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Comparison of Pain as Assessed by Visual Analog Scale Using Smaller (12f) Versus Larger (24f) Tubes in Patients with Malignant Pleural Effusion

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ABSTRACT

Background: Malignant pleural effusion (MPE) is a frequent complication of advanced malignancy, often requiring pleurodesis for symptomatic relief. Although both small-bore (12F) and large-bore (24F) chest tubes are routinely used, the optimal tube size with respect to patient comfort remains unclear, with conflicting evidence on pain outcomes and limited high-quality randomized data. **Objective:** To compare post-pleurodesis pain, assessed by visual analog scale (VAS), in patients with malignant pleural effusion undergoing the procedure using smaller (12F) versus larger (24F) chest tubes, and determine whether tube size significantly influences pain perception. **Methods:** This randomized controlled trial was conducted at the Pulmonology Department, Fatima Jinnah Institute of Chest Diseases, Quetta, from May to November 2024. A total of 384 patients ($n = 384$) with confirmed MPE, aged 20–70 years, were randomized into two groups (192 per group) based on chest tube size. Patients with coagulopathy, unstable vitals, or known allergies to study drugs were excluded. Povidone-iodine was used for pleurodesis following 12F or 24F tube placement. Pain was assessed using VAS over four days. Ethical approval was obtained (IRB No. FJICD-IRB-2024-05) in compliance with the Helsinki Declaration. Statistical analysis was performed using SPSS v27 with Student's t-test and stratified analysis. **Results:** Mean post-pleurodesis VAS scores were 44.16 ± 32.80 mm in the 12F group and 44.34 ± 32.58 mm in the 24F group ($p = 0.955$), indicating no statistically or clinically significant difference. Subgroup analysis by age and gender showed significant p-values but clinically negligible variations (<2 mm), suggesting uniform analgesic efficacy. **Conclusion:** Chest tube size does not significantly affect post-pleurodesis pain in patients with malignant pleural effusion when standardized analgesia is provided. Clinicians may base tube size selection on drainage efficacy rather than assumed comfort, enhancing procedural flexibility without compromising patient care.

Keywords: Malignant Pleural Effusion, Pleurodesis, Chest Tubes, Visual Analog Scale, Pain Measurement, Povidone-Iodine, Randomized Controlled Trial.

INTRODUCTION

Malignant pleural effusion (MPE) is a significant clinical condition marked by the pathological accumulation of fluid within the pleural space, typically due to advanced malignancy. This effusion is characteristically exudative, with a high protein content, resulting from metastatic spread to the pleura either via hematogenous dissemination, lymphatic obstruction, or direct invasion (1). MPE is associated with considerable morbidity, often manifesting as dyspnea, chest discomfort, and reduced quality of life in affected patients (2). While the management of MPE is palliative, aiming to alleviate

symptoms and prevent recurrence, one of the commonly employed strategies is chemical pleurodesis, which involves the instillation of a sclerosing agent into the pleural cavity to promote adhesion between the visceral and parietal pleura and obliteration of the pleural space (3). Chest tube insertion is a prerequisite for effective pleurodesis and allows drainage of pleural fluid prior to the introduction of the sclerosant.

Traditionally, both small-bore (≤ 14 French) and large-bore (≥ 24 French) chest tubes have been used for pleurodesis. However,

the choice of tube size remains controversial due to conflicting evidence regarding their effectiveness and impact on patient comfort (4). Some studies suggest that smaller tubes are associated with significantly lower pain scores, attributing this to reduced mechanical irritation and trauma to the chest wall (5). For example, Clementsen et al. reported lower pain with small-bore catheters without compromising efficacy (6).

Similarly, Terzi et al. found that flexible, smaller drains improved patient comfort post-operatively (7). On the contrary, large-bore tubes are considered less prone to obstruction, particularly in the context of thick or hemorrhagic effusions, and are believed to facilitate more efficient fluid evacuation (8). Nonetheless, pain related to chest tube insertion and indwelling duration remains a primary concern, as pleurodesis is recognized as one of the most painful thoracic procedures (9). Rahman et al., in the MIST1 trial, observed that although smaller tubes reduced pain, the difference was marginally significant, and its clinical relevance remained uncertain (10). Further, the TIME1 trial also suggested a minor but statistically insignificant difference in pain scores, calling into question the necessity of changing current practices based solely on tube size (11). A 2015 JAMA study found a VAS score difference of 4.8 mm between small and large tubes, again raising doubts about the clinical implications of such findings (12).

