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Presidi Ospedalieri: - Molinette, Dermatologico S. Lazzaro, S. Giovanni Antica Sede - centr.: tel. +39.0116331633 - www.sangiovannibattista.gov.it
- Centro Traumatologico Ortopedico, Istituto Chirurgico Ortopedico Regina Maria Adelaide - centr.: tel. +39.0116933111 - www.cto.to.it
- Infantile Regina Margherita, Ostetrico Ginecologico S. Anna - centr.: tel. +39.0113134444 - www.olirmsantanna.piemonte.it

New hemostatic agent in General Thoracic Surgery

REDUCTION IN PLEURAL EFFUSION PRODUCTION AFTER LOBECTOMY AND SISTEMATIC LYMPHADENECTOMY FOR PRIMARY LUNG CANCER, USING A NEW HEMOSTATIC AGENT (SEALFOAM[®]): PRELIMINARY RESULTS

**Pier Luigi FILOSSO, MD; Enrico RUFFINI, MD; Roberto GIOBBE, MD;
Francesco GUERRERA, MD e Alberto OLIARO, MD**

**University of Torino Italy Department of Thoracic Surgery
Via Genova, 3 10126 Torino, Italy**

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*Corresponding Author:
Pier Luigi Filosso, MD
University of Torino, Italy
Department of Thoracic Surgery San Giovanni Battista Hospital
Via Genova,3 10126 Torino Italy
Tel: +39 011-6705387
Fax: +39 011-6705365
E-mail: pierluigi.filosso@unito.it*

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INTRODUCTION

Postoperative fluid overproduction and prolonged air leaks after resection of a primary lung cancer is one of the most common complications in General Thoracic Surgery (1,3). Air leaks and chest drainage are the major variables influencing duration of hospital stay and overall postoperative costs.

Several techniques and devices have been designed and clinically verified to try to reduce air leaks; very few are dedicated to the problem of continued fluid leak.

There is a paucity of literature concerning the optimal time to remove a chest tube on the basis of the amount of pleural drainage. Patient discharge is frequently delayed because the last chest tube is not removed since the drainage is "too high" to allow safe removal.

In particular, systematic hilar and mediastinal lymphadenectomy strongly impacts on prolonged chest tube stay, since chest drainage removal is usually done when fluid production is no more than 150/200 ml/per day. Despite fast track surgery protocols have been elaborated and clinically validated with the last chest tube removed when the nonchylous effluent was 450 mL/day or less (4,5), few studies were published concerning the use of devices able to reduce the maximal daily pleural drainage.

The aim of this study is to compare the results in term of pleural drainage using a new agent (SealFoam[®]) with hemostatic properties following systematic hilar and mediastinal lymphadenectomy (see Figure 1) after lung cancer resection.

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MATERIAL AND METHODS

A randomized clinical trial for the postoperative fluid production evaluation after an anatomic pulmonary resection (lobectomy) with systematic lymphadenectomy, amongst patients operated for primary lung cancer, was performed at our Institution, between January and June 2013.

Preoperative diagnostic workup included: chest X-ray; thoracic, upper abdomen CT scan, complete respiratory function tests, bronchoscopy, electrocardiogram and echocardiogram. Patients with radiological severe emphysema and clinical severe Chronic Obstructive Pulmonary Disease (COPD) were excluded from the study, as well as those in whom a chronic steroid use was evident. Patients with prolonged air leaks (>5 days) or those in which an incomplete lung expansion was postoperatively detected at the chest X-ray were also excluded. All surgical procedures were done through a posterolateral or anterolateral thoracotomy (according to the tumor location and surgeon's preference).

Intraoperative air leaks were managed simply by putting sutures into the parenchymal breaches: sealants or glues have never been used in this group of patients.

Lymphadenectomy was always performed according to the European Society of Thoracic Surgeons (ESTS) guidelines for the intraoperative lymph node staging (6): in particular, all the mediastinal tissue containing the lymph nodes were dissected and removed systematically within anatomical landmarks. Beside the mediastinal nodes, the hilar and the intrapulmonary lymph nodes were dissected as well (Fig. 1).

