

Covering the staple line with a polyglycolic acid sheet after bullectomy for primary spontaneous pneumothorax prevents postoperative recurrent pneumothorax

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Background: Postoperative recurrent pneumothorax (PORP) can arise after surgery for primary spontaneous pneumothorax (PSP) that is recurrent or involves prolonged air leakage. In this study, which included 265 patients (279 cases) with PSP who underwent surgery at our department, the percentage of patients that did not experience PORP was compared between a group that underwent bullectomy alone (group A) and a group in which the staple line and the surrounding visceral pleura were covered with a PGA sheet after bullectomy (group B) in order to study the utility of PGA sheets for preventing PORP.

Methods: Among the patients with PSP who underwent surgery, the cases of 92 patients (98 cases) from Group A and 173 patients (181 cases) from Group B were reviewed retrospectively. The incidence rates of PORP in these two groups were statistically analyzed in addition to the associations between PORP and age, gender, the affected side, height, body weight, height/weight ratio, smoking habits, or the surgical procedure.

Results: In total, 96.7% of the patients in group B did not suffer PORP, which was significantly higher than the equivalent figure for group A (83.7%, log-rank test: $P=0.0003$). Moreover, among the examined parameters, only covering the staple line with a PGA sheet was found to be an independent prognostic factor (Cox regression: $P=0.0003$; HR = 0.212; 95% CI, 0.082-0.547).

Conclusions: It was revealed that when bullectomy is performed in patients with PSP, wide coverage of the staple line and the surrounding visceral pleura with a PGA sheet significantly reduces the risk of PORP.

Keywords: Pneumothorax; recurrence; polyglycolic acid sheet

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Introduction

Bullectomy is often performed as a video-assisted thoracic surgery (VATS)-based treatment for recurrent pneumothorax and pneumothorax involving prolonged air leakage (1-8), but it seems to result in a higher frequency of postoperative recurrent pneumothorax (PORP) than conventional thoracotomy methods (lateral thoracotomy or axillary thoracotomy) (9-12). To prevent PORP, additional

therapies aimed at achieving pleural adhesion, such as performing pleurectomy after bullectomy, spraying talc within the chest cavity, or administering certain antibiotics into the chest cavity, have been examined and shown to be effective (13-22). In recent years, evidence has accumulated that the application of a covering material along the resection line after bullectomy is effective at preventing PORP (23-27). In this study, the factors associated with

Table 1 Patients' characteristics

Characteristics	Overall	Group A	Group B	P value
Age (years)	29.3±14.8	26.0±11.6	31.2±16.0	0.002
Gender				0.052
Male	231	87	144	
Female	48	11	37	
Side				0.874
Right	147	51	96	
Left	132	47	85	
Smoking				0.274
Yes	146	56	91	
No	133	42	90	
Surgical procedure				0.243
TS	208	69	139	
Others	71	29	42	
Height (cm)	170.0±8.2	170.4±6.9	169.9±8.7	0.898
Body weight (kg)	55.8±8.4	55.6±7.8	56.1±8.9	0.448
Height/body weight (cm/kg)	3.10±0.40	3.12±0.38	3.09±0.41	0.318
Mean duration of follow-up (days)	2,262±1,322	3,394±1,574	1,639±516	<0.001

TS, thoracoscopic surgery.

PORP are studied as well as the efficacy of covering the visceral pleura with a PGA sheet as a treatment for preventing PORP.

Materials and methods

Patients

Among the 265 patients (279 cases) with primary spontaneous pneumothorax (PSP) who underwent surgery at Nippon Medical School Chiba Hokusoh Hospital between April 1994 and December 2007, the cases of 92 patients (98 cases) that underwent bullectomy alone before September 2002 (group A) and 173 patients (181 cases) who underwent bullectomy followed by covering of the visceral pleura with a PGA sheet in October 2002 or later (group B) were reviewed retrospectively. The patients' characteristics are shown in *Table 1*. The patients included 231 males and 48 females, and their mean age was 29.3±14.8 years old. There were 87 males and 11 females in group A, and their mean age was 26.0±11.6 years old. The patients in group A underwent bullectomy alone. In addition, there were 144 males and 37 females in group B, and their mean age was 31.2±16.0 years old. In group B, bullectomy was performed, and then the staple line and the surrounding visceral pleura were covered with a PGA sheet. Surgery was performed

simultaneously on both sides in 14 cases. When the same patient underwent surgery on both sides, each side was treated as a separate case. Similarly, when postoperative recurrence was observed twice on the same side in the same patient each recurrent episode was treated as a separate case.

