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Original Research Article

Comparison of the Diagnostic Yield of Rigid and Semi Rigid Thoracoscopy in Undiagnosed Pleural Effusions

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Abstract

Background: Pleural diseases sometimes may present as a diagnostic challenge to the pulmonologist. The British Thoracic Society recommends thoracoscopy (diagnostic yield ≥ 90%) as the investigation of choice for an inconclusive pleural effusion after thoracentesis and pleural biopsy. Thoracoscopy can be performed using a rigid thoracoscope which requires more expertise or a semi-rigid thoracoscope which is more operators friendly but yield a smaller biopsy size. In this study, we are comparing the efficacy and safety of two procedures.

Aim and Objective: To compare the diagnostic yield and safety of rigid versus semi-rigid thoracoscopy in undiagnosed exudative pleural effusions.

Materials and Methods: Subjects with undiagnosed pleural effusions were allocated for either rigid or semi-rigid thoracoscopy randomly. The primary outcome measured was the diagnostic yield. The secondary outcomes measured were the requirement of sedative / analgesic, biopsy size, pain score, the operator's view of the procedure and complications.

Results: 70 patients with undiagnosed, exudative, low ADA (24.31±14.24) pleural effusions were enrolled in the study, 35 in each group with almost similar baseline characteristics. The diagnostic yield of rigid and semi-rigid thoracoscopy were almost comparable (88% v/s 82% p=0.49). The pain score, requirements of sedatives and analgesics were greater in rigid group, but biopsy sample size was distinctly larger (1.13 ± 0.26 cm v/s 0.57 ± 0.13, p=0.00). The number of complications were greater in rigid arm (2% v/s 7%, p=0.07).

Conclusion: Though the biopsy size seems significantly larger in rigid arm, patient comfort and lesser rate of complications were found in semi-rigid arm with a comparable diagnostic yield.

Keywords: Pleural Effusion; Rigid Thoracoscopy; Semi-rigid Thoracoscopy; Diagnostic Yield; Safety.

Introduction

Pleural diseases sometimes may present as a diagnostic challenge to the pulmonologist. The diagnostic yield from thoracentesis and/or closed pleural biopsy is poor, leaving between 25% and 40% of pleural abnormalities undiagnosed.[1,2] The British Thoracic Society recommends thoracoscopy as the next line of investigation after a negative or inconclusive pleural fluid aspirate in the setting of an exudative pleural effusion.[3] Thoracoscopy can be performed either using a rigid thoracoscope, which requires more expertise or a semi-rigid thoracoscope which is more operator friendly but yield a smaller biopsy size. Hence, objective of our study was to compare the diagnostic yield and safety of rigid and semi-rigid thoracoscopy in undiagnosed exudative pleural effusions.

Methodology

This was a cross sectional study conducted at Institute of Chest Diseases, Government Medical College, Kozhikode for a period of one and half years from January 2018 to June 2019 in patients hospitalised with exudative pleural effusion. All patients with exudative pleural effusion, above 18 years of age who had given their informed consent and in whom a specific diagnosis was not obtained after cytological and/or microbiological examinations and closed pleural biopsy were included in the study. The protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all subjects. 70 subjects were allocated for either rigid or semi-rigid thoracoscopy randomly, with 35 cases in each group. The primary outcome measured was the diagnostic yield. The secondary outcomes measured were the requirement for sedatives and analgesics, biopsy size (longest axis length), visual analogue scale pain score, the operator's view of the procedure and the complications.

Procedure

Thoracoscopy was performed in the bronchoscopy suite on a spontaneously breathing subject under conscious sedation, observing complete aseptic precautions. After inspecting parietal, visceral and diaphragmatic pleura, biopsies were taken under direct vision from suspected areas of the parietal pleura. Biopsies were performed using the respective biopsy forceps. The duration of intercostal tube drainage and complications were also recorded. The complications were classified as major (empyema, major hemorrhage [drop in hemoglobin by 1 g/dL or requiring blood transfusion], persistent air leak of > 3 days, and re-expansion pulmonary edema) and minor (subcutaneous emphysema, operative site infection, non-infective fever, and minor hemorrhage).

