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ORIGINAL ARTICLE

The Efficacy and Safety of Povidone-Iodine as a Pleurodesis-Inducing Agent in Spontaneous Pneumothorax: An Experience from a Tertiary Care Hospital for Publication

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Background: Primary or secondary spontaneous pneumothorax (PSP or SSP) is a common treatable disease but notorious for its recurrence over the years. Intercoastal tube (ICT) thoracostomy is often done to relieve pneumothorax. Simultaneous pleurodesis could be done by pushing pleurodesing chemical agent through ICT. Pleurodesis would obliterate the pleural space and prevent its recurrence. Povidone-iodine (10%) was a cheaper pleurodezing agent with efficacy rate of 60%–80% with minimal complication as per many studies. **Aims:** Our aims were to study the efficacy, that is, success rate as well as safety of povidone-iodine for pleurodesis in the treatment of PSP or SSP by tube thoracostomy and also to study the demographic characteristic. **Setting and Design**: A prospective observational study was conducted over 30 patients of PSP and SSP in a rural tertiary care hospital. **Materials and Methods**: As per inclusion and exclusion criteria, consecutively attending patients (male: female 26:4) were admitted. Clinicoradiologically, the diagnosis of PSP or SSP was made. Patients were treated by ICT thoracostomy under LA to relive pneumothorax. After lung expansion, pleurodesis was done by pushing the povidone-iodine solution (80 ml) through same thoracostomy tube. Follow-up (FU) was done up to 180 days. The outcome was analyzed statistically. **Statistical Analysis**: Descriptive statistics were used using Microsoft Excel 2007. **Results:** The "efficacy or success rate" of povidone iodine-induced pleurodesis was 90% (27/30) up to 3rd FU. However, the success rate of pleurodesis was 80% (24/30) till 180 days (4th FU). The procedure showed minimal complication. Chest pain occurred in majority 76% (23/30) of patients after pleurodesis. Spirometry, visual disturbance, and thyroid dysfunction were unaffected. **Conclusion:** Povidone-iodine (10%) came out as efficacious, safe, sclerosing agent for pleurodesis in PSP or SSP treatment by tube thoracostomy with a good success rate and minimal complication.

Key words: Pleurodesis, povidone iodine, spontaneous pneumothorax

INTRODUCTION

Spontaneous pneumothorax refers to spontaneous air accumulation in pleural space without any trauma. It often occurs unexpectedly and traditionally subdivided into "primary" and "secondary" depending on underlying lung disease. Studies have shown that one episode bears the risk of recurrence over the years up to the rate of 20%–50%[1] and would increase morbidity for repeated intervention and also increased the cost of treatment. Intercoastal tube (ICT) thoracostomy is one of the easy methods to treat spontaneous pneumothorax and also make possible to induce pleurodesis by injecting chemical sclerosing agent through that tube. It is the iatrogenic induction of symphysis of the visceral and parietal pleural.[1] The aim of pleurodesis is to obliterate the pleural space and prevent its recurrence.[1] Pleurodesis now plays an established role in spontaneous pneumothorax management. This procedure is usually achieved by either using a chemical agent (chemical pleurodesis) or by physical abrasion of the pleural surfaces during thoracotomy or thoracoscopy. Olivares-Torres *et al.*, in their study, showed success of povidone-iodine (10%) as plerodesing agent.[2] Other

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studies also showed that povidone-iodine was an effective agent for chemical pleurodesis in patients with recurrent pneumothoraces.[3] Thus, the pleurodesis was established as an easy, safe, and cost-effective treatment using povidone-iodine, being primarily a tropical antiseptic agent, induces inflammation in pleural surfaces to produce pleurodesis but exact process is unknown. However, it should not be used in iodine allergic patients. However, a lot of other plerodesing agents are also available now, such as tetracycline derivatives (doxycycline or minocycline), talc (insufflation or slurry), bleomycin, nitrogen mustard, silver nitrate, povidone-iodine, and dry killed *Corynebacterium parvum* with their different success rate.[1] Selection of agents needs to done cautiously depending on its availability, safety, cost, side effects, and also efficacy.[4] Pleurodesis through tube thoracostomy has comparable success rates to surgical pleurodesis and potentially cheaper and does not involve general anesthetic risks.[3] No universally recognized criteria exist to define pleurodesis success. However, response to pleurodesis was subdivided into many trial settings into "success" or "complete response" and "partial response" or "failure." This present study was conducted to show the efficacy of povidone-iodine as a chemical pleurodesis agent through ICT thoracostomy in spontaneous pneumothorax and to identify any adverse effect or complication during follow-up (FU) period of up to 6 months.