To avoid bleeding and/or lymphatic effusion after lymphadenectomy, accurate coagulation and titanium metal clips placement were the routine procedures. The patients were divided in 2 groups: 1) those receiving Tabotamp[®] (Ethicon Sarl, Neuchatel, Switzerland) placement, and 2) those in which SealFoam[®] was used (Fig. 2).

At the end of the operation a large bore chest drain (28 Ch) was placed and left under suction (-20 cm H₂O), connected to a collection system (Drentech[®] Compact, Redax Poggio Rusco Mantova, Italy). Pleural drainage was assessed twice/day during the morning and afternoon round, by direct visualization of the collection system; data were reentered in an *ad hoc* designed database.

According to our Institution clinical practice, chest drain was removed when no air leak was detected and when the overall pleural fluid amount was not higher than 180 ml/24 hours.

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RESULTS

Twenty consecutive patients (12 female, 60%) were enrolled and randomized for this study. All patients had a preoperative diagnosis of primary lung cancer (14 Adenocarcinoma, 4 Squamous Cell Carcinoma and 2 Large Cell Carcinoma), achieved by bronchoscopy or Fine Needle Aspiration Biopsy (FNAB).

No patient had postoperative pneumonia, lung atelectasis, pneumothorax sputum retention, chylothorax, or atrial fibrillation.

By randomization, 10 patients received treatment 1, and 10 treatment 2. There were no problems concerning Tabotamp[®] or Seal Foam[®] placement, and no patient experienced adverse effects caused by the devices.

For this study, we focused on the 1st and 2nd postoperative day fluid amount collected in the chest drain (Table 1). Figure 3 and 4 show in detail the comparison between the 2 groups of patients the trend in daily fluid production.

The limited number of cases detracted a statistical significance achievement: anyway a clear trend towards a reduction in fluid production in both 2 days was evident in those patients in which SealFoam[®] was used. This strongly influenced the chest drain duration as well as the overall hospitalization length.

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DISCUSSION

We reported the preliminary results of a clinical study conducted in our Institution concerning the possible reduction in pleural fluid production after lobectomy and systematic lymphadenectomy for primary lung cancer. A comparison between two techniques has been done: the clipping/coagulation plus Tabotamp[®] and the clipping/coagulation plus SealFoam[®]. This new haemostatic agent demonstrated its effectiveness also in case of systematic lymphadenectomy, in which the risk of fluid overproduction is higher than in sampling procedure.

A prolonged chest drainage means a longer chest tube duration, as well as an increase in hospitalization length and costs.

An easy placement was experienced when SealFoam[®] was used: in particular the sponge was perfectly adapted to the surfaces on which it was positioned, making its use very simple and easy (Fig. 2).

SealFoam is a novel hemostat with characteristics we have not seen before, it's obvious propensity for adhesiveness and it's absorptive abilities make it versatile as a hemostat to stop mild bleeding to a post surgical sponge that absorbs excess fluid a benefit I describe in this article.

The fact that it is made of plant polysaccharide or modified starch polymers makes this a product we feel is safe to use as well as ECO friendly since it resorbs and is eliminated from the body through the patients amylase phase in a few days, other products such as Oxidized cellulose or thrombin/collagen type products take weeks to resorb thus having their own inherent risks associated with foreign pathogens that stay in the body for excess lengths of time.

On the basis of these preliminary results we recommend the clinical use of SealFoam[®] whenever an extended lymphadenectomy should be performed. Future clinical studies are requested to confirm these data, and to explore other possible fields of application.

The ability to save money on the reduction of medical interventions saves this hospital money, again a great benefit to our surgical department at a time where money all over Italy and Europe is in short supply.