Statistical Analysis

Data was analyzed using SPSS (statistical package for social sciences) software. Quantitative data were expressed as the mean ± SD or percentage. Differences in categorical data were compared using the chi-square test (or Fisher exact test). A p value of < 0.05 was considered statistically significant.

Results

70 subjects with exudative pleural effusions were enrolled in the study, 35 patients each being randomized to semi rigid and rigid thoracoscopy arms. The mean age of study population was 61.39 ± 12.6. There were 46 males (65.7%) and 24 females (34.3%) in the study group.

The baseline characteristics of the study subjects in each group are shown in Table: 1. There was no significant difference in any of these characteristics. Dyspnoea, cough, chest pain and fever were the most

common symptoms in order of frequency. 59 patients (84.3%) had loss of appetite and weight. 22 patients (31.4%) were smokers. 9 patients (12.9 %) had underlying co morbidities, commonest being diabetes mellitus. 4 patients (5.7 %) had history of malignancy and 8 patients (11.4 %) had history of tuberculosis. 27 cases (38.6%) had clubbing on examination. Out of the 70 patients, 43(61.4%) had left sided effusion. There was massive effusion in 43 cases (61.4%) and moderate effusion in 27 cases (38.6%). Pleural fluid study showed lymphocytic exudative effusion in all cases (100%). 44 cases (62.9%) had haemorrhagic fluid and 26 cases (37.1%) had straw coloured fluid. All cases had low Adenosine Deaminase (ADA) levels with mean value of 24.31 ± 14.24.

Radiological investigations including chest X ray, CECT thorax and USG thorax were done prior to thoracoscopy. Findings are noted in Table: 2. CECT was done to look for loculations or encystment, pleural nodules, pleural thickening and any evidence of metastases. Out of the 70 cases, only 1 case (1.4%) had loculations. There were enhanced pleural nodules in 25 cases (35.7%) and pleural thickening in 15 cases (21.4%). 23 cases (32.9%) had mediastinal adenopathy and 14 cases (20%) had evidence of distant metastases. The presence of pleural nodules showed increased risk for malignancy with odds ratio (OR) of 4.16.

USG was done prior to the procedure to assess the amount of fluid, underlying loculations, septations, pleural nodules and pleural sliding. Average size of effusion

Table 1: Baseline Characteristics

Characteristics	Semi Rigid Thoracoscopy(n=35)	Rigid Thoracoscopy(n=35)	Total (n=70)	p value
Age	62.54±10.68 years	60.23±14.36 years	61.39±12.6 years	0.442
Sex:male/female	21/14	25/10	46/24	0.314
Symptoms				
Dyspnoea	35/35 (100.0%)	35/35 (100.0%)	70/70(100.0%)	
Cough	25/35(71.4%)	31/35 (88.6%)	56/70(80.0%)	0.073
Chest pain	16/35 (45.7%)	14/35 (40.0%)	30/70 (42.9%)	0.062
Fever	7/35 (20.0%)	9/35(25.7%)	16/70(22.9%)	0.569
Hoarseness	3/35 (8.6%)	0/35(0.0%)	3/70(4.3%)	0.077
Loss of Appetite	31/35 (88.6%)	28/35(80.0%)	59/70(84.3%)	0.032
Loss of Weight	31/35 (88.6%)	28/35(80.0%)	59/70(84.3%)	0.032
Comorbidities				
Diabetes	5/35 (14.3%)	4/35 (11.4%)	9/70 (12.9%)	0.072
Hypertension	3/35 (8.6%)	4/35 (11.4%)	7/70 (10.0%)	0.690
CAD	2/35 (5.7%)	1/35 (2.9%)	3/70 (4.3%)	0.555
Previous Malignancy	4/35 (11.4%)	0/35 (0.0%)	4/70 (5.7%)	0.039
Previous Tuberculosis	4/35 (11.4%)	4/35 (11.4%)	8/70 (11.4%)	1.00
\Smoking status	14/35 (40.0%)	8/35 (22.9%)	22/70 (31.4%)	0.122
Clubbing	12/35 (34.3%)	15/35 (42.9%)	27/70 (38.6%)	0.461

was 6.86 ±2.67 cm. Sliding was present in all cases. There were no cases with loculations but one case had septations (1.4%). 22 cases (31.4%) showed pleural nodules and 69 out of 70 cases (98.6%) had thickened pleura. The presence of nodules in ultrasound increased the risk for malignancy by odds ratio (OR) of 7.8.

