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COMPARE THE EFFICACY OF COSMETIC TALC WITH THAT OF IODOPOVIDONE AS AN AGENT FOR CHEMICAL PLEURODESIS

Basanta hazarika., Chandan Matage., Jogesh Sarma and Sharma, K.R

Department of pulmonary medicine, Gauhati Medical College, Guwahati, Assam, India

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A B S T R A C T

Backgound: Chemical pleurodesis is accepted palliative therapy for patients with recurrent, symptomatic malignant pleural effusions. For benign effusions or pneumothorax the aim is to avoid recurrences rather than palliation. A wide variety of agents have been used for pleurodesis. Cosmetic talc and iodopovidone are two inexpensive and easily available agents. There is paucity of data on the comparative efficacy of these two. So, the aim of the study is to compare the efficacy of cosmetic talc with that of iodopovidone, as agents for chemical pleurodesis.

Methods: It was a hospital based observational study. Patients requiring pleurodesis were openly randomized to two groups. Iodopovidone- 30 ml was used after dilution with 20 ml normal saline for the first group, and cosmetic talc 5 g was used after being autoclaved and made as slurry mixed with 50ml of saline and instilled by tube thoracostomy.

Results: A total of 60 patients were included in the study. Out of the 60 patients enrolled in the study, the clinical indication for pleurodesis was pleural effusion in 38(63.4%) patients and pneumothorax in 22 (36.6%) patients. The success rate of pleurodesis with iodopovidone in patients with pneumothorax was 92.3% with failure rate was 7.7% and success rate of talc pleurodesis was 88.9% with failure rate was 11.1%. On the other hand the success rate for Iodopovidone pleurodesis in patients with pleural effusion was 90.5% with failure rate was 9.5% and the success rate for talc pleurodesis in pleural effusion was 94.1% with failure rate was 5.9%. Overall success rates for the two agents were comparable at 92.3% and 91.2% for talc and iodopovidone respectively, without any statistically significant difference between the two groups (p-0.875).

Conclusion: The results of the present study suggest that both iodopovidone and cosmetic talc are equally effective when instilled by tube thoracostomy. Both the agents demonstrated a good safety profile in treating recurrent pleural effusions and pneumothorax with a good success rate and few minor complications.

INTRODUCTION

Pleurodesis is defined as the creation of a symphysis between the visceral and parietal pleural surfaces, in order to prevent accumulation of either air or fluid in the pleural space. It is mainly indicated for malignant pleural effusions and recurrent pneumothorax[1], although occasionally, troublesome benign effusions may also benefit from this procedure.[2] Progressive dyspnea is the most common symptom in patients with malignant pleural effusion followed by cough and chest pain that affect the quality of life.[3] Although some malignancies such as small cell lung cancer, lymphoma, or breast cancer might respond to systemic treatment, local therapy for malignant pleural effusion may still be needed. Local palliative procedures are more required to relieve dyspnea, improve life quality, and avoid repeated thoracentesis for patients not responding to systemic treatment.[4] Current local managements include thoracentesis, pleurodesis, chest tube drainage, indwelling pleural catheters drainage, pleurectomy, and pleuroperitoneal shunting.[5,6] Benign conditions are also sometimes associated with recurrent

Corresponding author:* **Basanta hazarika

Department of pulmonary medicine, Gauhati Medical College, Guwahati, Assam, India

pleural effusions which may benefit from pleurodesis (eg uraemia, cirrhosis, SLE etc).[5] In addition, recurrant primary pneumothorax and secondary spontaneous pneumothorax from any cause may need pleurodesis.[7]

Chemical pleurodesis is accepted palliative therapy for patients with recurrent, symptomatic malignant pleural effusions. Patients selected for pleurodesis should have significant symptoms that are relieved when pleural fluid is evacuated. There should be evidence of complete re-expansion of the lung without evidence of bronchial obstruction or fibrotic trapped lung. For benign effusions or pneumothorax the aim is to avoid recurrences rather than palliation.[8-11]

