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TO STUDY IODINE VERSUS TALC PLEURODESIS IN RECURRENT SUSPICIOUS MALIGNANT PLEURAL EFFUSION AND RECURRENT PNEUMOTHORAX: A COHORT STUDY.

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ABSTRACT

Background

Malignant pleural effusion (MPE) significantly diminishes the quality of life in individuals with advanced lung cancer and other malignancies. Effective management is crucial for symptom relief and improved outcomes. This study compares the safety, efficacy, and success rates of talc versus povidone-iodine pleurodesis in patients with recurrent MPE and spontaneous pneumothorax.

Methods

The study involved 66 MPE patients who underwent medical thoracoscopy followed by either talc (Group A) or povidone-iodine (Group B) pleurodesis. Data on demographics, clinical presentation, radiological findings, pleural fluid analysis, thoracoscopic findings, complications, and pleurodesis outcomes were collected. Statistical analysis compared the efficacy and safety of both methods.

Results

The study comprised 66 participants, with an average age of 57.86 ± 9.92 years. Pleurodesis was successful in 90.90% of the talc group (n=30) and 100% of the povidone-iodine group (n=33). Complications associated with talc included ARDS (4.5%, n=1) and empyema (4.5%, n=1), whereas povidone-iodine was associated with higher incidences of pain (63.63%, n=14) but no cases of ARDS or empyema. The mean duration of intercostal tube drainage was 4.8 ± 2.1 days for talc and 4.2 ± 1.8 days for povidone-iodine. The mean hospital stay was 8.4 ± 1.8 days for talc and 9.2 ± 2.2 days for povidone-iodine. Povidone-iodine pleurodesis had a slightly higher success rate and fewer severe complications compared to talc pleurodesis.

Conclusion

Both talc and povidone-iodine pleurodesis are effective for managing MPE, with povidone-iodine showing a higher success rate and fewer severe complications. These findings suggest that povidone-iodine may be a safer alternative to talc for pleurodesis in MPE patients.

Recommendations

Further research is recommended to optimize pleurodesis techniques and agents, considering patient-specific factors to improve outcomes and minimize complications. Clinicians should weigh the benefits and risks of each pleurodesis agent to make informed treatment decisions.

***Keywords*:** *Malignant pleural effusion, Pleurodesis, Talc, Povidone-iodine, Thoracoscopy*
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INTRODUCTION

Since lung cancer accounts for 13% of every new cancer case and 19% of deaths due to cancer globally, it is becoming progressively recognized as a serious global health issue [1]. It accounts for 9.3% of fatalities due to cancer in India for both sexes and 6.9% of all new cases of cancer [2]. Alongside lung cancer, primary pleural tumors such as mesothelioma are also on the rise. A common complication of advanced malignancies, malignant pleural effusion (MPE), frequently results from lung and breast cancers, making up 50 to 60% of MPE cases [3]. The main symptoms of MPE include chronic shortness of breath, cough, and pain, significantly diminishing the quality of life for cancer patients. The primary goal in treating MPE is to alleviate dyspnea, restore normal activity and function, and minimize hospitalizations.

Treatment options for MPE involve draining the pleural fluid through methods such as thoracocentesis, tube thoracostomy, and thoracoscopic drainage [4].

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Thoracocentesis, while providing temporary relief, often results in fluid reaccumulation. Tube thoracostomy involves placing a tube for continuous drainage, but recurrence of MPE is common within 30 days [5]. Pleurodesis, aimed at preventing fluid reaccumulation, is performed when the pleural space drains minimally, and the lung is fully expanded. This procedure induces inflammation to adhere to the parietal and visceral pleurae, typically using chemical agents.

Chemical pleurodesis, particularly with talc, is the most commonly used method. Talc pleurodesis, first introduced by Bethune in 1935, has proven effective and cost-efficient [6]. Medical thoracoscopy (MT), offering excellent visualization and biopsy capabilities, enhances the efficacy of talc pleurodesis. Talc insufflation through thoracoscopy ensures even distribution and effective pleurodesis. Despite potential complications, talc remains a preferred agent due to its high efficacy and low cost.

