

Effect of Bovine Pericardial Strips on Air Leak After Stapled Pulmonary Resection

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Background. Surgical procedures for emphysema have been proposed and in many settings resulted in significant improvement in dyspnea and function. The most prevalent surgical problem in all series is prolonged postoperative air leak.

Methods. One hundred twenty-three patients undergoing stapled thoroscopic unilateral lung volume reduction operation were prospectively randomized to receive either no buttressing of their staple lines or buttressing of all staple lines with bovine pericardial strips.

Results. The two groups were comparable in preoperative risks and in the severity of their emphysema. Postoperative complications were identical in the two groups with respect to pneumonia, empyema, and wound infection; however, there was a significant difference in the duration of postoperative air leaks. Those

having the pericardial strips used to buttress their staple lines had chest tubes removed 2.5 days sooner and were discharged from the hospital 2.8 days sooner as a result. The cost data revealed that because of the cost of the pericardial sleeves, the overall hospital charges were almost identical for the two groups (\$22,108 bovine, \$22,060 no bovine) in spite of the shortened hospital stay.

Conclusions. The use of bovine pericardial sleeves to buttress the staple lines in thoroscopic unilateral lung volume reduction operation results in a shorter duration of postoperative air leaks. Total hospital charges were comparable in the two groups as the 2.8 days saved in the hospital were offset by the cost of the pericardial sleeves.

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Surgical procedures for emphysema have created enthusiastic debate and resulted in numerous publications in the thoracic surgical literature. There has been a perceptible evolution in technique during the past 5 years from the initial laser techniques to the now more frequent stapled volume reduction procedures [1-6].

Although surgical techniques and patient selection have evolved, air leaks remain the most frequently seen complication in all reported series. Typical times for chest tubes to be required after operation are more than 7 days, often approaching 2 weeks. Prolonged air leaks after lung resections have always been an occasional postoperative management problem; however, the emphysematous lung is particularly unforgiving in this regard.

Understandably there have been attempts to decrease the duration of postoperative air leaks by using several techniques to buttress the areas of stapled resection. The most frequently used maneuver has been to use strips of bovine pericardium on the staple lines [7]. The use of heterologous pericardium could have an impact both on the incidence of postoperative infections and on total hospital costs. We performed a prospective trial to study

the effect of heterologous pericardium on air leak duration.

Material and Methods

One hundred twenty-three consecutive patients undergoing lung volume reduction (LVR) were prospectively randomized to receive bovine pericardial strips on either all staple lines or none of them.

All patients enrolled met standardized criteria for inclusion in the LVR research protocol approved by the Investigational Review Board at both institutions. Inclusion in this study required disabling dyspnea at less than 50 yards with a forced expiratory volume in 1 second of less than 35% predicted. All patients had marked hyperinflation with residual volumes more than 175% predicted and all patients had pulmonary rehabilitation and could ambulate more than 350 yards preoperatively.

Preoperative parameters recorded included age, sex, spirometric values, plethysmography results, diffusion capacity for carbon monoxide, and exercise testing by 6-minute walk distances. All surgical procedures were performed in an identical fashion with the exception of whether or not bovine pericardial strips were used. The technique was a unilateral thoroscopic LVR in which the typical resection resulted in a disproportionate resection of the upper lobe to produce a 20% to 30% reduction in the volume of the lung. Areas of resection were guided

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Table 1. Preoperative Characteristics

Variable	Bovine (n = 58)	No Bovine (n = 65)	p Value
Age (yr)	66.7 ± 6.9	65.9 ± 7.7	0.56
Sex	42 M/16F	40 M/25F	0.20
FEV ₁ (L)	0.73 ± 0.30	0.74 ± 0.32	0.80
FEV ₁ (% predicted)	25.8 ± 8.5	28.8 ± 11.9	0.12
RV (L)	5.17 ± 1.6	4.8 ± 1.3	0.20
RV% (% predicted)	231 ± 66	235 ± 65	0.71
DLCO (units)	8.5 ± 3.7	8.4 ± 4.2	0.87
DLCO (% predicted)	42.8 ± 19.4	43.4 ± 16.6	0.86
Six-minute Walk (ft)	854 ± 344	949 ± 327	0.12

DLCO = diffusion capacity for carbon monoxide; FEV₁ = forced expiratory volume in 1 second; RV = residual volume.

by preoperative perfusion scans and computed tomographic scans as well as visual intraoperative findings.