Operative procedure

At our institution, surgery is mainly performed for the following types of pneumothorax: cases of recurrent pneumothorax in which bullae are observed in the lungs on CT or cases of primary pneumothorax involving prolonged air leakage (for ≥5 days) after the start of chest cavity drainage. In all cases, a double lumen endotracheal tube was inserted into the airway under general anesthesia, and surgery was performed during selective ventilation of the contralateral lung. In all cases, surgery was carried out whilst the patient was in the lateral position. As for the thoracotomy method, thoracoscopic surgery (TS) was performed in 208 cases, axillary thoracotomy was carried out in 49 cases, lateral thoracotomy (>10 cm) was employed in 14 cases, and TS + minithoracotomy (<10 cm) was performed in 8 cases. TS was performed using the three-port method. In this method, the first 2 cm port is created along the anterior axillary line of

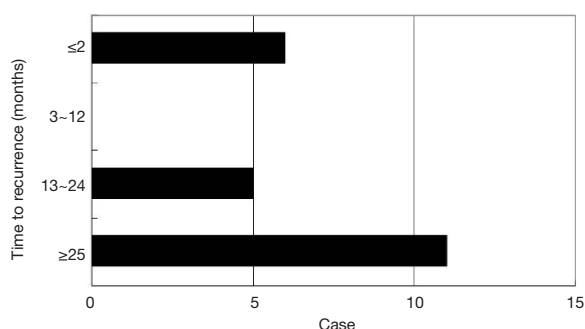


Figure 1 Distribution of the number of cases of PORP according to the time to recurrence. PORP, postoperative recurrent pneumothorax.

the fifth or sixth intercostal space, and then two 0.5 or 1.5 cm ports are created in the chest wall according to the degree of adhesion and the locations of any bullae. A careful search for bullae was performed by examining the surface of the visceral pleura, and a leak test was simultaneously conducted at a pressure of 20 cmH₂O in order to check for air leakage. After bullectomy of any bullae observed on the lung surface using an endoscopic stapling device [either an Autosuture GIA Universal, Tyco Healthcare (Convivial), Norwalk, CT, USA, or an Endopath ETS45, Ethicon Endo-Surgery, Cincinnati, OH, USA, depending on the surgeon's preference], another leak test was conducted at an airway pressure of 20 cmH₂O in order to confirm that there was no air leakage from the resection line, etc. In Group B, a PGA sheet (either an DexonTM Mesh, Syneture, USA, or Neoveil, Gunze, Kyoto, Japan, depending on the surgeon's preference) that had been cut to an appropriate size (approximately 5 cm × 5 cm) was inserted through the relevant port and was used to cover the surface of the visceral pleura around the staple line. Fibrin glue was used to fix the sheet in place. A 20 Fr chest tube was inserted through one of the ports and connected to a continuous suction system, and continuous suction was performed at a negative pressure of 10 cmH₂O. After it was confirmed that there was no air leakage and good re-expansion of the lungs had been confirmed on a chest X-ray, the chest tube was generally removed on postoperative day 1.

Statistical analysis

All data in the text and tables are expressed as mean ± SD values. All statistical analyses were performed using the software SPSS (SPSS for Windows v. 15, SPSS, Inc. Chicago, IL, USA). Comparisons of the patients' characteristics were made using the two-tailed Student's

t-test or chi-square test.

Univariate analyses (log-rank test) were performed to examine the associations between PORP and age, gender, the affected side, smoking habits, surgical procedure, height, body weight, height/weight ratio, or the application of a PGA sheet, and multivariate analysis (using the Cox proportional hazards method) was performed to extract independent prognostic factors from among the parameters that demonstrated significant associations in the univariate analysis.

P values of <0.05 were considered to indicate statistical significance for all parameters.