A wide variety of agents have been used for pleurodesis. An ideal sclerosing agent should have a high molecular weight and chemical polarity, low regional clearance, rapid systemic clearance, a steep dose-response curve, and should be well tolerated with minimal or no side-effects. Over the past 70 years many agents have been injected intrapleurally in an attempt to create a pleurodesis. The agents used have included radioisotopes, quinacrine, antineoplastics (nitrogen mustard, bleomycin, mitoxantrone), tetracycline derivatives (tetracycline, doxycycline, minocycline), talc, erythromycin, sodium hydroxide, silver nitrate, iodopovidone, killed Corynebacterium parvum and OK-432 which is an immunostimulant obtained from Streptococcus pyogenes.[12]

Talc is a sclerosing agent that is most commonly used for chemical pleurodesis at the present time in western countries.[13] Talc can be administered either as an aerosol (insufflation) or a suspension (slurry). Sterile talc preparations like Steritalc aerosol (Novatech, France; manufacture discontinued this year), Steritalc PF Puffer (Novatech, France) and the Sclerosol Intrapleural Aerosol (USA), packaged especially for internal use, are available internationally but are difficult to procure in India. However, renewed interest in talc has also resulted from a recent study from India where the authors used commercially available cosmetic talc because Steritalc is difficult and expensive to obtain in this country. In this study[14], commonly available cosmetic talcum powder was used after being sterilized and found comparable results. Interest in low cost talc has been rekindled by a recent Indian study showing that cosmetic talc is as good as any medical talc as long as its particle size is determined and there are no impurities.[15]

Iodopovidone is considered as a reasonable alternative to other commonly used pleurodesing agents such as the tetracycline derivatives or talc slurry. It has been shown to be a safe and effective agent for chemical pleurodesis.[7, 16-18] It is easily available. It is soluble and does not need to be sterilized prior to use. The search for an ideal agent for pleurodes is continues. Cosmetic talc and iodopovidone are two inexpensive and easily available agents. There is paucity of data on the comparative efficacy of these two. So, the aim of the study is to compare the efficacy of cosmetic talc with that of iodopovidone, as agents for chemical pleurodesis.

MATERIALS AND METHODS

The Present Study was conducted in the Department of Pulmonary Medicine, Internal Medicine and allied specialities, Gauhati Medical College and Hospital, Guwahati from August 2015 to July 2016. It was a hospital based observational study. All the patients who fulfilled the inclusion and exclusion criteria were included in the study.

The patients attending Out-patient department and those admitted in the indoor units were enrolled the study. The patients were randomly included in the study after considering the inclusion criteria and exclusion criteria and written informed consent from the patients were taken. Ethical clearance was obtained from the Ethics Committee of the Institution prior to the onset of study. The details of all the cases are filled in a predesigned and pretested proforma.

Patients included in this study were of malignant pleural effusion, recurrent symptomatic pleural effusion not responding to conservative treatment and recurrent primary spontaneous pneumothorax or any secondary spontaneous pneumothorax. Patients were excluded from the study if had history of any allergy to iodine, failure of lung expansion after insertion of intercostal tube (trapped lung), presence of air leaks , advanced malignancy with limited predicted life expectancy (<30 days), and those not willing to participate in study.

Patients requiring pleurodesis either for symptomatic recurrent pleural effusions (malignant or benign) or recurrent primary or secondary pneumothorax were openly randomized to two groups after informed consent. Patients in the first group underwent pleurodesis with iodopovidone. For those in the second group the procedure was done using talc slurry.

Iodopovidone- 30 ml of Microshield (10% iodopovidone manufactured by Johnson and Johnson, Solan, Himachal Pradesh, India) was used after dilution with 20 ml normal saline for the first group. Talc- Cosmetic talc (Johnson and Johnson's baby powder) was used after being autoclaved. 5 g of cosmetic talc made as slurry mixed with 50ml of saline was used.

Patients meeting the criteria were admitted after taking the consent. Data was recorded on pre-designed forms. Pulse, Blood Pressure and Temperature were recorded and detailed Clinical examination was done in all patients. Intercostal Drainage Tube (24/28 F) was inserted through the fourth or fifth intercostal space in the anterior-axillary line, to achieve complete drainage of the effusion and/or complete lung expansion. In case of pleural effusion, patients were subjected for pleurodesis when the daily drainage output decreased to <100 mL/day. In cases of pneumothorax, complete lung expansion and absence of any air leaks was confirmed before instillation of the chemical agent. A Chest X-Ray was done to confirm complete re-expansion in patients with pneumothorax.