Postoperatively chest tubes were removed 24 hours after the last detected air leak. This was determined by a team and patients were evaluated at least twice daily. Patients were followed up to determine the incidence of complications, duration of air leaks, length of intensive care unit and hospital stays, and total hospital charges. Parametric data were analyzed using χ^2 and nonparametric data using the Wilcoxon rank sum test. Statistical significance required a *p* value of less than 0.05.

Results

Of the 123 patients, 58 were randomized to receive the bovine pericardial sleeves and 65 did not. Table 1 demonstrates that there were no significant differences in any preoperative characteristic between the two groups. Table 2 depicts postoperative complications, which were comparable in the two groups with the notable exception of the duration of postoperative air leak. There were no patient deaths nor were there any patients in whom empyema developed or who were readmitted for pneumothorax. Seven patients were discharged with Heimlich valves, and the chest tube duration included the time the Heimlich valves were in postoperatively as an outpatient. Patients with Heimlich valves were evaluated daily as outpatients in an attempt to define accurately the duration of air leak. There was a statistically significant difference in both chest tube duration (7.9 versus 10.4 days) and hospital days (8.6 versus 11.4 days) favoring the group with the pericardium (Table 3).

Table 2. Postoperative Complications

Complication	Bovine (n = 58)	No Bovine (n = 65)	p Value
Pneumonia	1 (1.7%)	2 (3.1%)	1.00
Wound infection	2 (3.4%)	1 (1.5%)	0.60
Heimlich valve	2 (3.4%)	5 (7.6%)	0.45
Empyema	0	0	
Death	0	0	

Table 3. Results

Variable	Bovine	No Bovine	p Value
Ventilator hours	2.1 ± 0.28	0.49 ± 0.06	0.08
Chest tube days	7.9 ± 8.2	10.4 ± 8.9	0.04
Intensive care days	0.69 ± 0.6	0.76 ± 0.1	0.60
Hospital days	8.6 ± 5.2	11.4 ± 8.1	0.03

The mean hospital charge for bovine pericardium was \$2,677 (range, \$925 to \$4,200) per case. In spite of a shortened hospital stay, the mean total hospital charges were still higher in the bovine pericardial group (\$22,108 versus \$22,060). This difference in hospital charges was not statistically significant.

Comment

The use of bovine pericardial strips has become prevalent in LVR operations despite a lack of objective data demonstrating efficacy. Early series on LVR operations have consistently reported prolonged air leaks (>7 days) in approximately 30% of patients and mean hospital stays of 11 to 18 days whether or not buttressing strips were used [2-6]. These figures combined with the relatively high cost of bovine pericardial sleeves caused us to question their routine use.

Our study population demonstrated no preoperative clinical differences in the two randomized groups. The surgical technique was identical with the exception of the use of the bovine pericardial sleeves. Our results demonstrated that the pericardial sleeve group had a shorter duration of air leaks by 2.5 days and hence a shorter total hospital stay by 2.8 days. This degree of difference in air leak and hospital stay is both clinically and statistically significant. All surgeons who deal with this population of patients recognize their propensity for postoperative complications and would agree that earlier mobilization and discharge are clearly desirable goals. Unfortunately even those patients in the bovine pericardial group had a mean hospital stay of 8.6 days, which is still longer than we would prefer and suggests that further work in this area is required.

Apart from air leak, there were no other differences in the two groups with regard to postoperative complications. Specifically, the infectious complications were not apparently increased in the bovine pericardial group. No empyema developed in any patient in this study. There were no deaths in this study, probably related to both careful patient selection and a large prior experience with this operation.

