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A Randomized Controlled Study Evaluating the Efficacy and Safety of Silver Nitrates Injection Through Chest Tube Thoracostomy Versus Thoracoscopic Talc Insufflation for Pleurodesis in Cases of Malignant Pleural Effusion

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Abstract

Background: Malignant pleural effusions are one of the leading causes of recurrent pleural effusions worldwide causes substantial morbidity, which lead to affection of the quality of life. The principal goal in treating malignant pleural effusions is to improve respiratory status which lead to improvement in the quality of life, Pleurodesis is accepted to provide effective control of recurrent malignant pleural effusion. but, there is no existing consensus on the best way to achieve pleurodesis.

Aim of Study: To compare the efficacy and the safety of Silver Nitrates given via thoracostomy tube versus thoracoscopic insufflation of Talc, in the treatment of symptomatic malignant pleural effusion.

Subjects and Methods: This study included 40 patients with malignant pleural effusion presented to Chest Departments of Al-Azhar University Hospitals (Al Hussine and Bab Al Shearea) from March 2016 to September 2017. They were randomisedly classified into two groups:

- Group (I) where pleurodesis was done using 0.5% Silver Nitrates through chest tube thoracostomy.
- Group (II) where pleurodesis was done through thoracoscopic insufflation using 5g sterilized asbestos free talc.

Results: The outcome was 19 patients (95%) for group (I) responsive after a month of follow-up with one patient (5%) failed (unresponsive) during this period, and 18 patients (90%) for group (II) responsive with 2 patients (10%), failed (unresponsive) during the same period as regard pleurodesis related complications, The most common was chest pain, was recorded in all patients from group (I), and group (II). The second prevalent complication was fever; it was reported in 4 patients (20%) from group (I) and 7 patients (35%) from group (II). Only one patient (5%) from group (II) developed transient hypoxemia during thoracoscopic pleurodesis.

Conclusion: SN was an effective agent for producing a pleurodesis. Because of easy instillation through Chest Tube Thoracostomy. It appears to be at least as effective as talc. The side effects of intrapleural SN at aconentration of 0.5% appear to be minimal and were comparable to those with talc, no evidence that the intrapleural injection of SN produces ARDS, it should be considered tobe a viable alternative to talc and other sclerosing agents for production of apleurodesis.

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Key Words: *Malignant pleural effusion – Pleurodesis – Silver nitrates – Thoracoscopic Talc insufflation.*

Introduction

PLEURAL effusion is common in various diseases and especially malignant diseases. Malignant effusions can have rapid onset of symptoms such as dyspnea, chest pain, and cough. The diagnosis and the treatment approaches requireseveral pleural techniques to detect concomitantdiseases [1]. Migration of tumor cells to the pleural space results in obstruction of the lymphatic network and blood vessels, leading to pleural effusion. The principal goal in treating malignant pleural effusions is to improverespiratory status [2]. Pleurodesis is frequently performed to prevent recurrence of effusion in benign or malignant conditions. It involves producing an area of adhesion between the parietal and the visceral layers of the pleura. The approach to this procedure can be divided into chemical and mechanical methods. Chemical pleurodesis is performed by introducing various substances such as talc, and silver nitrates or other chemicals into the pleural space. The instilled substances cause inflammation of the parietal and the visceral layers of the pleura and leads to adhesion of the pleural surfaces, preventing further fluid or air accumulation [3]. The first pleurodesis was probably done by Spengler in the beginning of the 20 th century. He injected silver nitrates (SN) into the pleural space to control recurrent pneumothorax. Bethune introduced talc into the pleural space after lobectomy in patients with lung cancer. Since then,

variable agents have been injected in attempt-stocreatea pleurodesis [4].

Aim of the study: To compare the efficacy and the safety ofSilver Nitrates given via thoracostomy tubeversus thoracoscopic insufflation of Talc, in the treatment of symptomatic malignant pleural effusion.

Patients and Methods

This study included 40 patients with malignant pleural effusion presented to Chest Departments of Al-Azhar University Hospitals (Al Hussine and Bab Al Shearea) from March 2016 to September 2017. They were randomisedly classified into two groups:

- Group (I) where pleurodesis was done using 0.5% Silver Nitrates through chest tube thoracostomy.
- Group (II) where pleurodesis was done through thoracoscopic insufflation using 5g sterilized asbestos free talc.

Inclusion criteria:

1- Documented malignant pleural effusion by cytology or histopathology.

