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ORIGINAL ARTICLE

Pleurodesis Using Bleomycin Ampoules, Doxycycline Capsules, and Povidone Iodine Solution in Patients with Malignant Pleural Effusion in Zagazig University Hospitals

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ABSTRACT

Background: Malignant pleural effusions (MPEs) can occur due to practically any type of cancer. MPEs frequently impair quality of life. There are numerous techniques for managing MPEs; each drains the pleural space and relieves respiratory symptoms. Pleurodesis is described as the formation of a symphysis between two layers of pleura to avoid the recurrence of effusions. Numerous chemical compounds are being investigated for use in pleurodesis. The purpose of this research was to examine the medical pleurodesis results performed with three different chemical agents in order to determine the most effective one with the fewest side effects.

Methods: This study enrolled 60 patients from the Medical Oncology department at Zagazig University Hospitals, Egypt between January 2021 and January 2022. All patients were with MPEs. We enlisted 60 patients, separated them into three groups of 20 each, and had them undergo medical pleurodesis with three different chemical agents in comparison: povidone-iodine, doxycycline, and bleomycin. Sex, age, side of the effusion, treatment outcome (success and failure), and adverse effects were analyzed.

Results: After pleurodesis, findings were evaluated, and the final success rates were 80% for povidone-iodine, 75% for bleomycin, and 65% for doxycycline.

Conclusions: When utilized appropriately, povidone-iodine, doxycycline, and bleomycin are practically similarly efficient and safe sclerosing agents. While the povidone-iodine and doxycycline are similarly efficient and secure as bleomycin as chemical agents for pleurodesis in cases of MPEs, they are less costly and more commonly available.

Keywords: Pleurodesis ; Effusion ; Doxycycline ; Bleomycin; Povidone-iodine.

INTRODUCTION

Malignant pleural effusions (MPEs) are a widespread consequence in individuals with advanced cancer. Around 25% with lung carcinoma, 35% with lymphoma, and 50% of individuals with breast cancer acquire a malignant effusion during their illness [1]. This disorder is characterized as an aberrant buildup of pleural fluid containing malignant cells, which can be validated cytologically or by pleural biopsy [2]. The major mechanism is disturbed lymphatic drainage of the pleural space [3]. Most patients present with symptoms that adversely affect their quality of life, including cough, progressive dyspnea, and/or chest pain [4].

Various therapeutic plans were done to overcome the high recurrence rate of MPEs, such as pleurodesis using various agents, intrapleural catheter, and repeated thoracocentesis, pleurodesis is the most common plan used [5]. Pleurodesis and implantation of an indwelling pleural catheter (IPC) are both successful therapies for recurrent MPEs, with both procedures improving dyspnea and quality of life [6]. Not only is fluid evacuation the treatment objective, but also symptom reduction (especially dyspnea), maximizing the time spent outside the hospital and enhancing the quality of life (QoL) [7].

Pleurodesis is a procedure that establishes adhesion and prevents air or fluid collection in the pleural cavity. Additionally, this procedure is

employed in situations of recurrence. Pleurodesis may be accomplished chemically or physically by thoracotomy or thoracoscopy [8]. The majority of chemicals employed in pleurodesis induce injury to the pleura and inflammatory response. Collagen is generated due to localized coagulation system activation and the release of fibrogenic cytokines such as transforming growth factor β, which might result in pleurodesis [9].

Chemical pleurodesis is a well-established operation that involves injecting a sclerosant into the pleural cavity, causing inflammation, fibrosis, and widespread adhesion between the visceral and parietal pleura [10]. The optimum chemical agent for pleurodesis should be very effective, have a large molecular weight, and have strong chemical polarity [8]. Up till now, there is no ideal sclerosing agent. So, each sclerosing agent has its advantages and disadvantages. Examples of these agents include talc, tetracyclines, doxycycline, bleomycin, silver nitrate (SN), povidone-iodine, etc. [11]. The choice of the sclerosing agent depends on its availability, price, patient characteristics, and facilities of each center [12].

Sclerosing agents such as povidone-iodine were employed to completely seal the pleural space and stop the exudation process. It is effective, safe, inexpensive, and widely accessible [13]. Bleomycin is another often prescribed medication for pleurodesis. Numerous studies had indicated comparable or greater success rates when bleomycin was used as a sclerosing agent compared to other chemical agents [1]. Doxycycline has been involved in many types of research for pleurodesis of MPEs and recurrent pneumothorax [14]. In the present study, we aimed to determine which of these chemical agents could perform efficient and safe pleurodesis and which of them is superior.

