes (Figure 2A) were used as an increased the view is necessary due to the variety of instruments required.

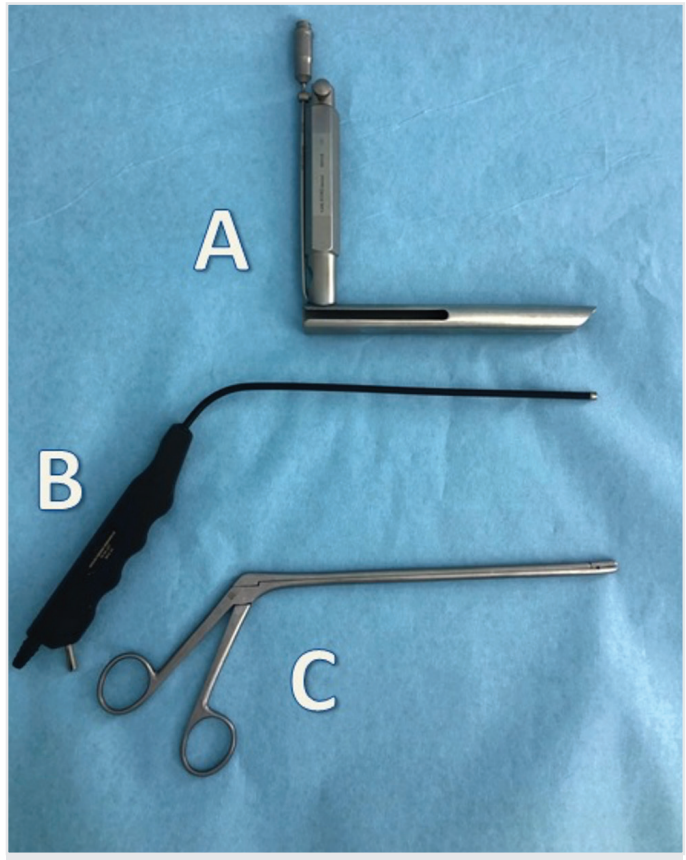

Figure 1. The SSI used in M: A) Standard mediastinoscopy, B) standard mediastinoscopy aspirator, C) standard mediastinoscopy forceps
SSI: Standard surgical instruments

Lymph node dissection; long and thin Med aspirator was used since the working area was narrower and deeper (Figure 2B).

Lymph node sampling; long and thin-tipped Med forceps were used where lymph nodes were small or unattainable with standard forceps (Figure 2C).

In some malignant or benign diseases, the mediastinal lymph node can neither be dissected with aspirator nor sampled with forceps because of the thickness of its capsule. Endoscopic scissors developed for video-assisted thoracoscopic surgery (VATS) (Figure 2D) can be used in these cases. An injection needle is placed at the tip of the forceps (Figure 2E), which then penetrates the lymph node at a depth sufficient to check the presence of any vascular formation inside or behind the capsule. The dissection was continued when there was no hemorrhage.

Bronchial artery hemorrhage may develop particularly during the dissection of the subcarinal lymph nodes and cannot be stopped by cauterization, unlike conventional hemorrhages. Therefore, VATS can be clipped with an endoclip (Figure 2F).

Statistical Analysis

Data obtained in the stud were analyzed statistically using SPSS 15.0 for Windows software. Descriptive statistics were expressed as number (n) and percentage (%) for categorical variables, and mean, standard deviation, minimum and maximum values for numerical variables. The rates were compared with chi-square test in independent groups and