Exclusion criteria:

1- Patients with loculated or trapped lungs after drainage of the effusion.
2- Karnofsky index score less than 60.
3- Life expectancy less than 1 month.
4- Patients who could not with stand the lateral decubitus for period long enough to perform the thoracoscopy procedure (usually in the range of 30-60min).
5- Patient with severe uncorrected hypoxemia despite administration of supplemental oxygen.
6- Patients with unstable hemodynamic status.
7- Patients with coagulation defects at least the prothrombin concentration should be greater than 60%, and the platelets count should be greater than 60,000/mm.
8- Patients with pleural thickening or pleural based mass without pleural effusion in radiological investigation.
9- For the thoracoscopic group, Patients with known subjective hypersensitivity to talc powder or one of its constituents.

All patients after giving written consent were subjected to the followings:

1- Full history taking.
2- Clinical examination; both general and local chest examination.
3- Chest X-ray postero-anterior view.
4- CT chest with contrast.
5- Arterial blood gas analysis (ABG).
6- CBC, liver and renal functions.
7- Coagulation profile.
8- Serum electrolytes (Na+ and K+).
9- Fifteen patients for chest tube thoracostomy.
10- Fifteen patients for medical thoracoscopy.

Procedure: 40 patients randomily grouped into tow groups:

- The Group (I): Included twenty patients managed by pleurodesis using 20mL 0.5% Silver Nitrates through chest tube thoracostomy.
- The group (II): Included twenty patients managed by pleurodesis through thoracoscopic insufflation using 5g sterilized Talc. Talc preparation in use will be asbestos-free.

Tube thorcostomy pleurodesis: The pleural injectate consisted of 20mL 0.5%. After the sclerosant was injected, the chest tube was clamped for 1h, and the patient was placed in the prone, supine, and right and left decubitus positions for periods of 10 to 15min. The chest tube was then unclamped and placed on suction of 20cm H_2O. Serial radiographs were used to document appropriatelung reexpansion. The first was performed 24h after the intrapleural injection. The patients were followed-up every day, and the chest tube was removed when the amount of fluidcollected in the previous 24h was 100mL [4].

Thoracoscopic pleurodesis: Pharmaceutical asbestos free Five grams talc was used.

Thethoracoscope connected to a small bottle containing talc, and to a pneumatic atomizer, introduced through the working channel of the thoracoscope was maneuvered and directed to all aspects of the pleural cavity to ensure overall coverage by talc powder (talc powder insufflation).

After performing pleurodesis, a 28 F or a 32 F chest tube was inserted to facilitate lung re-expansion. The chest tube was kept in position until the fluid drainage was between 50ml - 100ml per 24 hrs. The patient was discharged and followed-up after 1 month by chest radiograph to evaluate success of pleurodesis [5].

Follow-up: All patients had the same follow-up schedule with appointments 30 days post-pleurodesis. At all visits, chest X-ray and symptoms were evaluated.

Results

Table (1): Characteristics of the studied samples.

	Groups		FET	*p*-value
	Group (I) N (%)	Group (II) N (%)		
Sex:				
Females	12 (60)	11 (55)	0.10	1.000
Males	8 (40)	9 (45)		
Smoking habit:				
Smokers	6 (30)	8 (40)	0.91	0.633
Ex-Smokers	2 (10)	3 (15)		
Non-Smokers	12 (60)	9 (45)		
Presenting symptoms:				
Dyspnea	20 (100)	20 (100)	0.00	1.000
Chest Pain	14 (70)	13 (65)	0.11	1.000
Cough	11 (55)	9 (45)	0.40	0.752
Hemoptysis	4 (20)	2 (10)	0.78	0.661
Toxic Manifestations	3 (15)	2 (10)	0.23	1.000
Pressure Symptoms	2 (10)	1 (5)	0.36	1.000

Table (2): Primary source of malignant pleural effusion in the studied groups.

Primary source of malignant effusion	Groups		Total
	Group (I) N (%)	Group (II) N (%)	
Pleural	10 (50)	14 (70)	24 (60.0)
Breast	3 (15)	3 (15)	6 (15.0)
Bronchogenic	5 (25)	3 (15)	8 (20)
Thyroid gland	1 (5)	0 (0)	1 (2.5)
Muscle fibers	1 (5)	0 (0)	1 (2.5)

Table (3): Histopathological diagnosis of patients in the studied groups.

Diagnosis	Groups		Total
	Group (I) N (%)	Group (II) N (%)	
Mesothelioma	7 (35)	9 (45)	16 (40)
Adenocarcinoma	5 (25)	5 (25)	10 (25)
Mesothelioma vs Adenocarcinoma	2 (10)	4 (20)	6 (15)
Squamous cell carcinoma	3 (15)	1 (5)	4 (10)
Epithelial Type Neoplasm	2 (10)	1 (5)	3 (7.5)
Myosarcoma	1 (5)	0 (0)	0 (2.50

Table (4): Procedure related variables in the studied group.