Pain during the procedure was assessed subjectively by visual analogue scale (VAS) [Fig: 1] and objectively on the basis of amount of sedatives [Fig: 2 (a & b)] and analgesics [Fig: 3 (a & b)] used. The given graphs show comparison between 2 groups. Pain score was significantly higher in rigid thoracoscopy arm when compared to semi rigid thoracoscopy arm [74.74 ±10.5 v/s 63.71±7.9, p value=0.00]. The amounts of sedative and analgesic use were also greater in rigid arm. While doing semi rigid thoracoscopy, we had to give 2 mg midazolam for 33/35 cases (94.3%) as sedative while during rigid thorcoscopy, higher amount of midazolam (4 mg) was used in 24/35 (68.6%) cases [p value = 0.000]. Higher amount of fentanyl was also needed during rigid thoracoscopy when compared to semi rigid thoracoscopy [44.28 ±16.14 mcg v/s 29.43± 9.6 mcg p value=0.00]. In terms of need for analgesics like tramadol and paracetamol infusion, rigid arm showed higher consumption than semirigid arm for both [p values 0.324 and 0.001 respectively].

Table 2: Radiological Findings

Radiological findings	Semi Rigid Thoracoscopy n=35	Rigid Thoracoscopy n=35	Total n=70	p value
Chest X ray				
Side (left/right)	15/20	12/23	27/43	0.321
Size				
Massive	23/35 (65.7%)	20/35 (57.1%)	43/70 (61.4%)	0.562
Moderate	12/35 (34.3%)	15/35 (42.9%)	27/70 (38.6%)	
CECT thorax				
Loculations	0/35 (0.0%)	1/35 (2.9%)	1/70 (1.4%)	0.314
Pleural thickening	8/35 (22.9%)	7/35 (20.0%)	15/70 (21.4%)	0.771
Pleural nodules	15/35 (42.9%)	10/35 (28.6%)	25/70 (35.7%)	0.212
Mediastinal adenopathy	13/35 37.1%	10/35 28.6%	23/70 (32.9%)	0.445
Metastases	7/35 (20.0%)	7/35 (20.0%)	14/70 (20.0%)	1.00
USG thorax				
Size (cm)	7.43 ±2.25	6.29 ±2.50	6.86 ±2.67	0.022
Septations	0/35 (0.0%)	1/35(2.9%)	1/70 (1.4%)	0.314
Pleural nodules	14/35 (40.0%)	8/35 (22.9%)	22/70 (31.4%)	0.122
Pleural thickening	35/35(100.0%)	34/35 (97.1%)	69/70 (98.6%)	0.314