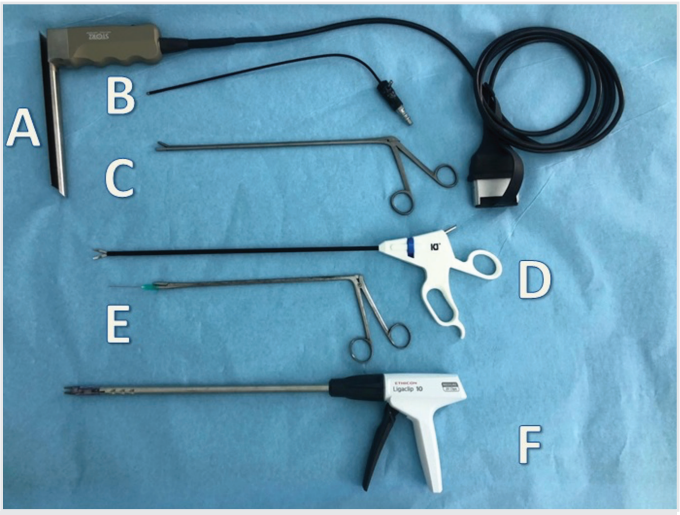

Figure 2. The NSSI used in M: A) Videomediastinoscope, B) long and thin M aspirator, C) long and thin-tipped M forceps, D) endoscopic scissors, E) forceps supported injection needle, F) endoclips
NSSI: Non-standard surgical instruments

the McNemar test in dependent groups. The statistical alpha significance level was accepted as $p<0.05$.

Results

In this study, the evaluation was made the diagnostic efficiency of using SSI and NSSI in mediastinoscopy performed in patients with mediastinal lymph nodes thought to be pathological. As sufficient tissue could be obtained from all patients for pathological interpretation, the two groups were equal in terms of diagnostic efficiency, and NSSI was found to be superior to SSI in terms of diagnosing TB (33.3% vs 2.2%) ($p<0.001$). From 1,310 operations performed between the specified datesin our clinic, 109 were Med. Two of these patients were excluded (1.8%) due to the lack of detailed operative notes, and the results of 107 patients were evaluated as follows:

Most of the patients were male (75.5%) and had malignant (82.2%) diseases (Table 1). In the mediastinal examinations of the patients with radiological and nuclear medicine methods, there were 57.9% malignant invasion, 9.3% sarcoidosis and 5.6% TB findings. PET-CT was performed in 63.5% of the patients and 67.6% of these scans had pathological (SUV_{max} >3) FDG uptake. EBUS was performed in 30.8% of the patients, of whom a diagnosis could be made in 27.3% (9 patients). While the procedure was continued vidomediastinoscopy in all the patients where SSI was used in Med, only 1 of those required videomediastinoscope due to poor vision. The regions sampled in the mediastinum were named stations and the stations were coded as 2R (right upper paratracheal region), 4R (right lower paratracheal region), 2L (left upper paratracheal region), 4L (left lower paratracheal region) and 7 (subcarinal region). During the process, 4R was sampled at the rate of 95.3%, 7 at 81.3%, and 4L at 80.4%.

During the Med procedure, it was observed that sampling was made from 3 (36.4%) or 4 (33.6%) different stations, while sampling was made from a single or all 5 stations less often (7.5%/8.4%). Complications occurred at a rate of 17.8% during the procedure (19 patients), of which 89.4% (17

Table 1. Demographic characteristics of the patients

		n	%
Gender	Male	81	75.7
	Female	26	24.3
Age (years) mean ± SD (min.-max.)		**58.0±11.2 (28-82)**	
Primary diagnosis	Malignant	88	82.2
	Non-malignant	19	17.8
Mediastinal prediagnosis	No	29	27.1
	Yes	78	72.9
	Tuberculosis	6	5.6
	Sarcoidosis	10	9.3
	Lymphoma	1	0.9
	Malignant	62	57.9
	Other	2	1.9
FDG-PET	No	39	36.4
	Yes	68	63.5
SUV_{max}	Physiological (<3)	22	32.4
	Pathological (>3)	46	67.6
EBUS-TBNA	No	74	69.2
	Yes	33	30.8
EBUS diagnosis	No	24	72.7
	Yes	9	27.3
Video mediastinoscopy	No	88	83.0
	Yes	19	17.0
Tool used	Standard surgical instrument	89	83.2
	Non-standard surgical instruments	18	16.8
Number of sampled mediastinal stations	1	8	7.5
	2	15	14.0
	3	39	36.4
	4	36	33.6
	5	9	8.4
Mediastinal stations	2R	52	48.6
	2L	15	14.0
	4R	102	95.3
	4L	86	80.4
	7	87	81.3
Complication	No	88	82.2
	Yes	19	17.8
Pathological diagnosis	Local hemorrhage	17	89.4
	Massive hemorrhage	1	5.2
	Hoarseness	1	5.2
	Malignancy	30	28.0
	Reactive	57	53.3
	Sarcoidosis	11	10.3
	Tuberculosis	8	7.5
	Other	1	0.9