Povidone-iodine, a broad-spectrum antiseptic, has emerged as an alternative pleurodesis agent since 1990 [7]. Its mechanisms, involving low pH and oxidative properties, induce a potent inflammatory response, enhancing sclerosis. Studies comparing talc and povidone-iodine show comparable efficacy and safety, with povidone-iodine presenting fewer side effects.

Given the effectiveness of both agents, this study aims to compare the safety, efficacy, and outcomes of talc and povidone-iodine pleurodesis in managing malignant pleural effusion. The findings could significantly impact therapeutic and palliative strategies for MPE patients, ensuring better quality of life and reduced recurrence of pleural effusion.

The current study aims to compare and assess the safety, efficacy, and permanence of talc versus povidone-iodine pleurodesis in recurrent malignant pleural effusion and spontaneous pneumothorax, and to evaluate which agent offers better patient quality of life and lower recurrence rates.

METHODOLOGY

Study Design

A hospital-based observational cohort study.

Study Setting

The study was done at Indira Gandhi Medical College (IGMC) Shimla, India, specifically within the Department of Pulmonary Medicine, spanning from August 2019 to August 2020.

Participants

A total of 66 participants were involved in the study.

Inclusion Criteria

Patients aged 18 years and above, with recurrent suspicious malignant pleural effusion, and with recurrent spontaneous pneumothorax.

Exclusion Criteria

Patients with severe chronic pulmonary disease, respiratory insufficiency characterized by hypoxemia and hypercapnia, transudative pleural effusion, endobronchial growth, unstable cardiovascular status, coagulation defects, bleeding diathesis, or thrombocytopenia, anticoagulation therapy, with a history of drug hypersensitivity reactions, experiencing fever and severe cough, with severe pulmonary fibrosis, unable to lie in a lateral decubitus position, and surgically unfit patients.

Sample size

To calculate the sample size for this study, the following formula was used for estimating a proportion of a population:

$$n = \frac{Z2 \times p \times (1-p)}{E2}$$

Where:

- n = sample size
- Z = Z-score corresponding to the desired level of confidence
- p = estimated proportion in the population
- E = margin of error

Bias

Bias was minimized through the use of simple randomization to assign patients into two groups (Group A and Group B) and by ensuring that all procedures were performed under similar conditions using a standardized technique.

Variables

Variables included the efficacy of pleurodesis, recurrence rates of pleural effusion or pneumothorax, and patient quality of life post-procedure, the amount of pleural fluid drained, pain levels, and any adverse effects or complications associated with the procedure.

Data Collection

Data collection involved detailed history taking, full clinical examinations, routine chemical and hematological blood analyses, including liver and renal function tests, complete blood count, coagulation profile, viral markers, chest x-rays (PA and lateral views), chest ultrasounds, contrast-enhanced computed tomography (CECT) scans of the chest, and bronchoscopy.

Procedure

All procedures were performed under local anesthesia using 2% lidocaine for skin, subcutaneous tissue, and periosteum anesthesia. Sedation and analgesia were provided with midazolam and tramadol. Patients were monitored for vital signs and oxygen saturation. The thoracoscopy was performed using a single-port entry technique. Pleural fluid was carefully aspirated, adhesions were dissected, and pleural biopsy samples were taken.

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- Group A: Received 3g of sterile, asbestos-free talc (sterile) instilled into the pleural space via poudrage or slurry methods. The chest drain was clamped for 2 hours post-instillation.
- Group B: Received 20 ml of 10% povidone-iodine mixed with 80 ml of normal saline and 2% lidocaine (2 mg/kg body weight) instilled through the chest drain, which was also clamped for 2 hours.

Pain management was provided as needed, and the chest tube was left in place for a minimum of 3 days, removed when fluid drainage was less than 100 ml/24 hours, and lung expansion was satisfactory.

Statistical Analysis

The statistical analysis involved descriptive statistics for baseline characteristics and outcome measures. Comparative analysis was conducted to assess the efficacy and safety between the two groups using appropriate statistical tests to determine significance. Follow-up data were analyzed to evaluate the long-term outcomes and recurrence rates. Statistical software was used for all analyses, ensuring rigorous and accurate interpretation of the data.