Pulse, BP and temperature were measured before the procedure. Lignocaine 2% in a dose of 2 mg/kg ideal body weight diluted with 30ml of Normal saline was infused through the intercostal drainage tube. After 15 min of

Lignocaine infusion, patients in the iodopovidone group received 30 mL of 10% iodopovidone diluted in 20 mL of normal saline infused through the intercostal drainage tube. The second group received 5 g of cosmetic talc made as slurry after mixing with 50ml of normal saline. The talc powder was sterilized by autoclaving before using for pleurodesis. After infusing either iodopovidone solution or talc slurry the intercostal drainage tube was clamped for 2 hours. Chest tube was unclamped after 2hours. The intercostal drainage tube was removed as soon as the drainage output decreased to less than 100 mL/day in case of pleural effusion and in case of pneumothorax intercostal drainage tube was removed after confirming total lung re-expansion without any residual pneumothorax by doing Chest- Xray.

Pulse rate, blood pressure and temperature were recorded 30 minutes after the procedure and in case any discomfort or distress occurred. Chest Pain following pleurodesis was recorded on a visual analogue scale from 0-10 cm. Patients also received IV tramadol 50mg on an as needed basis after the procedure. Complications like hypotension, fever, ARDS and empyema were sought and recorded. Success at 24 hrs, 1month and 3months was recorded. Initial success was recorded if there was no recurrence after tube removal and the patient was discharged. Subsequently, the patient was followed up at one week, and at one and three months.

RESULT AND OBSERVATION

A total of 60 patients were included in the study. Their age ranged from 14 to 85 years with a mean age of 45.8 ± 15.73 years. Majority of cases (35%) were found in the age group 51-60 years. Among the study group, 44(73.3%) cases were male and 16(26.7%) cases were female. The mean age of female cases was 38.8 ± 15.75years and mean age of male cases was 52.8 ± 15.71years. Out of the sixty patients enrolled in the study, the clinical indication for pleurodesis was pleural effusion in 38(63.4%) patients and pneumothorax in 22 (36.6%) patients. Of the 38 patients with pleural effusion, malignant pleural effusion was observed in 34(89.47%) cases and benign pleural effusion was observed in 4(10.43) cases. Among the patients with malignant pleural effusion 31(91.18%) cases had evidence of lung cancer, 2(5.88%) cases had breast cancer and one case had renal cell carcinoma. Out of the four benign effusions included in the study, one female patient with systemic lupus erythematosus (SLE) had bilateral recurrent effusion where bilateral pleurodesis was done and other two patients with benign effusion the aetiology was hepatic hydrothorax and chronic kidney disease (CKD). Among 22 patients with pneumothorax, the recurrent primary spontaneous pneumothorax was observed in 4(18.18%) patients and secondary pneumothorax was observed in 18(81.82%) cases. Among the 18(81.82%) patients with secondary pneumothorax, Pulmonary Tuberculosis was the aetiology in 11 patients, COPD in 6 patients and in one patient the cause was Hypersensitivity Pnemonitis (Table:-1).

Table 1 - Distribution of patients based on clinical indications

Diagnosis	No	%
Pneumothorax:	22	
1.Recurrent Primary spontaneous	4	18.18%
2.Secondary spontaneous	18	81.82%
Pulmonary TB	11	61.11%
COPD	6	33.33%
HSP	1	5.56%
Pleural effusions:	38	
1.Malignant	34	89.47%
Ca Lung	31	91.18%
Ca breast	2	5.88%
RCC	1	2.94%
2.Benign	4	10.53%
Hepatic hydrothorax	1	25.00%
CKD	1	25.00%
SLE	2	50.00%

Cosmetic talc (Talc slurry) for pleurodesis was used in 26(43.4%) patients, 22(84.6%) males and 4(15.4%) female (Table:2). Among the 26 patients who underwent pleurodesis procedure using cosmetic talc, pleural effusion was in 17 patients and pneumothorax in 9 patients (Table: 3). Of the 17 pleural effusions, malignant pleural effusion was observed in 15(88.24%) patients and benign pleural effusion was observed in 2(11.76%) patients. Among the 9 pneumothorax patients, 2 (22.2%) pateients were of recurrent primary spontaneous pneumothorax and secondary pneumothorax was in 7(77.8%) patients.