SD: Standard deviation, min.: Minimum, max.: Maximum, FDG-PET: Fluorodeoxyglucose-positron emission tomography, SUV: Substance uptake value, EBUS-TBNA: Endobronchial ultrasound-transbronchial needle aspiration

patients) were minor hemorrhage and could be controlled with local hemostatic agents containing cellulose, and hemoclips when necessary. Major hemorrhage developed in 1 patient (5.2%), and the pulmonary artery hemorrhage was primarily repaired by emergency thoracotomy. Hoarseness developed in 1 patient (5.2%) and was treated conservatively. Pathological diagnoses were made of reactive hyperplasia (53.3%) and malignancy (28%), and GD such as sarcoidosis and TB were diagnosed in 7.5% and 10.3%, respectively.

With the use of SSI and NSSI when necessary in mediastinoscopy, no difference was found in terms of gender, presence of malignancy, prediagnosis, FDG-PET, and SUV involvement (Table 2). In cases where EBUS-TBNA was applied, the need for NSSI in Med performed in the absence of a diagnosis was found to be statistically significantly higher than in those without EBUS-TBNA (55.6% vs 25.8%) (p=0.013).

The sampling rate of only 1 mediastinal station was found to be statistically significantly higher in mediastinoscopies using NSSI (27.8% vs 3.4%) (p=0.004). No difference was determined between the mediastinal stations in terms of the presence of complications. Complications such as massive hemorrhage and hoarseness were not seen in cases where NSSI was used, and in only case in the other group.

In mediastinoscopies in which NSSI was used, the TB rate of pathological diagnosis was found to be statistically significantly higher than in the other group where SSI was used (33.3% vs 2.2%) (p<0.001).

Discussion

The results of this study showed no difference in the diagnostic efficiency between the use of SSI and NSSI in addition to Med in patients mediastinal lymph nodes that were thought to be pathological. The use of NSSI was seen to be superior to SSI in terms of diagnosing TB in Med performed in patients with mediastinal lymph nodes that were thought to be pathological.

The patients in the current study showed similar demographic characteristics to those of some other Med studies conducted in Turkey (Table 1) (10-12). With the introduction of minimally invasive EBUS-TBNA throughout the world, the use of Med has gradually decreased, although it remains the gold standard in invasive mediastinal staging and diagnosis (9). Since standard or extended Med is a high-risk operation (13), the effectiveness of re-mediastinoscopy due to mediastinal fibrosis is low (14) and it is no longer used in clinical practice, Med should be performed at once and effectively. The effectiveness of the procedure is directly proportional to the amount of pathological tissue taken. In a study by Fu et al. (15), videomediastinoscopy was combined with EBUS to increase the amount taken, but it was stated that a wide pretracheal dissection should be performed for the EBUS probe to move effectively. Even in M, where EBUS-TBNA or SSI is used, sufficient pathological tissue may not be obtained. The current study results confirm this as the necessity of using NSSI in extended M performed in the absence of diagnosis in cases with EBUS-TBNA was found to be statistically significantly higher than those without (55.6% vs 25.8%) (p=0.013) (Table 2).