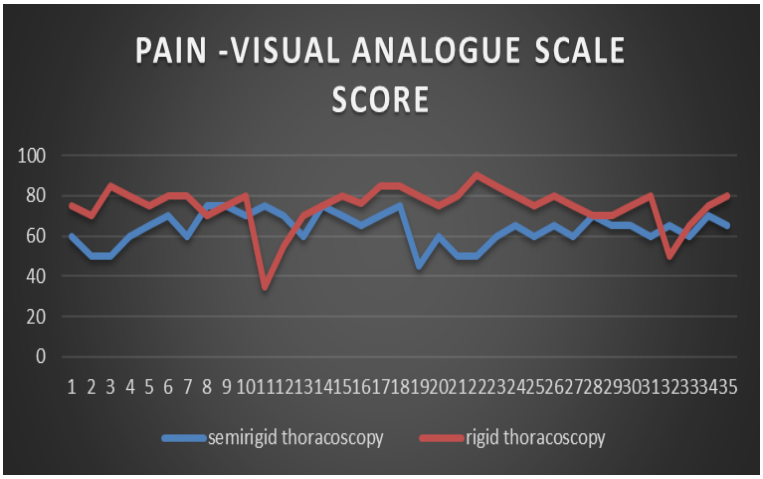

Figure: 1-Pain-VAS Score

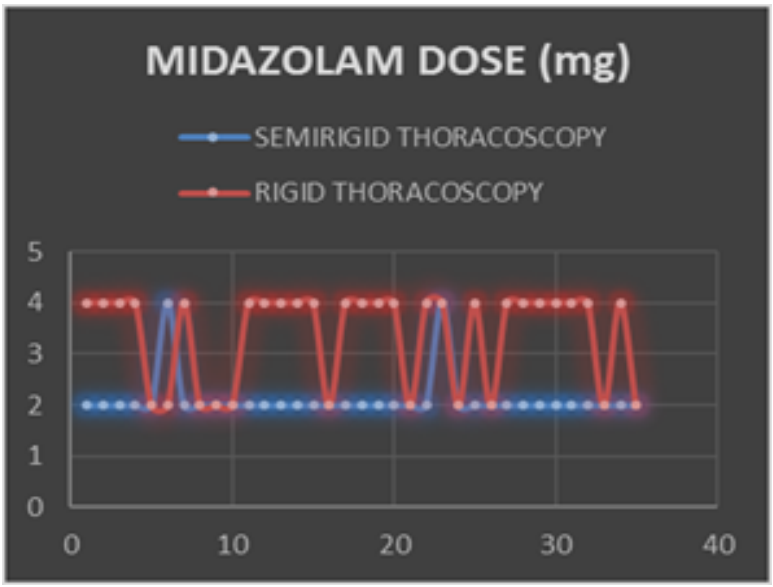

Figure: 2(a) - Comparison of Sedative Use

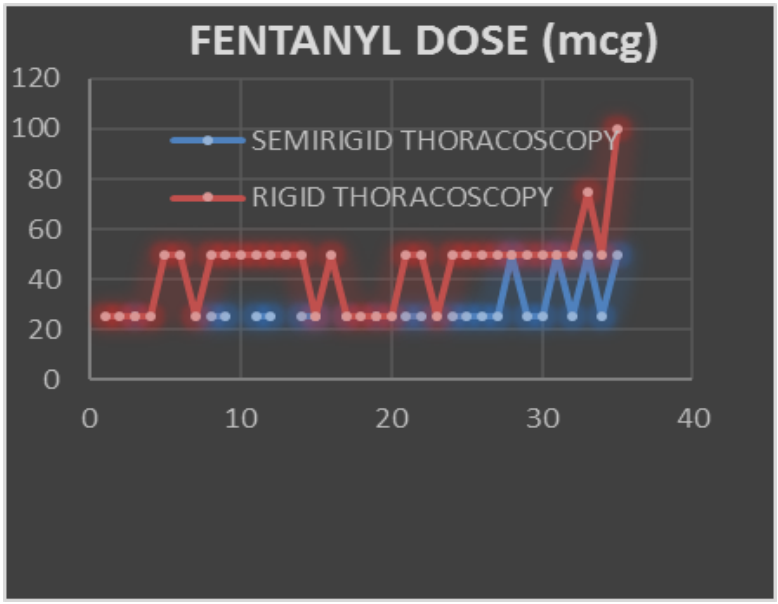

Figure: 2(b) Comparison of Sedative Use

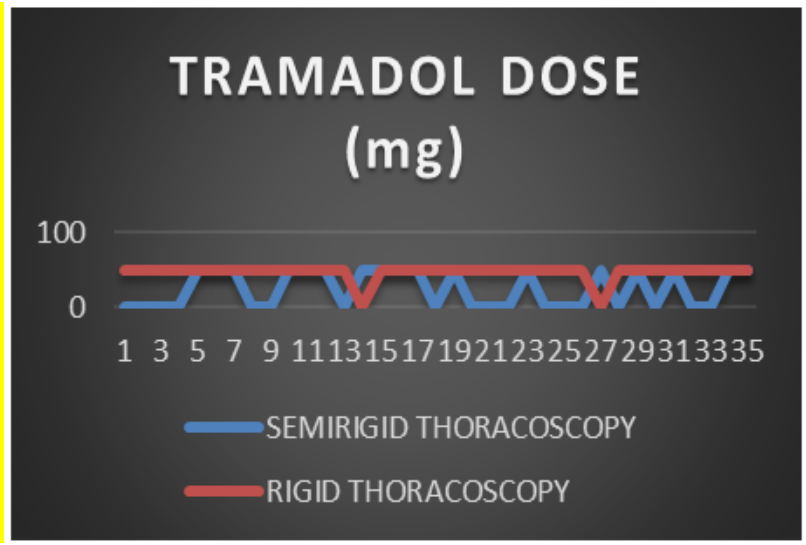

Figure: 3(a) - Comparison of Analgesic Use

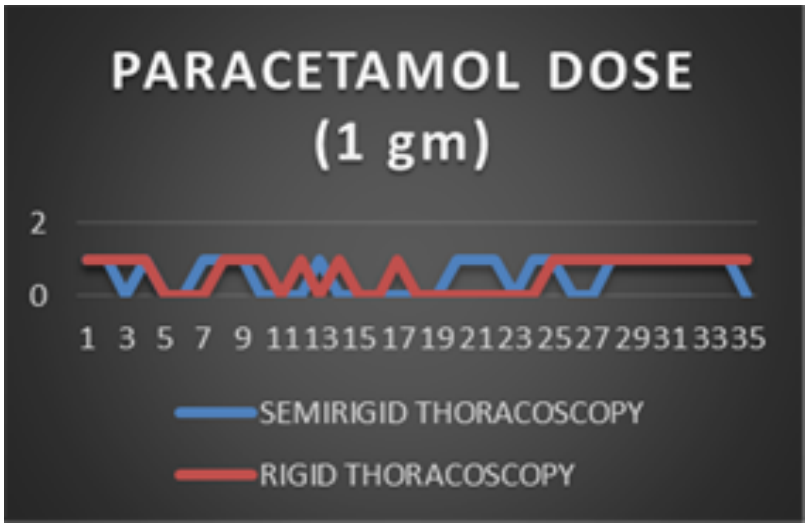

Figure: 3(b) - Comparison of Analgesic Use

Operator's easiness of doing procedure was assessed by visual analogue scale (VAS) regarding image quality, easiness of manoeuvering and taking biopsy. There was no much statistical difference between two groups (Table: 3). Rigid thoracoscopy was more time consuming when compared to semi rigid thoracoscopy [58.71 ± 9.8 v/s 43.85 ± 4.7 minutes, p value=0.00]. Rigid thoracoscopy yielded a larger biopsy size [1.13 ±.0.26 cm] when compared to semi-rigid thoracoscopy [0.57 ± 0.13 cm] and was statistically significant [p value=0.00].

Table 3: Operators Assessment of Procedure