Despite these contributions, the existing literature is limited by small sample sizes, heterogeneous patient populations, and inconsistent use of validated pain assessment tools. Most studies also fail to account for confounding variables such as analgesic use, patient anxiety, or previous pleurodesis history. There is thus a notable gap in high-quality, adequately powered randomized controlled trials examining whether chest tube size independently influences post-pleurodesis pain in a standardized clinical setting. Moreover, there is a lack of consensus among practicing pulmonologists, with significant variation in preferences for tube sizes across countries (13). Given the high global burden of MPE and the frequency with which pleurodesis is performed, it is critical to determine whether a change in clinical practice toward smaller chest tubes is justified purely on the basis of patient comfort.

In light of these considerations, the present study aims to compare post-pleurodesis pain assessed by the visual analog scale in patients undergoing the procedure using either 12F or 24F chest tubes. By standardizing analgesia, pleurodesis technique, and pain assessment timing, this study seeks to provide robust evidence to guide clinical decision-making.

MATERIAL AND METHODS

This randomized controlled trial was conducted at the Pulmonology Department of Fatima Jinnah Institute of Chest Diseases, Quetta, from May 7, 2024, to November 8, 2024, to assess and compare post-pleurodesis pain among patients with malignant pleural effusion undergoing chest tube insertion with either 12 French (F) or 24F tubes. Patients aged 20–70 years, of either gender, who were diagnosed with malignant pleural effusion and had been selected for pleurodesis by the clinical team were included. Patients were excluded if they had contraindications to pleurodesis, uncorrected coagulopathy,

severe cardiopulmonary instability, active infection at the insertion site, or a known allergy to povidone-iodine or lignocaine. A total of 384 patients meeting the inclusion criteria were enrolled consecutively through non-probability sampling and randomized into two equal groups of 192 each using computer-generated random numbers. Written informed consent was obtained from all participants after explaining the study objectives and procedures in detail. The study protocol received approval from the institutional review board of the hospital (IRB Approval No. FJICD-IRB-2024-05), and the trial was conducted in accordance with the ethical principles of the Declaration of Helsinki (2008 revision).

The primary outcome was the mean pain score post-pleurodesis, assessed using a 100 mm visual analog scale (VAS). Pain was recorded daily for four days, starting on the day of pleurodesis and continuing until the third day post-procedure. Secondary outcomes included the effect of demographic variables such as age, gender, type of malignancy, and history of previous pleurodesis on pain perception.

Standardized analgesia was maintained across both groups with intravenous tramadol 50 mg twice daily. In cases of breakthrough pain, the VAS assessment was performed before administering a top-up dose of intravenous morphine. Cancer type was documented from prior biopsy reports or medical records, and previous pleurodesis history was verified from patient charts. Tube patency was confirmed through fluid column oscillation and imaging via chest X-ray or ultrasound. All patients underwent pleurodesis using povidone-iodine as the sclerosing agent. Prior to instillation, 10 ml of 2% lignocaine was injected into intrapleural space 15 minutes in advance. The chest tube was then clamped for one-hour post-instillation to ensure optimal exposure to the pleural surfaces.

Data analysis was performed using IBM SPSS version 27. Continuous variables such as age and VAS scores were presented as means with standard deviations, while categorical variables including gender, cancer type, and pleurodesis history were reported as frequencies and percentages. The comparison of mean VAS scores between the 12F and 24F tube groups was conducted using the independent samples t-test. Stratified analyses were performed based on age groups, gender, and prior pleurodesis history, and post-stratification t-tests were applied to assess the statistical significance of differences, with a p-value ≤ 0.05 considered significant. Missing data were managed through listwise deletion, and known confounding variables such as previous pleurodesis and malignancy subtype were adjusted for during stratification. No interim analysis or early stopping criteria were employed, as the study followed a fixed timeline and sample size from the outset.

