An Economic Evaluation of Fibrin Sealants Used During Incisional Hernia With Dermolipectomy Procedures in Spain

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ABSTRACT

Purpose. Fibrin sealants (FS) are used during surgical procedures to achieve hemostasis, to seal, and to adhere tissues or implants to tissue. Because of added costs FS are not used in every procedure that could benefit. This study compared the average costs of incisional hernia procedures with and without use of FS.

Methods. Spanish cost data were applied to results from a prospective, randomized controlled trial of sixty patients undergoing incisional hernia with dermolipectomy treated with FS or no FS (controls). Data obtained from the clinical study included: Use of FS, prophylactic antibiotics and antithrombotics, duration of hospital stay, postoperative morbidity, need for blood transfusions and hernia recurrence. The study compared the average cost per surgery in both groups, the incremental cost for FS and the average costs for treatment of adverse events (AE) attributed to the surgery.

Results. Based on reported resource use the average costs per incisional hernia case were calculated as €7,284 and €12,744 for surgeries with and without FS use, respectively. The major cost driver was differences in hospitalization length of stay between the treatment arms. A sensitivity analysis that excluded hospitalization costs still found FS to be cost-saving. Significant differences in hematoma rates and blood transfusions increased the average costs per surgery by €1.77 and €43.20 in the control group, respectively. The cost of FS represented 2.5% of total costs in the active treatment arm (€179 per surgery).

Conclusions. The results suggest the costs of FS in incisional hernia may be offset by reduced ancillary surgical costs and shorter hospitalization periods. Future prospective randomized studies collecting more detailed resource use data are necessary to validate these findings.

INTRODUCTION

- Fibrin sealants have been used as an addition to (or substitute) for sutures/staples in aesthetic, reconstructive, burn, ophthalmology, and gastrointestinal surgery.
- Persistence of dead spaces within the muscle layer encourages fluid collection, which in turn causes hematomas, seromas, and abscesses in up to 23% of cases; therefore, any procedure that prevents dead spaces would partially eliminate these complications.[1]
- A supporting body of evidence has shown the value for fibrin sealants in ventral and inguinal hernia repair.[1-23]
- For example, Olmi et al. have demonstrated TISSEEL to be associated with a reduction in costs associated with staple fixation and shorter hospital length of stay when applied laparascopically in ventral hernia repair.[2]
- A prospective randomized study with cost benefit analysis by Fernandez-Lobato et al. was conducted to evaluate the clinical and economic advantages of using fibrin glue (TISSEEL) in incisional hernia repair with associated dermolipectomy.
- The results of this study demonstrated TISSEEL to improve the results of surgical repair of large abdominal incisional hernias repaired by mesh placement and dermolipectomy with reduction in global morbidity and hospital stay.
- In the spirit of improving hospital efficiency, it is important to have a comprehensive understanding of the cost implications of utilizing TISSEEL in this surgical setting so as to inform hospital decision-makers of the overall costs and benefits to their health system.

OBJECTIVE

- Our objective was to perform a budget impact assessment of incisional hernia repair with or without TISSEEL based on a prospective, randomized, controlled study performed by Fernando-Lobato et al.

METHODS

- Comparator Groups: Fibrin Sealant (TISSEEL) N = 30 and No Fibrin Sealant N = 30
- Budget Impact Model
- Hospital Perspective
- Data obtained from clinical study
  - Use of Fibrin Sealant
  - Antibiotic prophylaxis
  - Seroma
  - Hematoma
  - Need for Blood Transfusion
  - Ambulatory Wound Care
  - Hernia recurrence
  - Average Hospital Stay
- Spanish costs based on patient discharge records was collected to populate the model.
- Outcomes Measured:
  - Average Cost per Surgery Case
    - Incremental Cost for Fibrin Sealant
    - Average Costs for Treatment of Adverse Events (AE) attributed to surgery
- Time Horizon: Hospital Discharge

RESULTS

- The data obtained from the prospective, randomized clinical trial by Fernandez-Lobato et al. is described in Table 1.
- The estimated cost per case for using TISSEEL versus no TISSEEL is demonstrated in Table 2.
- The average cost per case using TISSEEL was €7383 versus €12,745 thereby demonstrating an average of €5462 cost-savings by using TISSEEL on every case (Figure 1).
- The main cost-driver for this savings is in the cost of hospital stay (€6895.38 TISSEEL versus €12,236.87 no TISSEEL).
- Significant differences in hematoma rates and blood transfusions increased the average costs per surgery by €1.77 and €43.20 in the control group, respectively.
- The cost of FS represented 2.5% of total costs in the active treatment arm (€179 per surgery).

Table 1: Baseline Inputs (Rates)