Results

After October 2002, when the covering procedure was introduced, the mean age of the patients who underwent surgery for PSP increased significantly ($P=0.002$). No significant differences were observed between the groups in terms of gender, the affected side, height, body weight, height/weight ratio, smoking habits, or surgical procedure (Table 1). The mean duration of the follow-up period was $3,394 \pm 1,574$ days in group A and $1,639 \pm 516$ days in group B. No surgery-related deaths occurred after the first or second surgical procedures in either group. The patients who developed PORP underwent a consultation after the first surgical procedure, during which they presented with chest pain and respiratory discomfort as major complaints, and recurrent pneumothorax was confirmed on a chest X-ray. PORP occurred in a total of 22 cases (7.9%), including 16 (16.3%) and 6 (3.3%) cases in groups A and B, respectively. The time until the development of PORP was less than 2 months in 6 cases, 3 to 12 months in 0 cases, 13 to 24 months in 5 cases, and ≥ 25 months in 11 cases (Figure 1). The characteristics of the recurrent and non-recurrent cases are shown in Table 2, and further details about the recurrent cases are shown in Table 3. A second surgical procedure was performed in 13 patients in whom bullae were observed on CT and air leakage occurred for ≥ 5 days after chest drainage. Eleven of these patients belonged to group A, and the other 2 were in group B. The remaining 9 patients who suffered PORP exhibited improvements in their conditions after chest cavity drainage, and therefore, did not undergo further surgery. Bullae were observed during the second surgical procedure in a total of 9 cases, including 8 of the 11 cases (73%) in group A and 1 of the 2 cases (50%) in group B. Of these, it is considered that the bullae found in patient 1, who suffered recurrence on postoperative day

Table 2 Characteristics of the PORP and no-PORP groups

Characteristics	PROP	No-PORP
Age (years)	22.3±8.9	30.0±15.1
Gender		
Male	20	188
Female	2	69
Side		
Right	13	134
Left	9	123
Smoking		
Yes	7	140
No	15	117
Surgical procedure		
TS	20	188
Others	2	69
Height (cm)	170.1±7.3	169.9±8.3
Body weight (kg)	55.0±7.8	55.9±8.5
Height/body weight (cm/kg)	3.15±0.42	3.10±0.39
Group		
A	16	82
B	6	175

PORP, postoperative recurrent pneumothorax.

20, had been overlooked during the original procedure, but in the other 8 cases the bullae were detected at ≥ 13 postoperative months, and therefore, it was difficult to determine with any degree of certainty whether they had been overlooked during the original operation or had developed during the postoperative period. Regarding other types of recurrence, air leakage from the area near to the staple line was observed in 1 case, air leakage from a pinhole in the visceral pleura was observed in 1 case, and PORP of unknown cause was seen in 3 cases (*Table 3*). Age, gender, the affected side, height, body weight, height/weight ratio, smoking habits, surgical procedure (TS *vs.* others), and the application of a PGA sheet were considered as factors that might affect the risk of recurrence. According to univariate analysis, the cumulative recurrence-free rate was highest among the patients that were ≥ 30 years old, smokers, and those in which the visceral pleura was covered with a PGA sheet (group B) (*Table 4*). A multivariate analysis involving these three items was performed, and only the covering of the visceral pleura with a PGA sheet was found to be an independent prognostic factor (*Table 5*). Kaplan-Meier

curves for group A and group B are presented in *Figure 2*.

Discussion

Surgical treatment used to be selected for prolonged air leakage or recurrent pneumothorax (28), but in recent years bullectomy using an endoscopic stapling device has been widely performed as a VATS-based procedure for such conditions due to its low degree of invasiveness (1-8). However, PORP, which frequently occurs after open thoracotomy, has become a problem (9-12). In the present study, the mean age of the patients who underwent surgery for PSP was 29.3 years old (*Table 4*), and that of the patients who developed PORP was 22.3 years old (*Table 2*), which indicates that both of these conditions predominantly affect young subjects. PSP and PORP are not life-threatening disorders, but as they occur at an age when many individuals are experiencing important life events such as entrance examinations for university, they can cause patients serious social disadvantages. Therefore, it is necessary to continuously make an effort to decrease the incidence of PORP.

In our study, when the time at which PORP occurred and the number of cases of PORP were plotted on a graph focusing on the presence of bullae during the second surgery, 2 peaks were observed (*Figure 1*). In other words, PORP mainly developed within 2 months after surgery (early) or >1 year after surgery (late), and no cases of PORP occurred between 3 and 12 postoperative months. A bulla was observed during the second surgical procedure in 1 of the 3 cases (33%) in which PORP occurred early in the postoperative period, and it was considered that it had been overlooked during the initial procedure. On the other hand, bullae were observed during the second surgical procedure in 8 of the 10 cases (80%) in which PORP occurred after >1 year after surgery (*Table 3*). Based on the timing and pattern (the presence/absence of bullae during the second surgery) of these PORP cases, it is possible that cases of PORP that occur early and late after surgery for PSP are caused by different mechanisms.