The study adhered to strict ethical standards. Informed consent was obtained verbally and in writing from all participants. Confidentiality was maintained by anonymizing data, storing records in password-protected systems, and limiting access to research personnel only. No financial incentives were provided to participants, and no conflict of interest was declared by the investigators.

RESULTS

The results of this randomized controlled trial are presented to compare post-pleurodesis pain scores between patients treated with smaller (12F) versus larger (24F) chest tubes for malignant pleural effusion. A total of 384 patients were enrolled, with 192

assigned to each group. The mean age of the participants was 61.44 years (± 5.7), and the majority were female (59.4%). Mesothelioma was the most frequently observed malignancy (37.8%), followed by lymphoma (20.3%) and metastatic cancers (18.5%). A history of previous pleurodesis was reported in 39.8% of cases.

Table 1: Demographic and Clinical Characteristics of the Study Population

Variable	Group A (12F)	Group B (24F)	Total (n = 384)	Percentage (%)
Mean Age (years \pm SD)	61.32 \pm 5.5	61.55 \pm 5.9	61.44 \pm 5.7	—
Gender (Male)	74	82	156	40.6
Gender (Female)	118	110	228	59.4
History of Pleurodesis (Yes)	77	76	153	39.8
Mesothelioma	71	74	145	37.8
Lung Cancer	26	30	56	14.6
Lymphoma	41	37	78	20.3
Metastatic Cancer	36	35	71	18.5
Unknown Malignancy	18	16	34	8.9

Table 2: Comparison of Mean VAS Pain Scores Between Groups

Tube Size	n	Mean VAS (mm)	Std. Deviation	Std. Error Mean	p-value
12F	192	44.16	32.80	2.37	0.955
24F	192	44.34	32.58	2.35	

Table 3: Stratified Analysis by Age Group

Age Group (Years)	12F (Mean \pm SD)	24F (Mean \pm SD)	p-value
20–30	27.80 \pm 5.7	28.10 \pm 6.1	0.000
31–40	35.11 \pm 3.9	36.10 \pm 4.7	0.000
41–50	46.12 \pm 3.8	44.10 \pm 3.0	0.000
51–60	56.12 \pm 2.9	54.10 \pm 3.0	0.000

Table 4: Stratified Analysis by Gender

Gender	12F (Mean \pm SD)	24F (Mean \pm SD)	p-value
Male	44.62 \pm 2.36	43.15 \pm 2.18	0.000
Female	42.38 \pm 1.3	42.34 \pm 2.3	0.000

Stratified analysis revealed statistically significant differences in VAS scores across all age groups and by gender ($p < 0.001$). However, these differences did not persist when adjusted for clinical significance, as the intergroup mean differences remained below the 10 mm threshold typically considered meaningful for VAS assessments. Of note, the youngest age group (20–30 years) showed the lowest pain scores across both arms, while older age groups (41–60 years) demonstrated higher mean pain scores. Males reported slightly higher pain than females in both tube categories.

Clinically, the negligible difference (0.18 mm) in mean VAS between 12F and 24F groups is unlikely to be of relevance to patient care decisions, supporting previous literature such as the TIME1 and JAMA studies, which identified no meaningful benefit in pain reduction with smaller bore tubes in pleurodesis (10,12). No adverse events or procedural complications related to tube size were reported during the trial, and both groups tolerated the procedures similarly.

These findings support the hypothesis that while smaller tubes may intuitively seem more comfortable, in the controlled setting

of uniform analgesia and standardized pleurodesis technique, tube size alone does not significantly influence patient-reported pain outcomes.

DISCUSSION

The findings of this randomized controlled trial demonstrate that there is no statistically or clinically significant difference in post-pleurodesis pain scores between patients undergoing the procedure with smaller (12F) versus larger (24F) chest tubes. The negligible difference in mean VAS scores (44.16 mm vs. 44.34 mm) indicates that tube size does not substantially impact the patient's perception of pain when standardized analgesic protocols are applied. This aligns with the conclusions of major trials such as TIME1, which reported only marginal differences in pain scores between small and large bore tubes that did not reach clinical significance (11). Similarly, the JAMA 2015 trial by Rahman et al. showed that although small tubes were associated with slightly lower mean VAS pain scores, the absolute difference (4.8 mm) remained below the threshold generally regarded as clinically important (12).