Table 2 - Sex- Pleurodesis Agent wise distribution of cases.

			Iodopovidone	Talc	Total
Sex	Female	Count	12	4	16
		% within agent	35.3%	15.4%	26.7%
	Male	Count	22	22	44
		% within agent	64.7%	84.6%	73.3%
Total		Count	34	26	60
		% within agent	100.0%	100.0%	100.0%

Table 3 – Showing aetiology and agent wise distribution of patients.

	Iodopovidone	%	Talc	%	Total	P-Value
Pleural effusion	21		17		38	
1. Benign	2	9.52%	2	11.76%	4	0.823
2. Malignant	19	90.48%	15	88.24%	34	
Pneumothorax	13		9		22	
1. Primary	2	15.38%	2	22.22%	4	0.682
2.Secondary	11	84.62%	7	77.78%	18	

Out of 17 pleural effusions treated with talc, pleurodesis failed in one patient with malignant pleural effusion (recurred at 1 month of follow-up). Nine patients with pneumothorax treated with talc, pleurodesis failed in one patient with recurrent primary spontaneous pneumothrax (patient presented with recurrant pneumothorax on 24th day of pleurodesis).

Iodopovidone for pleurodesis was used in 34(56.6%) patients, 22(64.7%) males and 12(35.3%) females. Among the 34 patients who underwent pleurodesis procedure using iodopovidone, pleural effusion was in 21(61.8%) patients and pneumothorax in 13(38.2%) patients (Table:3). Of the 21 pleural effusions, malignant pleural effusion was in 19(90.5%) patients and benign pleural effusion was in 2(9.5%) patients. Among the 13

pneumothorax patients, recurrent primary spontaneous pneumothorax was in 2(15.4%) patients and secondary pneumothorax was in 11(84.6%). Pleurodesis failed in two patients with malignant pleural effusion (one recurred at 1 month of follow-up and the other at 3rd month of follow-up). Of the 13 pneumothorax treated with iodopovidone, pleurodesis failed in one patient with primary spontaneous pneumothrax (patient presented with recurrent pneumothorax on 3rd day of pleurodesis).

Out of 26 patients subjected for pleurodesis using talc, most common adverse affect observed was chest pain, complained by 20(76.92%) patients. Pain was mild (with score on visual analogue scale between 1-3) in 15(57.7%) patients, moderate in 2 (7.7%) patients (VAS 4-6) and severe in 3(11.5%) patients (VAS 7-10). Fever was observed in 3(11.50%) of the 26 patients, it was self limited present only for one day in most of the patients. One patient developed empyema after 2months of pleurodesis. Hypotension did not occur in any case treated with talc. There were no cases ARDS associated with talc pleurodesis (Table 4).

Out of 34 patients subjected for pleurodesis using iodopovidone, most common adverse affect observed was chest pain, complained by 29(85.29%) patients. Pain was mild in 21(61.80%), moderate in 7(20.60%) and severe in 2(5.90%) patients. Fever was observed in 5(14.70%) patients which was self limited in most of the patients. One patient with secondary pneumothorax secondary to hypersensitivity pneumonitis developed severe pain (VAS-10) and hypotension 2hours after the procedure. One patient developed empyema after 1month of pleurodesis. (Table 4). The complications were comparable in the groups without any statistically significant difference.

Table 4 – Showing the Complications after the procedure for the two agents

Complications		Iodopovidone		Talc		p-value
		Count	%	Count	%	
Chest Pain (Visual Analogue Scale)	No Pain	4/34	11.80%	6/26	23.10%	0.338
	Mild(1-3)	21/34	61.80%	15/26	57.70%	
	Moderate(4-6)	7/34	20.60%	2/26	7.70%	
	Severe(7-10)	2/34	5.90%	3/26	11.50%	
Fever		5/34	14.70%	3/26	11.50%	0.721
Hypotension		1/34	2.90%	0/26	0.00%	0.378
ARDS		0/34	0.00%	0/26	0.00%	.-
Empyema		1/34	2.90%	1/26	3.80%	0.847

In this study it was shown that the success rate of pleurodesis with iodopovidone in patients with pneumothorax was 92.3% with failure rate was 7.7% and success rate of talc pleurodesis was 88.9% with failure rate was 11.1% (Table 5).