	Semi rigid thoracoscopy	**Rigid thoracoscopy**	**p value**
Image quality	76.8 ±3.8	74.5± 6.10	0.065
Ease of manoeuvring	72.85± 5.18	71.77± 7.18	0.471
Ease of taking biopsy	72.28±6.68	71.0 ± 4.9	0.364

Table 4: Histopathological Diagnosis

	Malignancy	Tuberculosis	Inconclusive
Semi rigid thoracoscopy	28/35 (80.0%)	1/35 (2.9%)	6/70 (17.1%)
Rigid thoracoscopy	28 /35 (80.0%)	3/35 (8.6%)	4/70 (11.4%)
Total	56/70 (80.0%)	4/70 (5.7%)	10/70 (14.3%)

29 out of 35 patients (82%) had a positive diagnosis in semi rigid arm whereas in rigid arm positive diagnosis was obtained in 31 out of 35 patients (88%). (Table: 4). The diagnostic yield of rigid thoracoscopy was thus found to be superior to semi-rigid thoracoscopy, though statistically not significant [p=0.49]. 56 patients (80%) had a histopathological diagnosis of malignancy with adenocarcinoma being the most common histological subtype followed by squamous cell carcinoma, mesothelioma, small cell carcinoma and lymphoma. Tuberculosis was diagnosed in 4 patients (5.7%).