PATIENTS AND METHODS

This Randomized Clinical trial study was performed at the Department of Medical Oncology, Faculty of Medicine, Zagazig University between January 2021 and January 2022. The study included 60 patients who were separated randomly using a computer-generated random table in a 1:1 ratio into three groups (20 in each group). Group I; 20 patients were subjected to pleurodesis with a 10% povidone-iodine solution. Group II; 20 patients were subjected to pleurodesis with bleomycin ampoules. Group III; 20 patients were subjected to pleurodesis with doxycycline capsules. Written informed consent was obtained from all participants, then The study was approved by the research ethics committee of the Faculty of Medicine, Zagazig University. The clinical trial followed the World Medical Association's guidelines for Good Clinical Practice in the Declaration of Helsinki.

Inclusion criteria: Patients with proved symptomatic malignant pleural effusion by fluid cytology or pleural histopathology, stable hemodynamics, no bleeding, and no coagulopathy.

Exclusion criteria: Patients refusal, trapped lung, patients with a history of previous pleurodesis or radiotherapy to the affected site, hemodynamic instability, hemothorax, chylothorax, or multiple etiology of pleural effusion, locations, and pregnancy.

Pre-procedural evaluation:

All patients had a thorough history collecting process that included personal information, smoking, and co-morbidities. A general and local clinical examination with eastern cooperative oncology (ECOG) score [11], dyspnea score of New-York heart association (NYHA) regular laboratory tests, and radiographic investigations (including CT chest) were recorded.

Operative steps: Sterilization, followed by local anesthesia with lidocaine 2%. A 30-French-gauge intercostal tube is inserted into the mid-axillary line's fifth intercostal gap. The pleural fluid was evaluated and gravity-drained until it discharged less than 150ml/day, with chest X-ray confirmation of complete lung expansion.

The following procedure was used to inject pleurodesis solutions; **Group I**: Pleurodesis was conducted on patients using 20 ml of povidone-iodine diluted in 50 ml of 0.9 percent saline and 10 ml of 2% xylocaine. **Group II**: Pleurodesis was performed on patients using 60 mg bleomycin sulfate dissolved in 50 ml 0.9% saline and 10 ml 2% xylocaine solution. **Group III** Pleurodesis was performed on patients using 10mg/kg of doxycycline dissolved in 50 ml 0.9% saline and 10 ml 2% xylocaine solution.

Following intrapleural injection of the sclerosing drug, the tube was secured for six hours, during which time the patient was instructed to rotate to ensure proper pleural distribution. After six hours, the tube was fully opened for up to 72 hours of drainage without using a negative vacuum, and it was withdrawn when the liquid discharge was less than 150 ml/24 hours and a chest X-ray documented no significant collection. All patients were monitored clinically as well as chest X-rays weekly for one month following pleurodesis; prolonged follow for more than one month was troubling as patients presented with malignant effusion are terminal with an expected short survival period. Patients who had a failed pleurodesis or a recurring effusion were required to return for additional treatment. As a result, a lack

of follow-up indicated either successful pleurodesis or the patient's mortality.

Definition of success: Symptomatic improvement with no recurrent fluid collection larger than that noted on imaging just taken after completed pleurodesis or small amounts of effusion that do not need to be drained on a routine basis.

***Definition of failure*:** Re-accumulation of symptomatic pleural fluid that needs aspiration.

Statistical analysis:

Data were analyzed using SPSS version 17 (Chicago). For properly distributed data, the mean and standard deviation were used for parametric data, while for non-parametric data, the median (quartile range) was utilized. The statistical comparisons between different groups were carried out using the Kruskal Wallis test for nonparametric and one-way ANOVA for parametric data. Categorical data were represented by frequency and percentage, as well as were compared by Fisher Exact (X2) test. P<0.05 was chosen as the degree of significance.