Intraoperative damage to the visceral pleura and the overlooking of bullae are considered to be potential causes of early PORP (17). Bullae can be overlooked due to endoscopic blind spots or intraoperative pulmonary collapse caused by separate ventilation (13). In order to prevent early PORP, it is important to prevent air leakage from areas of damaged visceral pleura and to avoid overlooking bullae during the initial procedure. In our series, the visceral

Table 3 Details of the recurrent (PORP) cases

No	Group	Age	Gender	Side	Time to recurrence (days)	First operative findings	Second operative findings
1	A	18	M	L	20	Bulla (apex)	Bulla (s ⁶)
2	A	28	M	R	23	Bulla (apex)	Chest drainage
3	A	17	F	L	33	Bulla (wide area)	Chest drainage
4	A	21	M	L	35	Bulla (wide area)	Air leaking from staple line
5	A	21	M	L	61	Bulla (apex)	Chest drainage
6	A	47	F	R	407	Air leaking from apex, bulla (–)	Unknown
7	A	50	M	R	467	Bulla (wide area)	Chest drainage
8	A	17	M	L	502	Bulla (apex)	Bulla near staple line
9	A	15	M	L	680	Bulla (S ⁶)	Unknown
10	A	18	M	R	694	Bulla (apex)	Bulla (apex)
11	A	19	M	L	787	Bulla (apex)	Bulla (apex)
12	A	16	M	L	969	Bulla (apex)	Bulla (apex)
13	A	18	M	L	1,057	Bulla (apex)	Bulla (apex)
14	A	18	M	R	1,138	Bulla (apex)	Bulla near staple line
15	A	21	M	R	1,139	Bulla (apex)	Chest drainage
16	A	21	M	R	1,558	Bulla (apex)	Bulla (apex)
17	B	21	M	R	48	Bulla (apex)	Unknown
18	B	20	M	R	721	Bulla (apex)	Bulla (apex)
19	B	21	M	R	1,125	Bulla (apex)	Chest drainage
20	B	21	M	R	1,320	Unknown	Chest drainage
21	B	20	M	R	1,321	Bulla (apex)	Chest drainage
22	B	16	M	R	1,674	Bulla (apex)	Chest drainage

PORP, postoperative recurrent pneumothorax.

Table 4 Univariate analysis of predictors of freedom from PORP (log-rank test)

Variables	Freedom from recurrence (%)	P value
Age (≤30 vs. >30 years)	89.6:97.7	0.026
Gender (M vs. F)	91.3:95.8	0.321
Side (R vs. L)	91.2:93.1	0.597
Smoking (yes vs. no)	95.1:88.5	0.034
Surgical procedure (TS vs. others)	90.4:97.2	0.057
Height (≤170 vs. >170)	92.6:90.9	0.421
Body weight (≤56 vs. >56)	92.0:92.0	0.958
Height/body weight (≤3.1 vs. >3.1)	92.5:91.4	0.819
Group (A vs. B)	96.7:83.7	<0.001

pleura were not covered with a PGA sheet in 5 of the 6 cases (83%) in which PORP occurred early after surgery.

Previous studies have also reported the detection of

Table 5 Multivariate analysis of predictors of freedom from recurrent pneumothorax (Cox regression)

Variables	HR (95% CI)	P value
Age (≤30 vs. >30 years)	0.345 (0.078-1.533)	0.162
Smoking (yes vs. no)	0.423 (0.169-1.062)	0.067
Group (A vs. B)	0.212 (0.082-0.547)	0.001

bullae during surgery for PORP (14,22-25,27), and bullae were observed in 9 of the 13 cases (69%) in which second surgical procedures were performed for PORP in our study (*Table 3*). Among these 9 cases, with the exception of 1 case in which it was considered that the bulla had been overlooked during the first procedure, all 8 cases involved late PORP. In the latter 8 cases, it was difficult to determine whether the bullae observed during the second surgical procedures had been overlooked during the initial procedure or had subsequently developed. However,

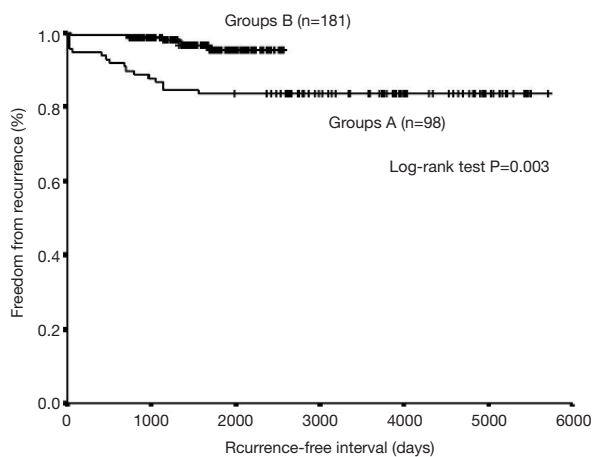


Figure 2 Cumulative frequency of freedom from recurrence in group A and B.