Dott. Pier Luigi Filosso





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- Centro Traumatologico Ortopedico, Istituto Chirurgico Ortopedico Regina Maria Adelaide - centr.: tel. +39.011.6933111 - www.cto.to.it
- Infantile Regina Margherita, Ostetrico Ginecologico S. Anna - centr.: tel. +39.011.3134444 - www.oirmsantanna.piemonte.it

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FIGURES and TABLES

Figure 1: An example of lymphadenectomy: the right parathacheal area

Figure 2: SealFoam: correct placing during lymphadenectomy

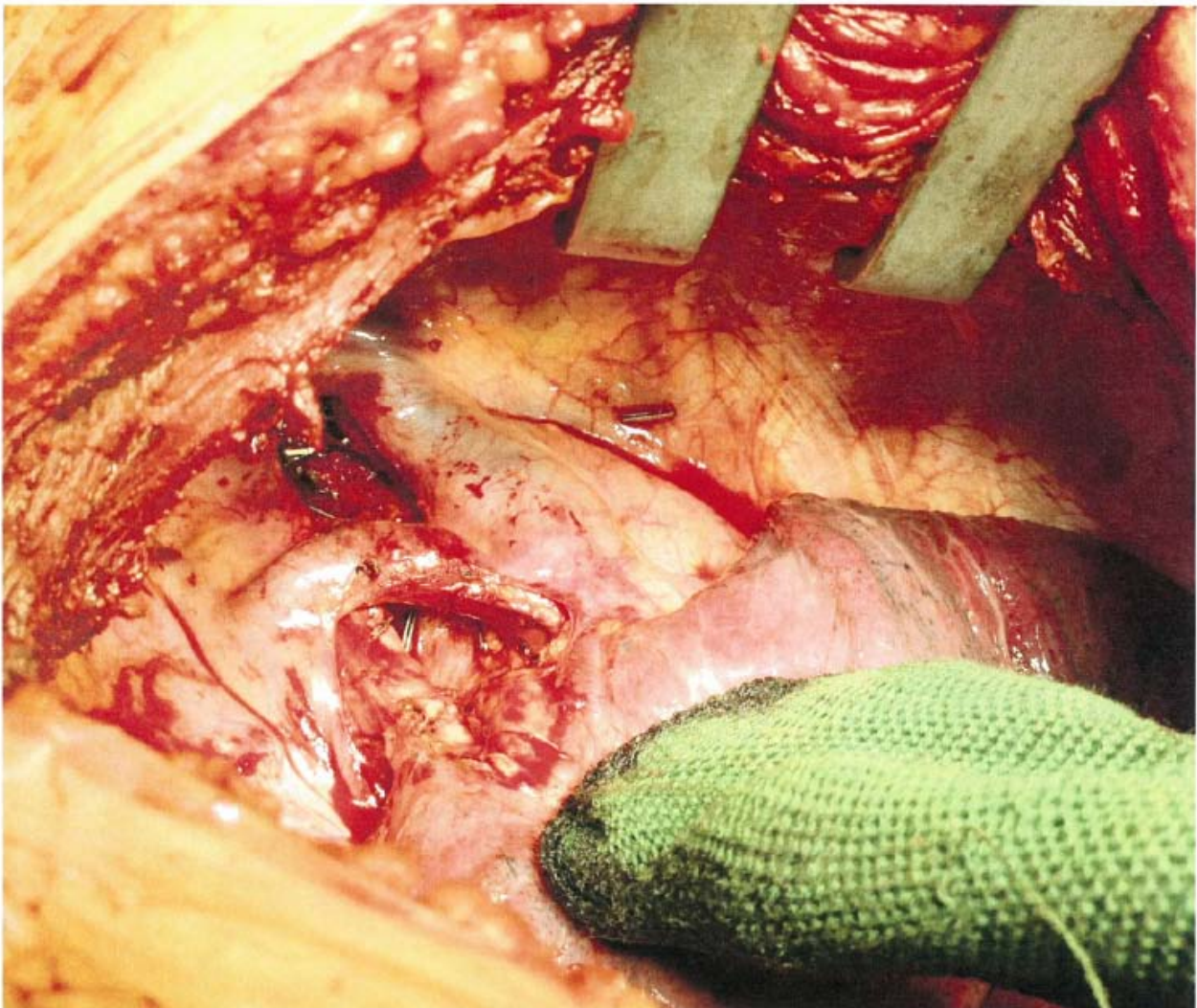
Figure 3: trend in 1st postoperative day pleural drainage