RESULTS

The current research examined demographic data and discovered that patients in Group I ranged in age from 46 to 64 years with an average of 55.1 ±5.2 and had 12 men and 8 females, 7 smokers, 4 NYHA II, 9 NYHA III, and 7 NYHA IV with 12 ECOG 0-2 and 8 ECOG 3-4. In Group II: the age of patients varied from 35 to 67 years with an average value of 52.1 ± 8.1 and had 11 males and 9 females, and 6 smokers, 3 NYHA II, 7 NYHA III, and 10 NYHA IV with 14 ECOG 0-2 and 6 ECOG 3-4. In Group III: the age of patients ranged from 38 to 69 years with an average value of 54.6 ± 7.4 and had 7 males and 13 females, and 11 smokers, 5 NYHA II, 7 NYHA III, and 8 NYHA IV with 11 ECOG 0-2 and 9 ECOG 3-4. There was no significant variation in age, sex, smoking, NYHA score, ECOG score, or co-morbidities between the patients in the various study groups (Table 1).

The diagnosis of the cases was in Group I; 50% NSCLC, 5% HCC,5% Metastasis of unknown origin 5% Mesothelioma, 20% Breast cancer, 5% Pancreatic cancer, and 10% Ovarian cancer, In Group II; 30% NSCLC, 10% NHL, 10% Metastasis of unknown origin, 30% Breast cancer, 15% Pancreatic cancer, and 5% Ovarian cancer, and In-Group III; 30% NSCLC, 5% NHL, 10% HCC, 10% Metastasis of unknown origin, 5% Mesothelioma, 15% Breast cancer, 5% Pancreatic cancer, 20% Ovarian cancer. There were no substantial differences in diagnosis between the patients in the various study groups (Table 2).

The side of effusion in Group I and Group II was 30% left and 70% right, and in Group III, 35% left and 65% right. No considerable difference between the 3 studied groups was observed (Table 3).

This study showed that the median duration of stay in the hospital following pleurodesis was 4.1± 4.7 in Group I, 3.1 ± 2.65 in Group II, and 3.5 ± 3.9 in Group III. There was no meaningful difference between the 3 examined groups in terms of hospital stay after pleurodesis (Table 4).

There was a substantial difference among the 3 studied groups in terms of pain which was higher in the povidone group than in the other two groups (P = 0.02), while there was no considerable difference regarding other adverse effects (Table 5).

This study showed that the final success rate was 80%, 75%, and 65% for Group I, Group II, and Group III, respectively. No notable difference among the 3 groups was observed (Table 6).

Table 1: Comparison of the investigated groups' demographic characteristics

Variable	Group I Povidone-iodine (n=20) N	%	Group II Bleomycin (n=20) N	%	Group III Doxycycline (n=20) N	%	X^2	P
Age								
Mean ± SD	55.1 ± 5.2		52.1 ± 8.1		54.6 ± 7.4		F	0.34
Range	46 – 64		35 - 67		38 - 69		1.07	
Sex								
Male	12	60%	11	55%	7	35%	2.7	0.3
Female	8	40%	9	45%	13	65%		
Smokers	7	35%	6	30%	11	55%	1.7	0.5
Co-morbidities								
IHD								
CHF	5	25%	7	35%	8	40%	1.05	0.59
DM	3	15%	4	20%	2	10%	0.78	0.68
HTN	8	40%	5	25%	9	45%	1.87	0.39

Variable	Group I Povidone-iodine (n=20) N	%	Group II Bleomycin (n=20) N	%	Group III Doxycycline (n=20) N	%	X^2	P
	6	30%	10	50%	8	40%	1.67	0.44
Dyspnea score (NYHA)								
NYHA II								
NYHA III	4	20%	3	15%	5	25%	1.4	0.84
NYHA IV	9	45%	7	35%	7	35%		
ECOG score	7	35%	10	50%	8	40%		
0 – 2							0.99	0.61
3 – 4	12	60%	14	70%	11	55%		
	8	40%	6	30%	9	45%		

Data are represented as a number (%). Data are represented as Mean ± SD

Data were analyzed by Fisher Exact test (X2) Data were analyzed by ANOVA test.

IHD ischemic heart disease. CHF congestive heart association. DM diabetes mellitus. HTN hypertension. NYHA New York Heart Association. ECOG Eastern Cooperative Oncology Group.