This can be considered to be because some mediastinal lesions are too rigid and thickly encapsulated to be sampled with TBNA or SSI. Additionally, the sampling rate of only one mediastinal station was found to be statistically significantly higher in mediastinoscopies using NSSI compared with SSI (27.8% vs 3.4%) (p=0.004). This demonstrated that NSSI is generally used in lesions difficult to sample and has a high tissue sampling capability. NSSI was successful in the sharp dissection of rigid encapsulated lymph nodes, and a significantly higher rate of TB diagnosis was made compared to the cases where SSI was used (33.3% vs 2.2%) (p<0.001). In this respect, the rigidity of the capsule in benign lesions may be a sign of TB.

Some patients who do not respond to standard TB therapy and who have radiological mediastinal lymphoid hyperplasia are primarily sampled with EBUS-TBNA. If a significant diagnosis is not made and sufficient pathological tissue cannot be obtained, Med is required. In a study of 321 patients by Cetinkaya et al. (16), sampling was performed with EBUS-TBNA and the majority (92%) received a diagnosis. Diagnostic Med was subsequently performed in 7 patients who could not be diagnosed with EBUS-TBNA and accepted the surgical procedure, and of these, 3 (42.8%) were diagnosed with GD. While the efficacy of EBUS-TBNA in the diagnosis and staging of LC is good, it is not so successful in the diagnosis of some GD such as TB and sarcoidosis, probably due of the density of the tissue taken. The current study results support this view.

Since many tests will be required, it may be particularly necessary to increase the amount of tissue in the diagnosis of diseases such as multi-drug resistant-tuberculosis (MDR-TB) (17). Mediastinoscopy is more frequently preferred over EBUS-TBNA for diagnostic purposes as it has the advantage of increasing the amount of tissue sampled. The current study result of a significantly higher TB diagnosis in Med where NSSI was used, shows the importance of the amount of tissue in diagnosis.

Researchers at Duke University Center for Evidence-Based Practice reported that concerning mediastinal staging with PET, the examination had sensitivity of 74% and specificity of 85% in detecting mediastinal metastases (18). The high false-negative and false-positive rates of this method also require invasive pathological confirmation to avoid unnecessary surgery and deprivation of necessary surgery (19). In this study, there was no significant difference in terms of NSSI requirement after PET-CT (p=0.83), and there was no significant difference in SUVmax involvement. It can be concluded that PET does not provide guidance in the need for NSSI use in mediastinoscopy. According to the current study results, it can be considered that the use of NSSI is only required to increase the effectiveness of the procedure in the light of perioperative findings.

The success of accurate mediastinal staging for non-small cell lung carcinomas increases to 71.6% with invasive and non-invasive methods (20). Accurate mediastinal assessment “leads to migration of patients to true (higher) stage and less likely to misclassify” (21). Despite advances in radiological and scintigraphic imaging, as well as minimally invasive methods (EBUS-TBNA and endoscopic ultrasound-guided fine needle aspiration), mediastinoscopy remains the gold standard for staging LC and increases the efficiency of the video-mediastinoscopy technique.

There was no difference between SSI and NSSI in terms of the presence of complications. Complications such as massive hemorrhage and

Table 2. Variation of standard and non-standard instrument usage requirements in mediastinoscopy according to patient characteristics