	Groups		FET	*p*-value
	Group (I) N (%)	Group (II) N (%)		
Post-Pleurodesis Hospital Stay/days:				
<7	17 (85)	15 (75)	0.63	0.695
≥7	3 (15)	5 (25)		
Outcome of survived patients 30 days after pleurodesis:				
Responsive	19 (95)	18 (90)	0.36	1.000
Failed	1 (5)	2 (10)		
Pleurodesis related complications:				
Pain	20 (100)	20 (100)		
Fever	4 (20)	7 (35)		
Hypoxemia	0 (0)	1 (5)		
ALI/ARDS	0 (0)	0 (0)		
Respiratory Failure	0 (0)	0 (0)		
Visual Loss	0 (0)	0 (0)		

Discussion

This study included 40 paients with malignant pleural effusion presented to Chest Departments of Al Azhar University Hospitals (Al Hussine and Bab Al Shearea) from March 2016 to September 2017. They were randomisedly classified into two groups:

- Group (I) where pleurodesis was done using 0.5% Silver Nitrates through chest tube thoracostomy.
- Group (II) where pleurodesis was done through thoracoscopic insufflation using 5g sterilized asbestos free talc.

In group (I) 12 patients were females (60%) and 8 were males (40%), while in group (II) 11 patients were females (55%) and 9 were males (45%). (Table 1).

Mean age in group I was 57.3 ±7.9 years that ranged from 47-72 years and the mean age in group II was 57.2±8.1 years that ranged from 45-73 years.

Among the patients of the two studied groups, 6 patients (30%) from group (I) were smokers, 2 patients (10%) were ex-smokers and 12 patients (60%) were non-smokers, while in group (II) 8 patients (40%) were smokers, 3 patients (15%) were ex-smokers and 9 patients (45%) were non-smokers. (Table 1).

All studied patients were complaining from dyspnea on their presentation due to moderate to massive pleural effusion, chest pain was the second leading symptom and it was present in 14 patients

(70%) in group (I) versus 13 patients (65%) in group (II), this relatively high percentage may be explained by the large number of malignant mesothelioma patients in the study, among whom agonizing chest pain is a frequent complaint.

The third prevalent presenting symptom was cough and it existed in 11 patients (55%) in group (I) facing 9 patients (45%) in group (II). Other symptoms were less frequent and they include; toxic manifestations [3 patients accounting for 15% in group (I) versus 2 patients with a percentage of 10% in group (II)], hemoptysis [4 patients accounting for 10% in group (I) and only 2 patients with a percentage of 5% in group (II)] and finally, pressure symptoms presented in 2 patients (10%) in group (I), versus only one patient (5%) in group (II); all of those 3 patients were having a mediastinal metastasis. (Table 1).

The primary sources of malignant effusion among the patients of group (I) were distributed as follow; pleural in 10 patients (50%), breast in 3 patients (15%), bronchogenic in 5 patients (25%), thyroid gland in one patient (5%), muscle fibers neoplasm in one patient (5%), while the pleural effusion in group (II) was secondary to; pleural malignancy in 14 patients (70%), breast carcinoma in 3 patients (15%), bronchogenic carcinoma in 3 patient (15%). (Table 2).

These results agree with (Kolschmann et al., 2005) **[6]** and (Das et al., 2008) **[7]** who have found bronchogenic carcinoma, breast carcinoma and malignant mesothelioma to be the leading primary sources of malignant pleural effusion, but in the present study, mesothelioma was by far occupying the first place, while in both studies bronchogenic carcinoma then breast carcinoma were the main primary sources. This deviation may be due to the large number of patients in the current study inhabiting Shobra El-Kheima, where malignant mesothelioma is not a rare tumor due to previous heavy asbestos exposure.

While the results of (Paschoalini Mda S et al. (2005) show that The primary sources of malignant effusion among the patients of group (I) were distributed as follow; Lung 5 patients (15%), Breast 22 patients (67%), Ovarian 2 (6%) patients and Other 4 patients (12%) of unknown primary. The primary sources of malignant effusion among the patients of group (II) were distributed as follow; lung 7 patients (26%), breast 14 patients (52%), ovarian 2 patients (7%) and other 4 patients of unknown primary **[8]**.

In comparison to (Menna et al. (2013), the primary sources of malignant effusion among the patients were distributed as follow; Lung 5 patients (29%), Breast 4 patients (24%), Kidney 3 patients (18%) and others 5 patients (29%) **[9]**.