Ethical considerations

The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

RESULT

In the study, out of the 66 patients, 59.09% were male. The majority of participants (40.90%) fell within the 61-70 age group, with a mean age of 57.86 ± 9.92 years, ranging from 35 to 75 years. In terms of smoking history, 36.36% were smokers, with all female patients being non-smokers.

Table 1: Clinical Symptoms and Signs

Variables	Frequency (n=66)	Percentage (%)
Symptoms		
- Dyspnea	66	100%
- Chest pain	50	75.76%
- Cough	27	40.91%
- Expectoration	9	13.63%
- Loss of appetite	21	31.81%
- Weight loss	15	22.73%
General Signs		
- Pallor	36	54.55%
- Clubbing	3	4.54%
- Pedal Edema	9	13.63%
- Lymphadenopathy	14	21.21%

Regarding the duration of symptoms, most patients (61.36%) presented with symptoms lasting more than 60 days. This was followed by 20.45% with symptoms lasting 30-59 days, 11.36% with symptoms lasting 15-29 days, and 6.81% with symptoms lasting less than 15 days. The predominant clinical presentation was dyspnea, seen in all patients (100%), followed by chest pain in 75.75%, cough in 40.91%, expectoration in 13.63%, loss of appetite in 31.81%, and weight loss in 22.72%.

On general examination, pallor was observed in 54.55%, clubbing in 4.54%, pedal edema in 13.63%, and lymphadenopathy in 21.21%. Respiratory examination revealed that all patients exhibited contralateral mediastinal shifting.

Comorbidities were present in 40.90% of the study population, with hypertension being the most common (22.72%), followed by type-2 diabetes mellitus (18.18%). Radiological findings showed that 63.63% had right-sided effusion, while 36.36% had left-sided effusion. Massive effusion was the most common finding, observed in 81.81%, followed by moderate effusion in 15.15%and loculated effusion in 3.03%.

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Table 2: Radiological and Thoracic Ultrasonography Findings

Variables	Frequency (n=66)	Percentage (%)
Radiological Findings		
- Right-sided effusion	42	63.63%
- Left-sided effusion	24	36.36%
- Massive effusion	54	81.81%
- Moderate effusion	10	15.15%
- Loculated effusion	2	3.03%
Thoracic Ultrasonography Findings		
- Pleural thickening	14	21.21%
- Multiple septations and loculations	9	13.63%
- Collapsed lung	66	100%
- Free-flowing effusion	65	98.48%
- Loculated effusion	1	1.52%
Pleural Fluid Examination		
- Hemorrhagic appearance	45	68.18%
- Serosanguinous fluid	21	31.82%
- Malignant cells detected	53	79.54%
- No malignant cells	13	20.45%
- Mean pleural fluid LDH (IU/L)	992.90 ± 472.68	-
- Mean pleural fluid sugar (mg/dl)	45.45 ± 18.32	-
- Mean pleural fluid protein (g/dl)	5.04 ± 0.63	-
- Mean pleural fluid ADA (IU/L)	20.14 ± 6.18	-

Thoracic ultrasonography revealed multiple septations and loculations in 13.63%, pleural thickening in 20.45%, and collapsed lung in all cases (100%). The CECT thorax findings indicated pleural effusion in 87.87%, pleural nodules in 60.60%, pleural thickening in 21.21%, and lung mass in 45.45%.

Pleural fluid examination showed that the most common macroscopic appearance was hemorrhagic, observed in 68.18%, while serosanguinous fluid was seen in 31.81%. The mean pleural fluid LDH was 992.90 ± 472.68 IU/L, sugar was 45.45 ± 18.32 mg/dl, protein was 5.04 ± 0.63 g/dl, and ADA was 20.14 ± 6.18 IU/L. Malignant cells were detected in 79.54%, with no malignant cells found in 20.45%.