Table 2: Comparative analysis of the examined groups in terms of diagnosis

	Group I Povidone-iodine (n=20)		Group II Bleomycin (n=20)		Group III Doxycycline (n=20)		X^2, P
	N	%	N	%	N	%	
NSCLC	**10**	**50%**	**6**	**30%**	**6**	**30%**	**11.3, 0.67**
NHL	**0**	**0%**	**2**	**10%**	**1**	**5%**	
HCC	**1**	**5%**	**0**	**0%**	**2**	**10%**	
Metastasis of unknown origin	**1**	**5%**	**2**	**10%**	**2**	**10%**	
Mesothelioma	**1**	**5%**	**0**	**0%**	**1**	**5%**	
Breast cancer	**4**	**20%**	**6**	**30%**	**3**	**15%**	
Pancreatic cancer	**1**	**5%**	**3**	**15%**	**1**	**5%**	
Ovarian cancer	**2**	**10%**	**1**	**5%**	**4**	**20%**	

Data are represented as a number (%).

Table 3: Comparison of the examined groups in terms of effusion side

Sides	Group I Povidone-iodine (n=20)		Group II Bleomycin (n=20)		Group III Doxycycline (n=20)		X^2	P
	N	%	N	%	N	%		
Left	6	30%	6	30%	7	35%	0.22	0.1
Right	14	70%	14	70%	13	65%		

Data are represented as a number (%). Data were analyzed by Fisher Exact test ($3x^2$)

Table 4: Comparison of the study groups in terms of length of stay in the hospital after pleurodesis

Variable	Group I Povidone-iodine (n=20)	Group II Bleomycin (n=20)	Group III Doxycycline (n=20)	Kruskal Wallis X^2	P
Hospital Stay/ day					
Mean ± SD	4.1 ± 4.7	3.1 ± 2.65	3.5 ± 3.9	F	0.69
Range	2 – 21	2 - 14	2 - 20	0.37	

Data were analyzed by the Kruskal Wallis test Data were analyzed by the ANOVA test Data are represented as Mean ± SD.

Table 5: Contrast the examined groups in terms of deleterious outcomes related to pleurodesis

Side effects of pleurodesis procedure	Group I Povidone-iodine (n=20)		Group II Bleomycin (n=20)		Group III Doxycycline (n=20)		X^2	P
	N	%	N	%	N	%		
Fever	7	35%	9	45%	10	50%	0.95	0.6
Pain	14	70%	5	25%	10	50%	8.14	0.02*
Empyema	0	0%	1	5%	1	5%	1.2	1
Hypotension	2	10%	0	0%	0	0%	2.7	0.3

* Significant

Table 6: Comparison of the examined groups' ultimate follow-up findings (after 1 month)

Final follow-up results	Group I Povidone-iodine (n=20)		Group II Bleomycin (n=20)		Group III Doxycycline (n=20)		X^2	P
	N	%	N	%	N	%		
Failure	4	20%	5	25%	7	35%	1.1	0.6
Success	16	80%	15	75%	13	65%		

Data are represented as a number (%). Data were analyzed by Fisher Exact test ($3x^2$)

DISCUSSION

MPEs, a wide category of illnesses, account for a considerable proportion of morbidity in patients with underlying malignancy. Pleural effusion management is often regarded as one of the most challenging medical problems. Pleurodesis is a treatment that involves merging the visceral and parietal pleurae with fibrous tissue to completely close the pleural gap in patients with recurring and symptomatic pleural effusions and pneumothorax [15]. The current study compared the efficiency and safety evaluation of three different chemical pleural sclerosing agents.

In line with our study objective, we discovered that Bakr et al. evaluated the outcomes of medical pleurodesis performed with four different chemical agents in similar situations to determine which one was the most effective and caused the fewest complications. The results indicated no statistically significant variations in age or sex between the patients in the various study groups [16]. Bagheri et al. compared bleomycin pleurodesis to povidone-iodine pleurodesis administered through a chest drain as supportive therapy for recurring malignant pleural effusions. According to the data, out of 60 patients, 36 (60.0%) were males, and 24 (40.0%) were females. The mean age was 58.80 ±8.48 years (interquartile range: 41–76 years) [17]. Saleh et al. stated that their study's objective was to evaluate our findings of medical pleurodesis utilizing three distinct chemical agents: povidone-iodine solution, bleomycin ampoules, and doxycycline capsules, administered via two various pathways: small-bore indwelling catheter and chest tube. Their study enrolled 104 individuals who suffered from recurrent malignant pleural effusions and were all dyspneic. 50 patients (48.1%) were males, while the remaining 54 (51.9%) were females. The patient's age ranged from 22 to 74 years (mean 57.55 ±9.02) [18].