Aims and objective

1. To assess demographic characteristics of the study population in spontaneous pneumothorax (primary and secondary)
2. To assess the efficacy of povidone-iodine as pleurodesis-inducing agent in spontaneous recurrent pneumothorax and indicated cases of primary spontaneous pneumothorax (PSP)
3. To assess the safety of povidone-iodine in this situation and to see if any adverse effects or complication.

Setting and design

Our study was conducted in a rural-based tertiary care hospital over 30 patients admitted consecutively in our ward with clinicoradiological features of pneumothorax (first episode or recurrent) during 1 year as a nonrandomized prospective study. The Institutional Ethical Committee clearance was obtained. Inclusion criteria were (a) adults patients aged 18 years or more, (b) either sex, (c) patients with recurrent spontaneous pneumothorax and indicated cases of first episode spontaneous pneumothorax, and (d) lung expansion after intercostal drainage.

Exclusion criteria were (a) known allergy to povidone-iodine; (b) prior history pleurodesis; (c) brochopleural fistulae; (d) plural space infection at time of diagnosis; (e) renal, hepatic, and thyroid dysfunction; (f) incomplete reexpansion of the lung after tube thoracostomy; (g) highly moribund patients or (h) those with very limited life expectancy; (i) cardiac disease like heart failure; (j) pregnancy and nursing mothers; and (k) those who denied consent for procedures. FU period was scheduled for each patient up to 180 days of postpleurodesis periods as an outpatient after discharge to note its success, any complication or adverse effects.

MATERIALS AND METHODS

At our inpatients department, detailed history taking and general surveys and physical examinations were done with all relevant investigations from our hospital-based laboratories and imaging facilities. After explanation about the diagnosis, management of the disease, and possible complication of this study, consent was obtained from the patients. In addition to asking common symptoms, special enquiries were made to note the smoking habit, the initial time delay to attend our hospital after symptoms developed, prior tuberculosis (TB) history or antitubercular drugs (ATDs) intake or prior pleurodesis, and thyroid dysfunction or any visual impairment. The side, timing (first episode or recurrent), and the degree of pneumothorax were noted in each case. Investigations were done for sputum for acid–fast bacillus (AFB), chest X-ray (CXR) posteroanterior (PA) and lateral view, routine blood test, fasting blood sugar, renal function test, liver function test, and human immunodeficiency virus for I and II study. Visual acuity test and thyroid function test (free T3 and T4 and thyroid-stimulating hormone assay) was done twice, first one at admission time and last one done during last FU on 180 days. Ultrasonography (USG) of the thorax was done at diagnosis if indicated and later routinely during FU for all cases period up to 180 days to look for its recurrence or any pleural effusion or thickening developing as a result of pleurodesis. Contrast-enhanced computed tomography (CT) scan of the thorax was done to see any underlying lung conditions precipitating pneumothorax and pneumomediastinum if indicated. The diagnosis of spontaneous pneumothorax was made clinicoradiologically. Provided pleural effusion would develop any point of time during follow up period, evaluation of that pleural fluid would be done for for cell type, count, AFB smear, protein, sugar, adenosine deaminase level and malignant cells. Decision to treat with ICT drainage (ICTD) under water seal was made in all recurrent pneumothorax cases and in first episode cases that exhibited more than 2 cm of pneumothorax at hilar level on CXR-PA or failed initial aspiration.[1] An ICT of size "24" F was inserted into the 5th intercostal space along midaxillary line using operative tube thoracostomy technique through the