Thoracoscopic findings highlighted multiple pleural nodules in all cases (100%), neovascularization in 54.54%, fibrous bands in 36.36%, and unhealthy rough pleural surfaces in 40.90%. Severe chest pain was the most common complication of thoracoscopy, affecting 13.63%, followed by subcutaneous emphysema in 4.54%. Histopathological diagnosis revealed that adenocarcinoma was the most common cause of malignant pleural effusion, observed in 68.18%, followed by squamous cell carcinoma in 25.0% and malignant mesothelioma in 2.27%.

Table 3: Outcome and Complications of Pleurodesis

Variables	Talc Poudrage (n=33)	Povidone-Iodine (n=33)
Outcome of Pleurodesis		
- The mean duration of ICTD	4.8 ± 2.1 days	4.2 ± 1.8 days
- Mean Duration of Hospital Stay	8.4 ± 1.8 days	9.2 ± 2.2 days
- Successful Pleurodesis	30 (90.91%)	33 (100%)
- Failed Pleurodesis	3 (9.09%)	0 (0%)
Complications of Pleurodesis		
- Pain	14 (42.42%)	21 (63.64%)
- Fever	10 (30.30%)	8 (24.24%)
- ARDS	1 (3.03%)	0 (0%)
- Empyema	1 (3.03%)	0 (0%)

In terms of outcomes, the mean duration of intercostal tube drainage (ICTD) for patients undergoing talc poudrage was 4.8 ± 2.1 days, and the mean hospital stay was 8.4 ± 1.8 days. For povidone-iodine pleurodesis, the

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mean duration of ICTD was 4.2 ± 1.8 days, and the mean hospital stay was 9.2 ± 2.2 days. Complications associated with talc poudrage included pain (42.42%), fever (30.30%), ARDS (3.03%), and empyema (3.03%). In contrast, povidone-iodine pleurodesis was associated with pain in 63.64% and fever in 24.24%, with no cases of ARDS or empyema.

The success rate of pleurodesis was 90.90% for the talc poudrage group, while povidone-iodine pleurodesis achieved a 100% success rate. These findings indicate that both talc and povidone-iodine pleurodesis are effective and relatively safe for managing recurrent malignant pleural effusion and recurrent spontaneous pneumothorax, with povidone-iodine showing a slightly higher success rate and fewer complications.

DISCUSSION

The study included 66 patients and most participants were male (59.09%) and aged between 61-70 years. A significant portion of the patients (61.36%) had symptoms for over 60 days. The primary clinical symptom was dyspnea, observed in all patients, with chest pain and cough also being common.

Radiological findings indicated that the majority of effusions were right-sided (63.63%) and massive in extent (81.81%). Thoracic ultrasonography and CECT thorax identified common features such as pleural thickening, multiple septations, pleural nodules, and lung mass. Pleural fluid examination revealed that most fluids were hemorrhagic, and malignant cells were present in 79.54% of cases.

The thoracoscopic findings frequently showed multiple pleural nodules and neovascularization. Complications from thoracoscopy included severe chest pain and subcutaneous emphysema. Histopathological analysis indicated that adenocarcinoma was the predominant cause of malignant pleural effusion.

Outcome analysis demonstrated that the mean duration of intercostal tube drainage was similar for both talc and povidone-iodine pleurodesis groups, with slightly longer hospital stays for the povidone-iodine group. Talc poudrage was associated with higher incidences of ARDS and empyema, while povidone-iodine had higher incidences of pain but no cases of ARDS or empyema. The success rate of pleurodesis was 90.90% for talc and 100% for povidone-iodine.

The study highlights the effectiveness of both talc and povidone-iodine pleurodesis in treating malignant pleural effusion. Povidone-iodine pleurodesis demonstrated a slightly higher success rate and fewer severe complications compared to talc poudrage, making it a potentially safer option for patients. However, talc remains a highly effective pleurodesis agent, particularly in cases where povidone-iodine is not suitable or available.

These findings suggest that povidone-iodine could be considered a preferred pleurodesis agent due to its high efficacy and lower incidence of severe complications such as ARDS and empyema. Nonetheless, the choice of pleurodesis agent should be tailored to the individual patient's condition, considering factors like underlying health status, comorbidities, and potential reactions to the agents used.