Figure 4: trend in 2nd postoperative day pleural drainage

Table 1: trend in postoperative drainage between the 2 groups

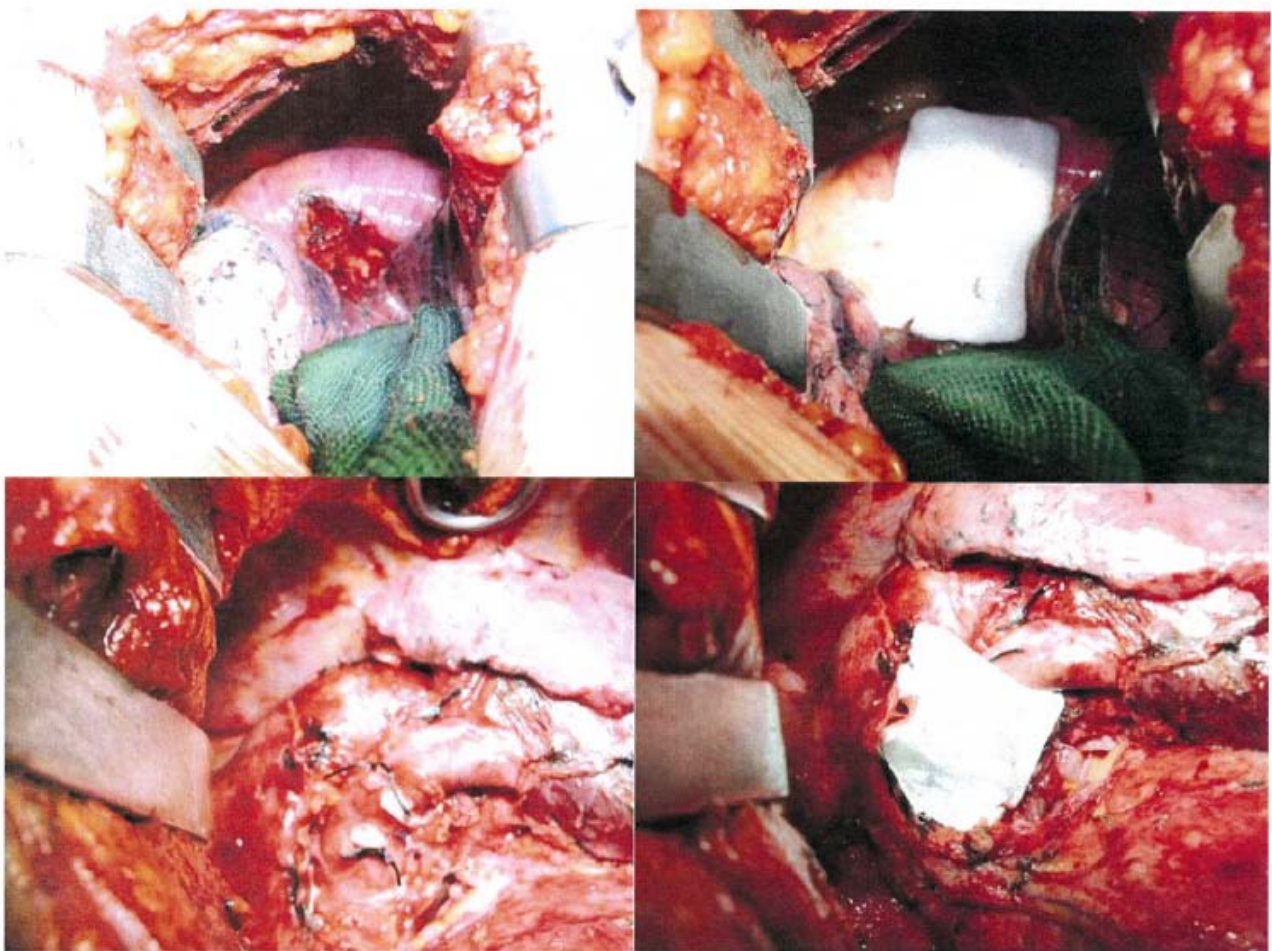
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Figure 1: An example of lymphadenectomy: the right paratracheal area