water seal drainage system.[1] The ICT was fixed to the skin nearby using silk suture material. ICT was given without delay. Time required to expand the lung fully after putting ICT was recorded. After complete drainage of air from the pleural cavity, that is, full lung expansion as evidenced by clinicoradiologically and ensuring the absence of any bronchopleural or alveolopleural fistula features, chemical pleurodesis with povidone-iodine (10%) was performed using the method described by Olivares-Torres *et al*. in their study.[2] Each patient was premedicated with 2 ml/kg lidocaine (2% topical) in 50 ml of normal saline through ICT. The pleurodesis solution, which was prepared by mixing 20 ml of 10% povidone-iodine and 80 ml of normal saline, was then be injected into the pleural cavity through ICT slowly using 50-ml sterile bladder wash syringe. The solution was allowed to remain in the pleural cavity for about 2 h by clamping the chest tube.[5] After that clamp was removed, the residual fluid from the pleural cavity was allowed to drain out spontaneously. No negative suction for tube drainage was applied. Any chest pain or elevation in body temperature or any other complications during or after pleurodesis procedure was recorded. Visual analog scale (VAS) was used to quantify the degree of postpleurodesis chest pain perception after the clear explanation about the scale. Body temperature was recorded twice daily. ICT was removed after satisfactory clinicoradiological situations, that is, full lung expansion, no bubbling chest drain, minimal column movement on deep respiration, no thick fluid or no debris collection and minimal or outpouring of any fluid 50 ml/day or less in chest drain, and absence of evidence of any infection.[1] CXR or USG thorax confirmed the absence of any air or fluid in pleural space. The "time interval between pleurodesis and ICT removal" was recorded in each case. Sputum for AFB was reexamined in all cases after lung expansion. Each patient was monitored after ICT removal to find any recurrent pneumothorax or any complication and so check CXR-PA and/or USG thorax done at 48 h after ICT removal. Patients were discharged thereafter with advice of periodic FU. FU was done at an outpatient basis at time scale of day 7, day 30, day 90, and day 180 by clinicoradiological method. Spirometry with reversibility test was undertaken after lung expansion and also in FU period on day 30 and 180 days in all cases to see the effect of pleurodesis. Pleurodesis efficacy was measured by "success," that is, "complete response" (no accumulation of air at any stage of FU).[6] "Partial Response" (i.e. air accumulation again after ICD removal, without any new symptoms and not requiring to put ICT again) and "Failure of Pleurodesis" (i.e. reaccumulation of air after ICD removal causing symptoms and requiring intervention such as ICD or surgery) were another two outcome in our study. In our study, success rates of pleurodesis were calculated using the numerator being the number of successful pleurodesis and the denominator being the total number of patients with pneumothorax. Descriptive statistics were used using Microsoft Excel 2007. Mean, median, proportion (%), and standard deviation (SD) were used as nature of variables.

RESULTS AND ANALYSIS

In our study, 26 male (86.7%) and 4 female patients (total n = 30) were included with mean age of 47.03 (±14.38 SD) years and ratio of male:female 6.5:1 [Table 1].

Mean body mass index was 22.82 (±1.85 SD) kg/m^2. Initial delay to attend our hospital was 1.7 (SD ± 0.89) days on average with maximum delay of 5 days and minimum 1 day. Only four cases (13.3%) declared prior ATDs intake and showed features of posttubercular lesions in radiology.

Our study showed that secondary spontaneous pneumothorax (SSP) cases (70%, i.e. 21/30) cases prepondered in frequency than PSP cases (30%, i.e. 9/30). Among (21) SSP cases, nine cases (30%) had chronic obstructive pulmonary disease (COPD), two cases (6.6%) had posttubercular lung fibrosis, and another two cases (6.6%) had combined lesion. The occurrence of pneumothorax was higher in the right side in either PSP (5 vs. 4) or SSP (11 vs. 10) variety. Pneumomediastinum was detected in two cases only in SSP by CT scan thorax. ICT was removed in 2 days in majority cases (66.6%) and none took beyond 5 days [Table 2]. Sputum for AFB at time of admission was negative among all cases. Later, two patients (2.67%) turned out sputum positive for AFBs on reexamination in early FU periods (day 7 and day 30). One patient later diagnosed bronchopleural fistula (BPF) on day 30 but never became sputum positive for AFB any in FU. At 2nd FU, on 30th postpleurodesis day, only two cases of "failure of pleurodesis" were found, one because of sputum positive TB and other one turned out BPF. Hence, up to 30 days (2nd) FU period, cumulative three cases had turned out to be "failure" and "pleurodesis success" was found in 27 cases (90%) and all these (90%) remained successful till 3rd FU (day 90). On 4th FU by 180 postpleurodesis days, another three cases did not turn up and these patients were successful till their 3rd FU checkup. Hence, cumulative success was 80% (24/30) till 4th FU. On 30th day (2nd FU), five cases showed USG measured thickening of pleura on pleurodesis side (>10 mm thick) and three cases showed minimal thickening (<10 mm thick pleura) but not evidenced in standing CXR-PA view. Majority of cases (22 out of 30) did not show any pleural thickening even by USG in FU. Spirometry was done on 30th and 180th FU day after relief of pneumothorax. On FU day 30th, spirometry was not