during the first procedure at least two people, including the operator and the supervisor, carefully observed the surface of the visceral pleura, and it is difficult to believe that all of these cases of PORP were due to the overlooking of bullae. In particular, we consider that the cases of PORP in which bullectomy were performed during the first procedure and bullae developed close to the staple line were caused by the rupturing of regenerated bullae. It is considered that bullae regeneration requires a certain amount of time, but no bullae were observed in any of the cases of early PORP other than the case in which it was considered that a bulla had been overlooked during the initial procedure. On the other hand, bullae were observed in 80% of the cases of late PORP, and therefore, it can be speculated that bullae regeneration contributes to PORP. It is suggested that weakening of the pleura due to the tensional force applied to the visceral pleura and/or the deformation of fine bronchial tubes due to the tensional force applied to the lung by staples, etc., are responsible for bullae regeneration (7,26,27). It is considered that it is necessary to prevent the regeneration and rupturing of bullae in order to avoid the late occurrence of PORP. In our series, the visceral pleura were not covered with a PGA sheet in 11 of the 16 cases (69%) in which late PORP developed.

The covering of the staple line with an absorbefacient sheet has been reported to be effective against PORP. In the present study, the covering of the visceral pleura with an absorbefacient sheet was found to be an independent prognostic factor (Table 5), indicating that this method helps to prevent PORP early and late after surgery. Similarly,

methods in which absorbefacient sheets were held in place with fibrin glue (23-26) or in which the staple line was reinforced with fleece-coated fibrin glue (TachoComb) (27) have also been reported to be effective against PORP. The application of fleece-coated fibrin glue close to the resection line has been reported to reduce the frequency of PORP to a similar level to that achieved by the use of absorbefacient sheets (27). Fleece-coated fibrin glue requires a few minutes of compression when it is used to bind the visceral pleura, and it is considered that it is difficult to redo such procedures if they fail. On the other hand, PGA sheets are easy to use in operations both in terms of their insertion through ports and their application, and it is considered that procedures involving PGA sheets can be redone if they fail. Although methods involving fibrin glue or fleece-coated fibrin glue have been demonstrated to inhibit PORP, both of these adhesives are derived from blood and so carry a risk of viral infection (29). In recent years, in order to eliminate the possibility of viral infection, different methods such as the application of PGA sheets using autologous blood (30,31) and other materials (32) and the fixation of PGA sheets to the visceral pleura using absorbefacient thread (33) have been reported. When these methods are employed, it takes a while to determine the strength of the fixation between the sheet and the target tissue and whether the sheet remains fixed to the intended site while it is being stretched. As it is impossible to confirm whether a sheet covers the intended area while it is being stretched during lung re-expansion using postoperative X-rays or CT scans, the long-term prognoses of such procedures need to be compared and investigated in the future in order to compare their relative merits. If the use of alternative adhesives such as autologous blood results in similar long-term prognostic outcomes to those seen after the use of fibrin glue, then PGA sheets should be fixed in place with these alternatives. Until then, our policy is to continue using fibrin glue. Sakamoto *et al.* (23) reported that in cases of PSP in which artificial absorbefacient sheets, such as PGA sheets, were used, thickening associated with fibrosis of the visceral pleura was observed in the resected lung specimens obtained during the second surgical procedure. In our study, no pathological analysis was conducted as no resected specimens of the covered regions of the pleura were obtained during the second surgical procedures in Group B. On the other hand, Nakanishi *et al.* (24) recently reported that no thickening of the pleura or associated reinforcement occurred when absorbefacient sheets were fixed to the visceral pleura with fibrin glue,

and it is speculated that the inflammatory reaction induced in the pleura by the absorbefacient sheets promoted their adhesion to the visceral pleura and the parietal pleura, and thereby, reduced the risk of PORP. Furthermore, it was pathologically confirmed that bullae regeneration occurs in the layer underneath the area covered by the absorbefacient sheet. Therefore, it is speculated that PGA sheets prevent PORP by stopping recurrent bullae from rupturing, rather than by inhibiting bullae generation.

In conclusion, according to the findings of both previous reports and this study, it is considered that covering large portions of the staple line and the surrounding region with a PGA sheet after bullectomy prevents both early PORP, which is associated with damage to the visceral pleura in the regions close to the resection line; air leakage from the staple line; and late PORP, which is related to the recurrence of bullae >1 year after surgery.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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