Bagheri et al. discovered comparable results to our study that lung cancer was the primary pathology in 22 (36.7%) patients and metastatic cancer was the primary pathology in the remaining 38 (63.3%) patients [17]. Shaaban et al. conducted a study on forty-five patients with MPEs eligible for pleurodesis, and showed compatible results to our study, that origins of MPEs were bronchogenic carcinoma (44.4%), breast cancer (20%), Hodgkin lymphoma (11.2%), mesothelioma (8.9%), thyroid carcinoma (6.7%), renal cell carcinoma (4.4.%), ovarian carcinoma (2.2%), and pancreatic carcinoma (2.2%) [19]. Abd El Zaher and El Dib described 26 patients who had malignant pleural effusion and gave roughly comparable outcomes to our study. MPEs were most frequently caused by metastatic breast cancer, followed by metastatic lung cancer and metastatic ovarian carcinoma [13].

Our study showed that the side of effusion in Group I and Group II, was right in 14 patients (70%), and in Group III, was right in 13 patients (65%). No substantial variance between the three groups was noted. Abd El Zaher and El Dib found a similar result, that most effusions were right-

sided [13]. Also chest X-rays demonstrated right-sided effusion in 59 patients (56.7%) and left-sided pleural effusion in 45 patients (41.3%), according to Saleh et al. [18]. On contrary, Shaaban et al. demonstrated that pleural effusions were right-sided in 24 cases in groups I, II, and III, whereas 31 were left-sided [19].

In this study, the average duration of hospitalization following pleurodesis was 4.1 ± 4.7 in Group I, 3.1 ± 2.65 in Group II, and 3.5 ± 3.9 in Group III, with no major difference between the three studied groups. This result was consistent with the findings of Bakr et al. that the average period of stay in hospital following pleurodesis was 4.6 ±1.2, 3.8 ±1.1, and 4.3 ±1.1 days for groups bleomycin, doxycycline, and povidone-iodine respectively, with no considerable difference [16].

Concerning adverse effects related to pleurodesis, the current study's findings indicated a significant difference in pain between the three analyzed groups but no considerable difference in the other adverse effects. Our results match the results of Shaaban et al. who documented a significantly higher rate of pain without notable difference in the other side effects [19]. Bakr et al. discovered no statistically considerable difference in adverse effects across all groups [16]. Saleh et al. discovered no significant changes between the three groups except for the extremely substantial post-maneuver discomfort associated with betadine. The discomfort associated with betadine was low to moderate in severity and reacted effectively to non-steroidal anti-inflammatory medications (NSAID). Thus, such discomfort was not a restricting factor in the usage of betadine [18].

The current study, regarding final follow-up after 4 weeks demonstrated that the final success rate for Group I, Group II, and Group III was 80, 75, and 65%, respectively, with no substantial variance between the three studied groups. These results were consistent with the findings of Bakr et al. that full response occurred in 70%, 60%, and 80% of patients treated with povidone-iodine, bleomycin, and doxycycline, respectively. After two and three months, the pleurodesis results in the different studied groups were identical, and the final success rate for povidone-iodine pleurodesis was 80%, and bleomycin pleurodesis was 70%, and doxycycline pleurodesis was 80% (the distinction between these three groups is negligible) [16]. Bagheri et al. reported that 83.3% of patients treated with povidone-iodine responded to therapy and 66.7% of patients treated with bleomycin; there was no statistically meaningful variation between the two groups [17]. Saleh et al. revealed that Bleomycin, doxycycline, and betadine had 79.1, 80.6, and 76% success rates, respectively [18].

CONCLUSIONS

We conclude that povidone-iodine solution and doxycycline capsules are efficient, inexpensive, and widely accessible sclerosing agents with few adverse effects. Their findings are similar to those achieved with bleomycin in pleurodesis, which is more costly, less accessible, and may have greater deleterious consequences owing to its cytotoxic nature. Multicenter trials with a large number of patients will help to find which protocol is effective and safe for pleurodesis in MPEs.

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