The complication rate was higher in rigid arm when compared to semi-rigid arm [p value = 0.074]. 7 out of 35 (20%) patients who underwent rigid thoracoscopy developed complications in the form of subcutaneous emphysema and persistent air leak. Only 2 out of 35 (5.7%) patients who underwent semi-rigid thoracoscopy developed complications in the form of noninfectious fever. In both groups, number of intercostal drainage days were around 4 to 7days [p value = 0.356]. None of our patients developed major complications like uncontrolled bleeding. There was no mortality following any thoracoscopy.

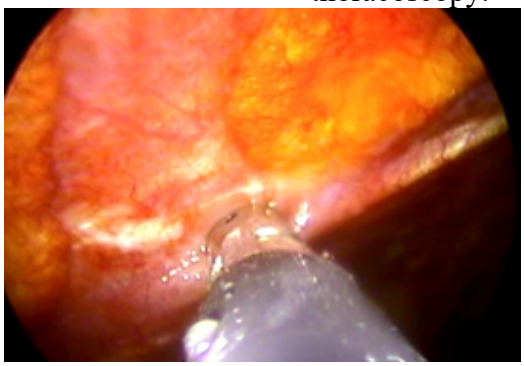

Figure 4(a) : Pleural biopsy taken using rigid thoracoscopy forceps

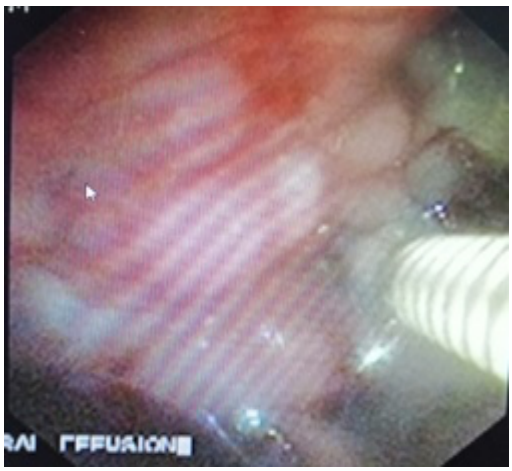

Figure 4(b) : Pleural nodule biopsy taken using semirigid thoracoscopy forceps

Discussion

Our study was a single centre prospective comparative study done at Institute of Chest Diseases, Government Medical College, Kozhikode in 70 patients with undiagnosed exudative effusion. The main objective of our study was to compare the efficacy and safety of rigid versus semi-rigid thoracoscopy in undiagnosed exudative pleural effusions.

In our study, the diagnostic yield of semi rigid thoracoscopy was 82% (29/35) and rigid thoracoscopy was 88% (31/35), which was statistically comparable, though there was statistically significant difference in pleural biopsy size. Rigid thoracoscopy yielded a larger biopsy size [1.12 ±.0.26 cm] when compared to semi-rigid thoracoscopy [0.57 ±0.13 cm]. Though larger specimens are preferred, two randomized trials and one prospective comparative study done previously showed no significant difference in the diagnostic yield between rigid and flexi-rigid pleuroscopy.[4-6]

In the study by Khan et al, a series of 66 patients with unilateral exudative pleural effusions were enrolled, 27 underwent rigid thoracoscopy and 39 underwent semi-rigid thoracoscopy.[4] Thoracoscopic pleural biopsy achieved a positive diagnosis in 26 of 27 patients in the rigid thoracoscopy group (96.3%) and 36 of 39 patients in the semi-rigid group (92.3%).[4] There was no statistically significant difference between these proportions (95% confidence intervals, 0.11 to 0.17) as obtained in our study. Compared to our study, this study had a higher diagnostic yield in both arms. The major drawback of the study was the procedures were performed by different operators at different hospitals.

It was Rozman et al, who published the first randomized study with 84 patients comparing the diagnostic adequacy of biopsy specimens obtained at rigid and flexi-rigid pleuroscopy.[5] They found similar diagnostic accuracy with rigid (100%) and flexi-rigid instruments (97.6%) even though specimens obtained through the rigid forceps were considerably larger [24.7 mm v/s. 11.7 mm].