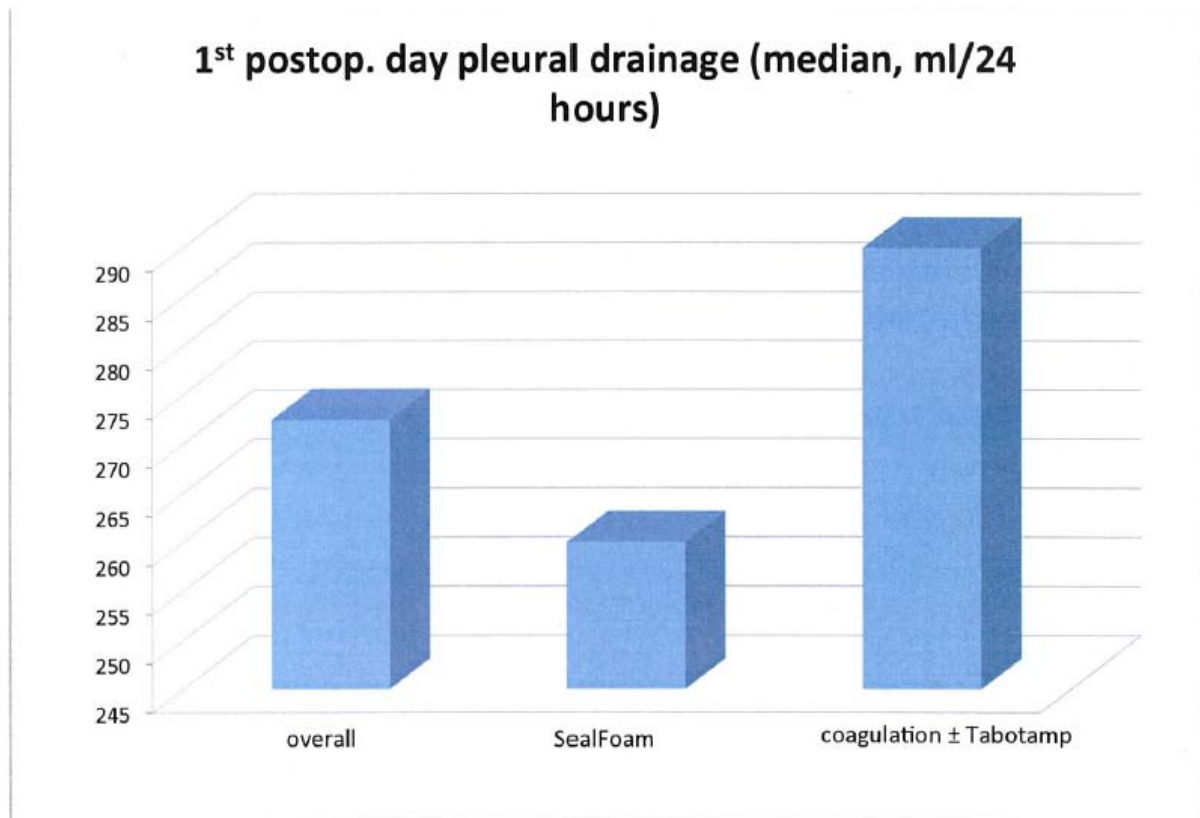
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Figure 2: SealFoam: correct placing during lymphadenectomy