Table 1: Basic demographic characteristics

(A) Study population distribution pattern as per demography data. N (%)						
Variables	Cases	Smoker	Non-smoker	Urban area	Rural area	Age pattern:
Male	26 (86.7%)	25	1	8	18	≤40 yrs: 10
Female	4 (13.3%)	1	3	3	1	40~50 yrs: 4
Total	N=30	26 (86.6%)	4 (13.4%)	11 (36.6%)	19 (63.4%)	> 50 yrs: 16

(B) Occupation- residence wise the study population distribution							
Variables	Farmer	Labour	Students	Housewife	Grocery workers	Smokers	Total
Urban	0	1	5	2	3	8 (26.6%)	11 (36.6%)
Rural	15	3	0	0	1	18 (60%)	19 (63.4%)

Table 2: Postpleurodesis intercoastal tube removal time pattern

Post-pleurodesis time interval	No of patients to remove ICT [*n* (%)]
on 48 hour: 2nd day	20 (66.6%)
48 to 72 hrs: 3rd day	8 (26.7%)
72 to 96 hrs: 4th day	2 (6.7%)
Beyond 96 hrs: 5th day onwards	0 (00%)

Table 3: Spontaneous pneumothorax case pattern in the study population

Category	Primary-spontaneous pneumothorax (PSP) [*n*=9 (30%)]		Secondary-spontaneous pneumothorax (SSP) [*n*=21 (70%)]	
	First episode	Recurrent episode	First episode	Recurrent episode
Right side	3	2	9	2
Left side	2	2	9	1
Pneumomediastinum detected	0	0	1	1
Underlying Lung diseases like COPD, post TB lesion	0	0	10	3

done in three sputum-positive cases; another three cases were unable to perform. However, nine cases were detected to have moderate obstructive type and two cases severe obstructive type and one had restrictive pattern in spirometry. Rest of the 12 (40%) cases showed normal pattern (FEV1, forced vital capacity [FVC] in liter and its ratio). On further spirometry on 180 FU days to see any change of spirometry data, 10 patients (33.4%) showed normal pattern, 3 patients were lost to FU, 2 cases restrictive, 7 cases had moderate and 2 cases severe obstructive, and 1 case combined obstructive and restrictive pattern of spirometry. Two patients (13.4%) could not perform. Two cases (13.4%) showed difference in spirometry result comparing to 1st FU time. Hence, pleurodesis showed no major effect on spirometry data in our study. Probably underlying diseases, that is, COPD, fibrosis might have effect on spirometric data over time. No visual disturbance or vision diminution was reported till 180 days postplerudesis period by visual acuity testing.

DISCUSSION

Recurrence in spontaneous pneumothorax is a serious concern with increased morbidity. Prevention by chemical pleurodesis using (10%) povidone-iodine was established for the last few decades because of its easy availability, cost, efficacy, and safety profile and reflected in many studies.[3,7] Exact mechanism of action by a sclerosing agent (povidone-iodine) leading to pleurodesis was unknown and probably a result of a complex inflammatory reactions of pleural mesothelial cells producing excess extracellular matrix proteins synthesis and collagenigation.[8] Our study showed that spontaneous pneumothorax prepondered among males (86.66%) (26/30 cases) and among smokers (26/30) like many other studies.[1] Patients of rural area suffered pneumothorax more that that of urban area (63.3% vs 36.7%). Among different occupation, rural farmers suffered most (15/30, i.e. 50%), followed by students (5/30, i.e. 16.7%) and least among homemakers (2/30, i.e. 6.67%) [Table 1]. SSP was observed in higher proportion than PSP (21 vs. 9). It prepondered in the right side both in PSP (5/9, i.e. 55.6%) and SPS (11/21, i.e. 52.4%) cases. First episode of pneumothorax in either type of PSP or SSP was observed to occur in higher proportion that their recurrent variety [i.e first episode of 55.6% in PSP(5/9) and 85.8% in SSP(18/21)]. An average duration of lung expansion after ICTD was 2.11 days in case of PSP in contrast to SSP requiring 2.95 days. Pleurodesis was painful, presumably from the intense pleural inflammation. Chest pain occurred among 76% (23/30) of patients after injecting pleurodesis solution and the severity score of pain in the VAS occurred in a mode of 7. However, rescue analgesia was required in 66.67% (20/30) of cases [Table 4]. Narcotic analgesia and/or conscious sedation should be used as premedication in the absence of contraindications. Average duration of 2.22 days after pleurodesis was required to remove ICD in PSP and that of average 2.47 days for SSP. Overall mean