In our present era no study is complete without cost information. As mentioned, the cost of bovine pericardial strips is significant, averaging \$925 (hospital charges) for a package that allows five endoscopic firings. The hospital costs are for the endoscopic 45-mm sleeves that are prepackaged as sleeves. The cost for other staple sizes are the same and hence a longer staple line may be less costly. The mean reduction in hospital stay of 2.8 days helps to offset this financial cost. The average hospital

charge in the nonbovine patients for their last 3 days in the hospital was \$2,099 (range, \$1,454 to \$2,988) and the mean hospital charge per patient for the bovine pericardial sleeves was \$2,677 (range, \$925 to \$4,200). This would suggest that the bovine pericardial sleeve group still incurred an increase in hospital charge of \$578 per patient in spite of an almost 3-day reduction in total hospital stay. Comparison of the actual hospital charges demonstrated that the mean total charge for the bovine pericardial group was \$22,108 (range, \$15,817 to \$32,856) compared with \$22,060 (range, \$11,777 to \$43,789) for the group not receiving any pericardial buttress strips.

This study was a prospective analysis addressing the impact of pericardial sleeves when LVR operation is undertaken in a "closed" or thoracoscopic fashion. Although it is likely that these results are also indicative of results when LVR is performed in an "open" fashion, it is possible that there are unique factors involved in the thoracoscopic technique that would alter these results. Trauma attributable to tissue handling may differ between the open and closed procedures and there are some minor differences in the types of stapling devices used.

In conclusion, the use of bovine pericardial sleeves is effective in reducing the duration of postoperative air leaks after thoracoscopic unilateral LVR operation. In spite of the reduction in hospital stay the total hospital

charges were comparable. The mean hospital stay even with these buttressing sleeves was 8.6 days, clearly leaving room for future improvement. We would currently recommend the routine use of bovine pericardial sleeves in LVR operation because of the marked improvement in air leak duration and hospital stay.

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DISCUSSION

DR DANIEL L. MILLER (Louisville, KY): Doctor Hazelrigg, I enjoyed your presentation. At the University of Louisville we have used bovine pericardial strips through the open technique for all 115 patients and we have seen a dramatic reduction in the cost of the procedure. We used to do multiple wedge excisions using a median of 18 firings per case with the 75 stapler. Now we are using between six and eight firings per procedure, and we have decreased our cost. With regard to this study, during the course of the evolution of technique, did you look at the difference in the number of firings as you went from multiple wedges to single wedges?

DR HAZELRIGG: No, we did not look at that. I would agree with you in general that I think we have had a general decrease in the amount of staples that we have used. We have moved from originally doing multiple wedge resections to more of a larger single or a couple areas that have been resected, but I do not know the data for this group.

DR JOSEPH B. ZWISCHENBERGER (Galveston, TX): Doctor Hazelrigg, that was an excellent study. Because of the critical nature of determining when the air leak was stopped, how did you control that observation for bias? Were the caregivers blinded as to which group these patients were in, or did you have a standard protocol that determined when you removed the chest tube? And the second question is, was this study company supported?

DR HAZELRIGG: We have a standardized approach, because we have had a large experience in this lung volume reduction group. We have a team that has included the resident on the thoracic service as well as a physician's assistant and nurse practitioners that make rounds twice a day. Air leaks are determined by this group as a team. In general, we pull chest tubes 24 hours after the last detected air leak. Therefore, in this study it was done the same way. The group was not blinded as to the patient's group.

DR LEWIS WETSTEIN (Freehold, NJ): This is a very nice study. It is nice to have confirmation for what most of us thought; regardless, however, this persists to be a vexing problem. Do you feel there is any role for some sort of pleurodesis at the end of the procedure?

DR HAZELRIGG: We believe that a mechanical or chemical pleurodesis does hasten the duration of postoperative air leak but at present we do not have data to substantiate this statement. We avoid pleural procedures when lung transplantation is a possibility in the future.

DR WETSTEIN: Specifically I was interested in whether you have ever used talc. In these situations we have been extremely successful with both insufflated talc and talc slurry.

DR MILLER: Doctor Hazelrigg, was this study sponsored by Biovascular, Inc?

DR HAZELRIGG: This study was not company supported but rather supported by an institutional research grant.