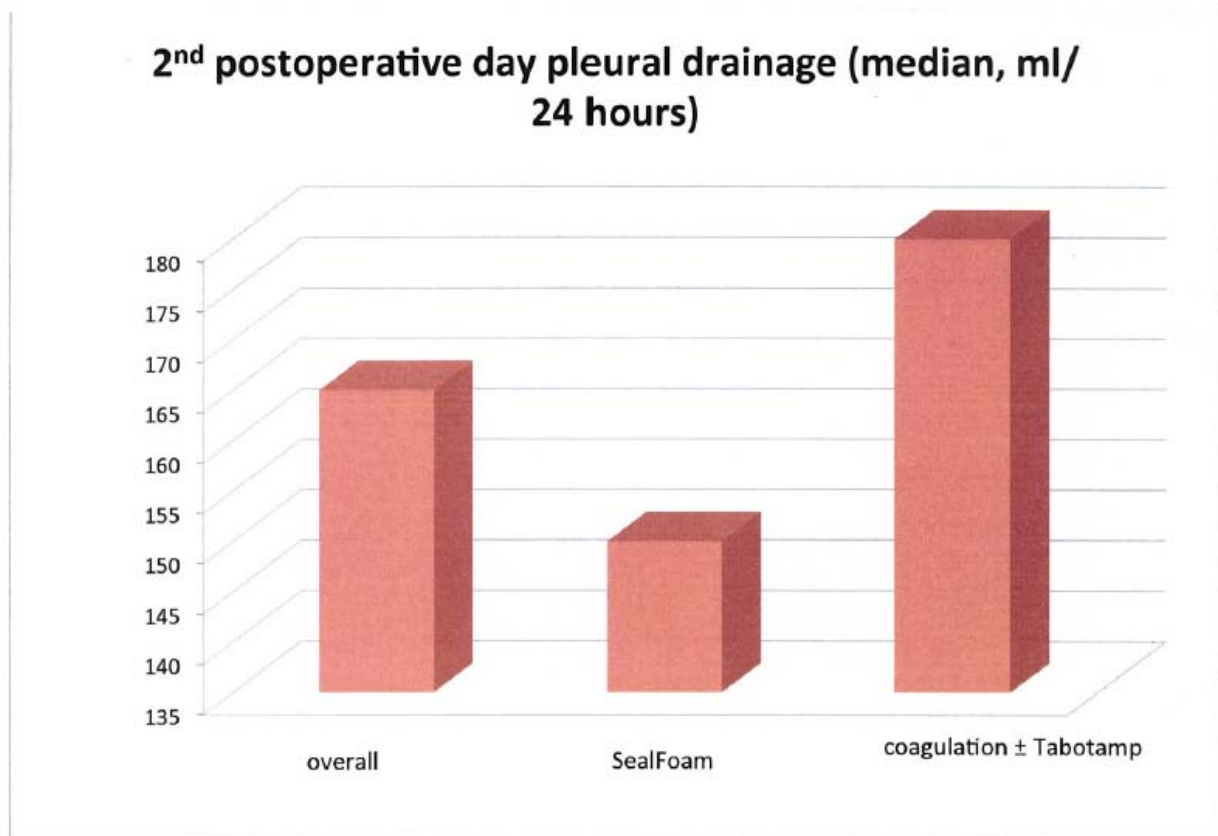
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Figure 3: trend in 1st postoperative day pleural drainage



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Figure 4: trend in 2nd postoperative day pleural drainage





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Table 1: trend in postoperative drainage between the 2 groups

	MEDIAN	MAX	MIN	P	95% CI	RR
1° postop day						
<i>SealFoam</i>	260	330	200	.19	0.7-5.19	2.0
<i>coag±Tabotamp</i>	290	330	230			
2° postop day						
<i>SealFoam</i>	150	200	110	.08	0.9-4.54	2.0
<i>coag±Tabotamp</i>	180	220	150			



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Dott. Pier Luigi Filosso