Table 4: Pleurodesis complication in our study

Complication	No of cases					
Pain	20	Severity of Pain				
		Mild pain 0~3 VAS	Moderate pain 4~6 VAS	Severe pain 7~10 VAS	Analgesis Required	Analgesia Not Required
		00	04	16	17	03
Feve	3					
Dyspnoea	4					
Combined (any two of above)	3	00	00	03	03	00
Hypotension	0					
Unstable vitals	0					

Table 5: Pleurodesis outcome pattern in our study

Category	Success	Failure	Lost to follow up
Ist follow up (D7)	29 (96.6%)	1(3.4%)	0
2nd follow up (D30)	27 (90%)	2	0
3rd follow up (D90)	27 (90%)	0	0
4th follow up (D180)	24 (80%)	0	3

Total success=27 upto 3rd FU and 24 at 4th; FU. Failure=3 cases. Lost to follow uo 3 cases who showed success till 3rd FU

duration of postpleurodesis chest tube removal was 2.4 days. Pleurodesis "success" on 7th and 30th day FU was 96.7% (29/30) and 90.0% (27/30), respectively [Table 5]. "Failure" was analyzed as 3.3% (1/30) on 1st FU and cumulative 10% (3/30) in 2nd FU because two cases turned out sputum smear (reexamined after lung expansion) positive TB (one case at 1st FU and other one case on 2nd FU time) and other one case detected BPF in 2nd FU [Table 5]. Because of the high prevalence of TB, TB needs to be checked among all chest symptomatic and on further 90th day postpleurodesis FU (3rd FU), success rate stood same as 2nd FU, that is, 90% (27/30) and failure 10% (3/30). On last FU on 180th day (4th FU), additional three cases were absent (lost to FU) and each of these three cases showed pleurodesis success till their 3rd FU. These three cases were students by occupation. Pleurodesis "success" on 4th FU thus stood as 80% (24/30). The safety and efficacy of pleurodesis using iodopovidone through tube thoracostomy method without any significant adverse effects was 89.47% in a study conducted by Dey *et al.*,[5] 90% in study by Agarwal *et al.*,[6] and 91.6% in a study conducted by Morales *et al*.[9] Our study revealed similar success. A transthoracic USG was performed over postpleurodesis cases on 2nd and 3rd FU time to see any air or fluid in pleura or any thickening. Majority of 73.4% (22/30) cases did not show any pleural thickening or abnormality. However, 16.7% cases (5/30) showed pleural thickening more than 15 mm and 13.4% (4/30) of cases showed < 10 mm pleural thickening. On 3rd FU (90 day), transthoracic USG did not detect any thickening of pleura. Probably, the pleural thickening developed because of inflammatory chemical reactions of pleural tissue to povidone-iodine which subsided with time spontaneously. Pleurodesis process did not show any residual pleural thickening effect even in long FU time period. Pleural thickening identification by CXR alone was difficult to assay as such in. Hence, transthoracic USG was undertaken to see the thickening in our hospital in a same machine and by the same radiologist. There were very few Indian studies to find pleural thickening by such povidone-iodine pleurodesis effect. More studies with large study population might require to analyze pleural thickening. Observer error to detect pleural thickening during USG might be possible. Postpleurodesis chest pain (66% i.e. 20 cases) was our main complication followed by dyspnoea (13.34%) (4/30 cases). High VAS score of pain or pleural thickening could not be correlated in our study for small sample size. Hypotension or unstable vital did not occur in any as a postpleurodesis complication. Thyroid function did not alter among patients till FU 180 days as seen in the study by Yeginsu *et al*.[10] Overall, the procedure was tolerated well by all the patients (100%). Pleurodesis did not show significant change in office spirometry, that is, FEV1 or FVC data. Visual disturbance did not occur in our study population. Our study was undertaken to determine the safety and efficacy of povidone-iodine (10%) as (chemical) pleurodesis agents in the management of pneumothorax and its recurrence using ICT-thoracostomy method with a FU period up to 180 days. The difficulty in the form of increased resistance during pushing the sclerosing solution through thoracostomy tube was not experienced by us as in the study by Dey *et al*.[5] No death or allergy was reported in our study. A small sample size (30) was a limitation in our study.

CONCLUSION

Povidone-iodine (10%) was a safe, cost-effective, easily available, and tolerated sclerosing agent for pleurodesis in

spontaneous pneumothorax by tube thoracostomy method showing success rate of 90% up to 180 days of postpleurodesis day with minimal complication or adverse effect. The procedure could be done safely under local lignocaine anesthesia. Major side effect was chest pain as a complication but was manageable and tolerated. The long-term outlook in patients following pleurodesis for spontaneous pneumothorax was good.

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Conflicts of interest

There are no conflicts of interest.

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