		Instruments used in mediastinoscopy				
		SSI		NSSI		p
		n	%	n	%	
Gender	Male	68	76.4%	13	72.2%	0.765
	Female	21	23.6%	5	27.8%	-
Primary diagnosis	Malignant	74	83.1%	14	77.8%	0.735
	Non-malignant	15	16.9%	4	22.2%	-
Prediagnosis	No	28	31.5%	1	5.6%	0.022
	Yes	61	68.5%	17	94.4%	-
	Tuberculosis	4	4.5%	2	11.1%	0.265
	Sarcoidosis	9	10.1%	1	5.6%	1.000
	Lymphoma	1	1.1%	0	0.0%	1.000
	Malignant	49	55.1%	13	72.2%	0.178
	Other	1	1.1%	1	5.6%	0.309
FDG-PET	No	33	37.1%	6	33.3%	0.832
	Yes	56	62.9%	12	66.7%	-
SUV_{max}	Physiological (<3)	20	35.7%	2	16.7%	0.311
	Pathological (>3)	36	64.3%	10	83.3%	-
EBUS-TBNA	No	66	74.2%	8	44.4%	-
	Yes	23	25.8%	10	55.6%	**0.013**
EBUS diagnosis	No	17	73.9%	7	70.0%	1.000
	Yes	6	26.1%	3	30.0%	-
Number of mediastinal stations sampled	1	3	3.4%	5	27.8%	**0.004**
	2	13	14.6%	2	11.1%	-
	3	36	40.4%	3	16.7%	-
	4	28	31.5%	8	44.4%	-
	5	9	10.1%	0	0.0%	-
Mediastinal station	2R	43	48.3%	9	50.0%	0.896
	2L	13	14.6%	2	11.1%	1.000
	4R	86	96.6%	16	88.9%	0.196
	4L	74	83.1%	12	66.7%	0.117
Complication	No	73	82.0%	15	83.3%	1.000
	Yes	16	18.0%	3	16.7%	-
Complication type	None	72	80.9%	14	87.5%	**1.000**
	Local hemorrhage	15	16.8%	2	12.5%	-
	Massive hemorrhage	1	1.1%	0	0.0%	-
	Hoarseness	1	1.1%	0	0.0%	-
Pathological diagnosis	Reactive	49	55.1%	8	44.4%	0.411
	Malignancy	27	30.3%	3	16.7%	0.289
	Sarcoidosis	10	11.2%	1	5.6%	0.686
	Tuberculosis	2	2.2%	6	33.3%	**<0.001**
	Other	1	1.1%	0	0.0%	-

SSI: Standard surgical instruments, NSSI: Non-standard surgical instruments, FDG-PET: Fluorodeoxyglucose-positron emission tomography, SUV: Substance uptake value, EBUS-TBNA: Endobronchial ultrasound-transbronchial needle aspiration

hoarseness were not seen in cases where NSSI was used, although each was seen only once in the other group. Therefore, it can be considered that NSSI can be used safely when necessary, with no extra costs incurred.

Study Limitations

There are several limitations within our study. PET-CT or EBUS-TBNA were not performed in all included patients. Thus, their effect on MDR-TB has not been fully determined. More than one lymph node station was not

sampled in cases where sufficient diagnostic samples were acquired. If it had been sampled, the rate of pathological diagnosis would have increased instead of reactive hyperplasia. Microbiological evaluation for tuberculosis was not performed in the sampled lymph nodes, except those with granulomatous reaction. If it had been done, the probability of TB incidence would have increased in stations sampled with SSI.

Conclusion

Despite the small number of cases, based on our experience, it can be said that this requirement is also present in MDR-TB. It can be considered that the use of NSSI will increase the diagnostic power of Med, where there is an increasing incidence of TB and particularly MDR-TB cases. In this respect, the rigidity of the capsule in benign lesions suggests that it is a sign of TB disease, and therefore, this issue should be further investigated. The use of NSSI such as long and thin M aspirators and forceps, endoscopic scissors, injection needles, and endoclips in addition to SSI in mediastinoscopy increases the success of diagnosing TB.

Ethics Committee Approval: Approval for the study was granted by the Clinical Research Ethics Committee of University of Health Sciences Turkey, Yedikule Chest Diseases and Thoracic Surgery Training and Research Hospital (approval number: 2020-59, date: 17.12.2020).

Informed Consent: Retrospective study.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions: Surgical and Medical Practices - K.K., L.C.; Concept - K.K., A.M.A., M.A.B.; Design - K.K., Y.S., C.A.; Data Collection or Processing - K.K., M.Ö., Y.S., A.M.A., L.C.; Analysis or Interpretation - K.K., M.Ö., C.A., L.C., M.A.B.; Literature Search - K.K., M.Ö., A.M.A.; Writing - K.K., M.Ö.

Conflict of Interest: No conflict of interest was declared by the authors.

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