The histopathological findings among the patients of group (I) were distributed as follow; mesothelioma in 7 patients (35%), adenocarcinoma in 5 patients (25%), Squamous cell carcinoma 3 patients (15%) mesothelioma versus adenocarcinoma in 2 patients (10%), Epithelial Type Neoplasm 2 patients (10%), Myosarcoma 1 patient (5%), while this histopathological findings among the patients of group (II) were distributed as follow; mesothelioma in 9 patients (45%), adenocarcinoma in 5 patients (25%), mesothelioma versus adenocarcinoma in 4 patients (20%) and one patient for each of epithelial type neoplasm (5%), Squamous cell carcinoma (5%). (Table 3).

As regard the overall post-pleurodesis mean hospital stay of patients in the studied groups, showed that 85% of patients in group I stayed in hospital $^{<7}$ days compared to 75% of patients in group II, and those who stayed >7 days were 15% in group I compared to 25% in group II. (Table 4).

This result shows difference in the mean number of days spent in the hospital in contrast with that obtained by (Paschoalini Mda S et al. (2005), as they found that the The mean number of days spent in the hospital was nearly the same in the group that received intrapleural SN (3.7-0.15 days) and in the group that received talc (3.6-0.13 days). (p-value = 0.167) with no statistical significant difference **[8]**.

The range of post-pleurodesis hospital stay for group (I) was dropped in the range found by Menna et al., which was The mean number of days spent in the hospital 8.2 ± 2.8 **[9]**.

The mean post-pleurodesis hospital stay for group (II) was higher than that obtained by (Aelony and Yao 2005) (3.9 ± 2.7 days), however, the previous study dealt only with 26 patients with pleural effusion due to malignant mesothelioma **[10]**.

The range of post-pleurodesis hospital stay for group (II) was dropped in the range found by (Mohsen et al., 2011) as they found that the mean hospital stay after pleurodesis was 4.5 ± 1.1 days for the thoracoscopic talc insufflation group **[11]**.

The outcome was readjusted to be 19/20 responsive patients after a month of follow-up (95%) for group (I) with 1/20 failed (unresponsive) pa-

tients during this period (5%), and 18/20 responsive patients after one month of follow-up (90%) for group (II) with 2/20 failed (unresponsive) patients (10%). (Table 4).

The success rates of talc poudrage for pleurodesis in the published literatures range from 68% to 97%. Variation in the definition of recurrence (radiological and clinical), and the choice of denominator may account for some discrepancies among studies **[11]**.

(Kolschmann and colleagues 2005) published results about the efficacy of thoracoscopic talc pleurodesis were 76/85 (89.4%) after 30 days and 49/59 (83.1%) after 90 days **[7]**, while Stav reported failure of thoracoscopic talc insufflations in only 2 out of his 32 patients of malignant pleural effusion with a success rate of 93.75% **[13]**.

(Hartman et. al., 1993) reported a success rate of 97% after 30 days and 65% after 90 days of thoracoscopic-guided talc poudrage **[14]**. This great outcome was widely far from Love and colleagues results which point to a success rate of only 52% **[15]**.

(Barbetakis et al., 2010) met success in 340 patients out of 400 (85%), **[19]** while (Aelony and Yao 2005) emphasized the occurrence of symptomatic improvement in all of their 26 malignant mesothelioma patients **[10]**.

Although (Steger et al., 2007) stated a successful treatment in only 347 from all managed 506 patients (68.6%), he reported a symptomatic improvement in 451 patients (89.1%) **[17]**.

As regarding studies assessed the safety and efficacy of silver nitrates as a sclerosing agent, (Terra et al., 2011). In a larger study of 48 patients, presented by MPE demonstrated that SN slurry was effective at inducing pleurodesis. SN 0.5% was used in the outpatient setting and at the 30-day follow-up find that 46 (95.8%) patients from 48 patients, showing successful pleurodesis **[18]**.

Another study Menna et al., found that SN slurry was an effective agent for inducing pleurodesis after unsuccessful talc poudrage for unilateral malignant pleural effusion (MPE). In their cohort of 17 patients, 15 of them (89%) had successful pleurodesis at 30 days with intrapleural injections of SN **[9]**.

The most common pleurodesis-related complication was chest pain, which was easily to be distinguished from that caused by the operative incision; as the former was described as a deeply seated, diffuse, burning, dull-aching or less frequently sharp agonizing pain. Chest pain was recorded in all patients from group (I), and group (II). The pain was controlled by administration of routine non-opioid analgesics (Table 4).