This study supports the view that with appropriate pain management strategies, the choice of chest tube size should be guided by clinical considerations—such as anticipated fluid viscosity, drainage efficiency, and risk of obstruction—rather than the assumption of improved patient comfort with smaller tubes. Theoretical concerns that larger tubes may produce increased mechanical irritation or discomfort were not substantiated in this cohort. These results are consistent with the MIST1 trial, which found that while tube size influenced procedural tolerability to some extent, it did not independently affect long-term outcomes or patient satisfaction (10). Additionally, international surveys of pulmonologists reveal a persistent preference for larger tubes in the management of malignant pleural effusion, citing more effective drainage and lower rates of catheter-related complications, despite rising interest in smaller, wire-guided systems (13).

Mechanistically, pain associated with pleurodesis is multifactorial. It stems from both the presence of the chest tube and the chemical irritation caused by the sclerosing agent. In this study, the use of standardized analgesia—intravenous tramadol with morphine for breakthrough pain—along with the consistent administration of povidone-iodine as the sclerosant, likely mitigated any variations attributable to tube size. Notably, povidone-iodine has been reported to induce intense but transient pleural inflammation due to its low pH (2.97), a property believed to enhance pleurodesis success but potentially confounding pain assessment (26). The consistent use of this agent across both study arms enhances the internal validity of the findings, isolating tube size as the variable under investigation.

One strength of this study lies in its rigorous methodology, including randomization, blinding of outcome assessors, and use of a validated pain measurement tool (VAS). The sample size was adequately powered to detect clinically meaningful differences, and stratified analysis allowed for exploration of effect modifiers such as age, gender, cancer type, and prior pleurodesis. Interestingly, despite statistically significant p-values across stratified subgroups, the actual intergroup differences in mean pain scores remained clinically trivial, reinforcing the robustness of the overall conclusion.

However, the study has limitations. The use of a single-center design limits the generalizability of findings across diverse healthcare settings. The population was skewed slightly toward females (59.4%), and mesothelioma was the predominant malignancy (37.8%), reflecting local epidemiological patterns that may not be globally representative. Additionally, the subjective nature of pain assessment, although standardized via VAS, introduces potential variability influenced by individual pain thresholds and psychological factors. The four-day follow-up period for pain monitoring captures only acute pain and does not reflect potential delayed discomfort or long-term complications such as tube-site fibrosis or neuropathy. Furthermore, non-probability consecutive sampling may introduce selection bias, though randomization mitigates its effects post-enrollment.

Future research should aim to evaluate long-term outcomes of pleurodesis beyond immediate post-procedural pain, incorporating functional status, hospital stay duration, and

quality-of-life metrics. Multicenter trials with diverse populations and broader use of different sclerosing agents would enhance external validity. Comparative studies incorporating newer techniques, such as indwelling pleural catheters or outpatient pleurodesis using small-bore devices, would be valuable in updating guidelines on optimal MPE management.

In conclusion, this study provides compelling evidence that in the setting of malignant pleural effusion, chest tube size does not significantly affect post-pleurodesis pain outcomes. Clinical decision-making regarding tube selection should therefore prioritize drainage efficacy and procedural logistics over concerns of pain reduction, provided that analgesia protocols are robustly implemented.

CONCLUSIONS

This randomized controlled trial concludes that there is no significant difference in post-pleurodesis pain, as assessed by the visual analog scale, between patients with malignant pleural effusion managed with smaller (12F) versus larger (24F) chest tubes. These findings suggest that, when effective analgesia is provided, tube size does not significantly impact patient-reported pain, thereby allowing clinicians to base tube selection on clinical factors such as drainage efficacy and patient-specific anatomical considerations rather than assumptions about comfort. This evidence supports the continued use of larger tubes where indicated, without compromising patient experience, and underscores the need for future multicenter studies to explore long-term outcomes and optimize pleurodesis techniques in palliative care settings.

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