Overall, this study provides valuable insights into the management of malignant pleural effusion, supporting the continued use of both talc and povidone-iodine pleurodesis while highlighting the need for further research to optimize patient outcomes and minimize complications.

Recent research has examined the effectiveness and safety of iodine versus talc pleurodesis for recurrent malignant pleural effusions and pneumothorax. One study evaluated pleurodesis outcomes using talc and povidone-iodine in patients with these conditions. It found a 100% success rate for talc pleurodesis and an 81.25% success rate for povidone-iodine over six months. Post-procedure pain was more common with talc pleurodesis (57.14%) compared to povidone-iodine (31.25%), suggesting higher pain incidence with talc. Both agents were deemed effective, with povidone-iodine noted for its safety, availability, and cost-effectiveness [8].

Another study on povidone-iodine pleurodesis in 50 individuals with recurrent malignant pleural effusion reported an 80% recovery rate over six months. Higher post-procedure pain was associated with unsuccessful pleurodesis. This study concluded that povidone-iodine is an efficient and cost-effective alternative to traditional agents like talc [9].

In a study involving 104 cancer individuals with malignant pleural effusion, 79% did not experience fluid reaccumulation over a mean follow-up of 7.8 months. Despite some patients experiencing severe pain and fever, there were no periprocedural deaths. This study highlighted povidone-iodine as an effective and safe pleurodesis agent with minimal complications [10].

A randomized controlled trial compared silver nitrate injection through chest tube thoracostomy to thoracoscopic talc insufflation for pleurodesis in malignant pleural effusion. The trial, involving 40 patients, found both methods effective, with a higher grade of pleural symphysis for talc poudrage. Chest ultrasonography was recommended for assessing pleurodesis quality, suggesting talc poudrage might be more effective than talc slurry [11].

A retrospective analysis of 114 patients with malignant pleural effusion found fewer inflammatory responses with iodine pleurodesis compared to talc and silver nitrate. Although adverse events like pain and low hemoglobin count were significant, iodine caused less severe inflammation, underscoring the need to consider systemic inflammatory response when choosing pleurodesis agents [12].

Finally, a study on the efficacy and safety of povidone-iodine pleurodesis reported a 53.57% complete response rate and 82.2% treatment efficacy. Pain during instillation was the most common complication, occurring in 26.9% of individuals. This study concluded that povidone-iodine

is a safe, effective, and low-cost pleurodesis agent with minimal side effects [13].

Generalizability
The study's results, demonstrating the efficacy and safety of both talc and povidone-iodine pleurodesis for managing malignant pleural effusion, suggest that povidone-iodine may be a safer alternative due to fewer severe complications. Applying these findings to a larger population could enhance treatment protocols, improving patient outcomes and reducing recurrence rates of pleural effusion in broader clinical settings.

CONCLUSION
The study demonstrates that both talc and povidone-iodine pleurodesis are effective treatments for malignant pleural effusion, with povidone-iodine showing a slightly higher success rate and fewer severe complications. While talc remains a highly effective option, povidone-iodine may be preferred due to its lower incidence of adverse effects like ARDS and empyema. The choice of pleurodesis agent should be personalized based on the patient's specific medical conditions and overall health status. These findings support the continued use and further investigation of both agents to optimize treatment strategies for malignant pleural effusion.

Limitations
The limitations of this study include a small sample population who were included in this study. Furthermore, the lack of a comparison group also poses a limitation for this study's findings.

Recommendation
Further research is recommended to optimize pleurodesis techniques and agents, considering patient-specific factors to improve outcomes and minimize complications. Clinicians should weigh the benefits and risks of each pleurodesis agent to make informed treatment decisions.

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List of abbreviations
MPE: Malignant Pleural Effusion
ARDS: Acute Respiratory Distress Syndrome
ICTD: Intercostal Tube Drainage
CECT: Contrast-Enhanced Computed Tomography
PA: Posteroanterior
MT: Medical Thoracoscopy
LDH: Lactate Dehydrogenase
ADA: Adenosine Deaminase

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Conflict of interest
The authors have no competing interests to declare.

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