In another study, Dhooria et al, randomized 90 patients to undergo rigid or semi rigid thoracoscopy.[6] The diagnostic yield for rigid thoracoscopy was noted to be superior to flexi-rigid pleuroscopy on an intention-to-treat analysis (97.8% versus 73.3%) but was similar (100% versus 94.3%) after excluding patients in whom thoracoscopy was not feasible because of extensive adhesions. The biopsy sample size was distinctly larger in the rigid arm [13.9 ± 4.4 v/s 4.4 ±1.4 mm, p=0.001]. Seven of the forty-five patients from the flexi-rigid thoracoscopy arm crossed over to the rigid thoracoscopy arm because of the lack of pleural space.

It is mandatory to do USG thorax before thoracoscopy to localize the site for incision, to assess the fluid status and to look for nodules or adhesions. Presence of large nodules and absence of septations in USG can help us to select semi-rigid thoracoscopy as the desired procedure of choice as evident from our study. If the pleura is thickened and uniformly dense without any obvious nodules, it is difficult to get a desired biopsy by semi-rigid thoracoscopy. In such cases rigid thoracoscopy is always the better option.

Pain during the procedure was assessed subjectively by visual analogue scale (VAS) and objectively on the basis of amount of sedatives and analgesics used. Patients pain score was significantly higher in rigid thoracoscopy arm when compared to semi rigid thoracoscopy arm [74.74 ± 10.5 versus 63.71 ± 7.9, p value=0.00], which was not assessed in any other previous studies. The amount of sedatives and analgesic used were also greater in rigid arm. Higher amount of midazolam [4 mg in 24/35 versus 2 mg in 33/35, p value=0.00] and fentanyl [44.28 ± 16.14 mcg v/s 29.43 ± 9.6 mcg, p value=0.00] were needed during rigid thoracoscopy when compared to semi rigid thoracoscopy. In terms of need for analgesics like

tramadol and paracetamol infusion also, rigid arm showed higher consumption than semi rigid arm [p value=0.324 and 0.001 respectively]. Larger trocar used during rigid thoracoscopy can cause greater pain and discomfort to the patient necessitating the need for more amounts of sedatives and analgesics during the procedure.

In our study, operator-rated visual analogue scale score for the ease of taking a biopsy sample [VAS: 72.28 ± 6.68 v/s 71.0 ± 4.9, p value=0.364] and manoeuvring thoracoscope [VAS: 72.85 ± 5.18 v/s 71.77 ± 7.18, p value =0.471] were comparable in both arms.

The complication rate was found higher in rigid arm in our study in contrary to other studies which showed similar rate with both procedures.[7,8] There was no mortality following thoracoscopy in our study. Complications like subcutaneous emphysema and persistent air leak were higher in rigid arm. Larger scope used during rigid thoracoscopy can cause trauma to lung especially when patient is restless or coughing, necessitating the need for proper sedation of the patient. The intercostal tube remained for a mean ± SD duration of 7.7 ± 3 days, which did not differ significantly between the two groups. Many of our patients had longer days with intercostal tube when compared to previous studies as we proceeded with pleuorodesis via intercostal tube only after getting a definite histopathological report.

The main drawback of our study is that it was done by different operators and their operator skill varies which indirectly affect the diagnostic yield. We could not follow up our patients with inconclusive results. We also were not able to compare the results with gold standard VATS biopsy.

Conclusion

Medical thoracoscopy should be done in all undiagnosed exudative pleural effusion to rule out the common differentials tuberculosis and malignancy which require early diagnosis and treatment. Ultrasound scan of thorax prior to the procedure helps us in detecting pleural nodules, adhesions and multiple loculations which guide the operator to go for the convenient thoracoscope. Overall, the choice of thoracoscope should depend upon the operator expertise, availability of the scope and the type of effusion. Our study showed comparable diagnostic yield between two types of thoracoscopes, though biopsy size was significantly larger in rigid arm. Patient comfort and lesser complications were noted in semi rigid arm. Further studies have to be undertaken in large sample of patients to accurately compare the two procedures.

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