The second prevalent complication was fever; it was reported in 4 patients (20%) from group (I) and 7 patients (35%) from group (II). It was not available to determine whether the fever was a complication of the operating maneuver itself, or as a result of talc or S.N absorption via the pleural surface. Nonetheless the cause is, the fever occurred was of low-grade, being easily controlled by tap-water fomentations with no need for giving additional medications. (Table 4).

Only one patient (5%) from group (II) developed transient hypoxemia during thoracoscopic pleurodesis, diagnosed by dropping of their oxygen saturation on the monitor, but not reaching a clinically detected cyanosis, and they were easily controlled by elevating the flow of oxygen given during the procedure, and this hypoxemia did not appear after that. (Table 4).

Respiratory failure (RF), acute lung injury (ALI) and acute respiratory distress syndrome (ARDS) were not reported as complications of pleurodesis in the present study. (Table 4).

These results were correlated with the findings of Kolschmann and colleagues study, as they reported transient mild fever in 29 patients out of 102 patients (28.4%), which required no additional therapy. Thoracic pain was present in most of the patients, and it was controlled by routine analgesics. Talc-induced ARDS was not observed during the study **[8]**.

Kennedy and Sahn 1994 reported talc to cause fever (usually 38.8C°) in 16-69% of cases, characteristically occurring 4-12 hours after instillation and lasted no longer than 72 hours **[19]**.

Neto et al., 2010 reviewed the occurrence of adverse events after 18% of pleurodesis procedures. The most frequent complication was mild thoracic pain that occurred immediately after 16.4% procedures **[20]**.

In the study of Das and colleagues chest pain occurred in 4 patients (16.7%), 3 patients (12.5%) had fever after talc pleurodesis **[21]**.

Barbetakis et al., 2010 reported post–thoracoscopic talc insufflation complications in 66 patients (16.5%) **[16]**.

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دراسة منضبطة معشاة لتقييم فعالية وسلامة حقن نترات الفضة خلال الأنبوبة الصدرية مقابل نفخ التلك بالمنظار الصدرى لعمل التصاق بللورى فى حالات الإنسكاب البللورى الخبيث

لا تزال الانسكابات البللورية السرطانية مشكلة شائعة فى الكثير من مرضى السرطانات المنتشرة، مما يؤدى إلى اختزال ذى أهمية فيما يتعلق بجودة حياة المرضى كتابع لبعض الأعراض المرضية المؤرقة كصعوبة التنفس والسعال المتكرر. وتعد علاجات الانسكابات البللورية السرطانية علاجات تهدف إلى تقليل الأعراض المرضية، وينحصر مرماها فى تحسين الجودة الحياتية للمرضى بأقل قدر ممكن من المضاعفات. وتتمثل الغاية من إجراء الالتصا قات البللورية فى الحيلولة دون معاودة تراكم الارتشاحات البللورية، وبالتالى عدم عودة الأعراض المرضية الناشئة عنها، وتفادى الإقامة المتكررة للمريض بالمستشفى بغرض البذل البللورى. وقد أنجزت العديد من الدراسات السريرية فى محاولة لإدراك التدبير الأمثل لإجراء الالتصاقات البللورية. ويعتبر مسحوق التلك العامل المصلب المعيارى الذى يقدم أفضل النتائج المسجلة، جنباً إلى جنب مع توفير احتمالية بالغة الصغر لحدوث مضاعفات كبيرة، مما دفع به إلى صدارة كل العوامل المصلبة المعروفة حتى الآن، غير أن عملية الحصول على مسحوق تلك آمن ومثالى الصنع ومعقم جيداً لا يمكن تصنيفها أبداً كأمر يسير. وقد أوصى العديد من الباحثين بإجراء الالتصاقات البللورية باستخدام نثر مسحوق التلك بين طبقتى الغشاء البللورى تحت إرشاد منظار التجويف البللورى، باعتبارها الوسيلة المثلى للحصول على التصاق بللورى آمن وفعال، لكن عدم توافر هذا المنظار فى العديد من المتشفيات نظراً لكونه جهازاً طبياً متطوراً، حدا بابتكار بديل معقول لأن يصبح ضرورة طبية ملحة.

وقد خلصت الدراسة إلى أن إجراء الالتصاق البللورى عن طريق حقن مادة نترات الفضة بأنبوب الصدر يعد بديلاً فعالاً لإجراء الالتصاق البللورى عن طريق نثر مسحوق التلك باستخدام منظار التجويف البللورى، حيث يمكن للأول القيام بنفس مهام الثانى بتداخلية أقل، مع الاحتفاظ بنفس المدى من المخاطر والمضاعفات والنتائج.