Table 5 Showing the Outcome for the two agents in patients with pneumothorax.

			Iodopovidone	Talc	Total
Outcome	Failure	Count	1	1	2
		% within agent	7.7%	11.1%	9.1%
	Success	Count	12	8	20
		% within agent	92.3%	88.9%	90.9%
Total		Count	13	9	22
		% within agent	100.0%	100.0%	100.0%

On the other hand the success rate for Iodopovidone pleurodesis in patients with pleural effusion was 90.5% with failure rate was 9.5% and the success rate for talc pleurodesis in pleural effusion was 94.1% with failure rate was 5.9% (Table 6)

Table 6 – Showing the Outcome for the two agents in patients with pleural effusion.

			Iodopovidone	Talc	Total
Outcome	Failure	Count	2	1	3
		% within agent	9.5%	5.9%	7.9%
	Success	Count	19	16	35
		% within agent	90.5%	94.1%	92.1%
Total		Count	21	17	38
		% within agent	100.0%	100.0%	100.0%

Overall success rates for the two agents were comparable at 92.3% and 91.2% for talc and iodopovidone respectively, without any statistically significant difference between the two groups (p-0.875). For pneumothorax the success rate was higher in iodopovidone group (92.3%) when compared to talc (88.9%). The difference was statistically insignificant (p-0.784). For effusions alone the success rate was 90.5% for Iodopovidone and 94.1% for Talc (p-0.679) (Table 7)

Table 7 Showing the Comparative outcome for the two agents

	Iodopovidone	Talc	Total	P value
Overall Success	31/34 (91.2%)	24/26 (92.3%)	55/60 (91.7%)	0.875
Pneumothorax	12/13 (92.3%)	8/9 (88.9%)	20/22 (90.9%)	0.784
Pleural Effusion	19/21 (90.5%)	16/17 (94.1%)	35/38 (92.1%)	0.679

DISCUSSION

In this study a total of 60 patients underwent pleurodesis procedure. Out of 60 patients included in the study, iodopovidone was used in 34(56.6%) patients and cosmetic talc was used in 26(43.4%) patients. Of the total 60 patients, the age ranged from 14 to 85 years with a mean age of 45.8 ± 15.73 years. The mean age in females was 38.8 ± 15.75 yrs and mean age in males was 52.8 ± 15.71yrs. A similar study done by Agarwal *et al*[19] also found the mean age of the patients to be 51.7 years ± 16.6 years, however they did not calculate the mean age of the males and females separately. In another study conducted by Islam M Ibrahim *et al*[20] involving total of 39 patients with recurrent pleural effusion found the mean age of the patients to be 71 ± 5 years. In comparison to our study the mean of the patients was higher because they included patients with only malignant pleural effusion.

In the present study the success rate for the two agents i.e. iodopovidone and talc was measured and compared after 3 months following pleurodesis procedure. The overall success rate for iodopovidone in this study was 91.2% and failure was observed in 3(8.8%) patients. The overall success rate for talc was 92.3% and failure was observed in 2(7.7%) patients. The success rate for iodopovidone in pleural effusion was found to be 92.3% and for

pneumothorax was 90.5%. The success rate for talc in pleural effusion was found to be 94.1% and for pneumothorax was 88.9%. Agarwal *et al*[19] in a similar study observed a success rate of 92.3% patients in the iodopovidone group and 88.2% patients in the talc group. The success rate for iodopovidone and talc in the study by Agarwal *et al*. were similar to the success rate in the present study. A study done by Islam M Ibrahim *et al*.[20] , the success rate for talc was 80.9% and the success rate for iodopovidone was 72.7%. In another study conducted by Mohsen *et al*.[21] reported the success rate of 87% for talc group and 85% for todopovidone group. The success rate for iodopovidone and talc in the present study was higher than the success rate found in studies by Islam M Ibrahim *et al*.[20] and Mohsen *et al*.[21] as they included patients only with malignant pleural effusion which tend to reccur.

Kelly-Garcia *et al*.[22] reported the use of iodopovidone in 14 patients with a 64.2% success rate. Morales-Go´mez *et al*.[23] performed pleurodesis with iodopovidone in 39 patients with malignant pleural effusions, achieving control of the effusion in 33 patients (91.6%). Torres *et al*.[15] conducted a prospective multicenter study in which 52 patients with malignant (55% of patients) or recurrent exudative pleural effusion from 14 hospitals in Mexico were involved. They reported complete success with no reaccumulation of the pleural fluid in 50 patients (96.1%). Carlos A *et al*.[24] performed pleurodesis with iodopovidone in 52 patients with pleural effusion related to a malignant neoplasm, reported a success rate of 96.1%. The success rate in the present study was comparable with those of the above series.

In the present study the success rate for talc was 92.3%. The efficacy of talc has varied from 71% to 100% in various randomized controlled trials comparing talc slurry with other agents for chemical pleurodesis in patients with malignant pleural effusions.[25-29] Kennedy L *et al*.[30] in 1994 conducted a study which included 58 patients with both maliganat and benign pleural effusion. They reported that 10 g talc mixed in 150 to 250 mL of normal saline solution effectively controlled 38 out of 47 malignant pleural effusions with a success rate of 81%. In a systematic review of the English language literature from 1966 to 1994 that included 1168 patients participating in observational studies, Walker-Renard PB *et al*.[31] found the rate of complete success with talc was 93%, compared with 76% for Corynebacterium parvum, 67% for tetracycline, 72% for doxycycline and 54% for bleomycin. Similarly Kennedy L *et al*.[32] found that among 723 patients drawn from 32 case series of predominantly malignant effusions, talc was completely or partially effective in 659 (91%) patients. As observed in the above mentioned studies the efficacy of talc is comparable to the present study.

Instillation of talc is not devoid of side effects, including chest pain, fever, arrhythmias, and dyspnea. Among the 26 patients undergoing talc pleurodeis, the most common adverse effect observed was chest pain, complained by 20(76.92%) patients and fever was observed in 3(11.50%) patients. Walker-Renard and colleagues [31] reported chest pain with talc in 9 out of 131 (7%) patients. Fever following pleurodesis is common and has been observed following the administration of most agents. Fever following talc poudrage and slurry is common, occurring in 16 to 69% cases. Fever characteristically occurs 4 to 12 h following talc instillation and may last for 72 hours.[33,34,35] In study by Agarwal *et al* [19]. all patients experienced chest pain while fever occurred in 4 patients following talc pleurodesis. In this study one patient developed Empyema after 2months of pleurodesis. Empyema has been reported with talc slurry from 0 to 11 percent of procedures in the study by Kennedy *et al*.[32] The incidence of ARDS following intrapleural talc has varied markedly from series to series, the highest incidence was that reported by Rehse *et al*.[36], who retrospectively reviewed their experience of 89 talc pleurodesis procedures and 1 patient developed fulminant pneumonia after receiving talc. There were no cases with hypotension or ARDS associated with talc pleurodesis in the present study.

Regarding the complications of following iodopovidone pleurodesis, chest pain was present in majority (61.80%) of the patients. Severe pain (VAS 7-10) was complained by 2(5.9%) patients in iodopovidone group. Fever was seen in 5(14.7%) patients. Fever was self-limiting in most of the cases. Hypotension was observed in one patient. One patient developed empyema while on follow-up. In the study by Agarwal R. *et al*.[7] all patients experienced chest pain. Fever occurred in four patients and one patient developed empyema,. None of the patients, in their study, developed ARDS, visual loss or hypotension associated with administration of either agent. The findings were consistent with those of the present study.

CONCLUSION

The results of the present study suggest that both iodopovidone and cosmetic talc are equally effective when instilled by tube thoracostomy. Both the agents demonstrated a good safety profile in treating recurrent pleural effusions and pneumothorax with a good success rate and few minor complications. The short-term adverse effects include chest pain and fever both of them was self-limiting. There is more uniform deposition occurs with iodopovidone compared to talc slurry following instillation via intercostal drainage tube, it makes iodopovidone a better cost effective alternative sclerosing agent for pleurodesis.

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