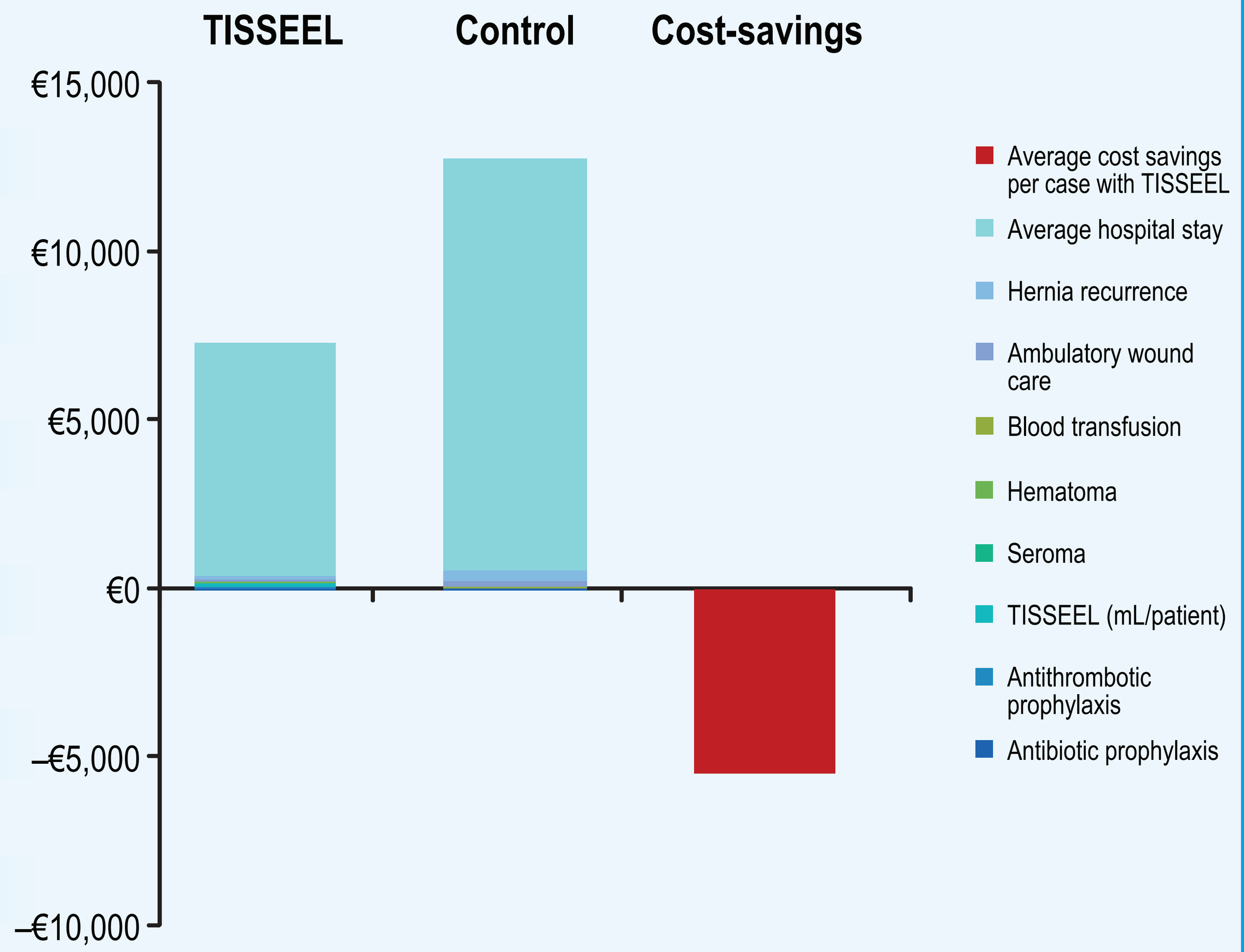
	TISSEEL (rate)	NO TISSEEL (rate)	Notes
Number of patients per group	30	30	
Antibiotic prophylaxis	1	1	Cephalosporin, for 24–48 hours
Antithrombotic prophylaxis	1	1	Enoxaparin
TISSEEL (2 mL/patient)	1	0	Applied over subcutaneous tissue and muscle (Average 1.9 mL/patient)
Seroma	0.1	0.067	Clear fluid vesicles developing
Hematoma	0.067	0.200	
Blood Transfusion	0	0.133	Average 2.7 units/patient
Ambulatory Wound Care	0.067	0.233	Assume average 2 months for all cases
Average Hospital Stay	7.1	12.6	
Hernia Recurrence	0.033	0.067	

Table 2: Baseline Inputs (Spanish Costs)

Health Resource Item	Unit Cost (€)	Avg. Units	Cost (€)	Notes
Antibiotic Prophylaxis	0.60	3	1.80	cephalosporin 24–48 hours post-op
Antithrombotic Prophylaxis	2.62	7	18.34	enoxaparin 20–40 mg/day for 7 days
TISSEEL 5 mL	457.35	1	457.35	
TISSEEL 2 mL	179.58	1	179.58	
Seroma (Total Cost)			16.98	
Nurse Time	21.96	0.5	10.98	
Syringe Costs	6.00	1	6.00	
Hematoma (Total Cost)	13.31		13.31	
Nurse Time	21.96	0.3	7.31	
Syringe Costs	6.00	1	6.00	
Blood Transfusion	120.00	2.7	324.00	
Ambulatory Wound Care	12.00	56 days	672.00	Based on 2 mos follow up wound care
Hospital Stay without Complications			971.18	
Hospital Stay with Complications			1203.04	
Hernia Recurrence			4250.00	

Figure 1: Cost Per Patient Per Hernia Procedure for TISSEEL and Non-TISSEEL (Control) Treated During Incisional Hernia Repair

	Average costs TISSEEL	Average costs Control
Antibiotic prophylaxis	€1.80	€1.80
Antithrombotic prophylaxis	€18.34	€18.34
TISSEEL (mL/patient)	€179.58	€0.00
Seroma	€1.70	€1.14
Hematoma	€0.89	€2.66
Blood transfusion	€0.00	€43.09
Ambulatory wound care	€45.02	€156.58
Hernia recurrence	€140.25	€284.75
Average hospital stay	€6,895.38	€12,236.87
Average cost savings per case with TISSEEL		
Average cost per case	**€7,283**	**€12,745**



DISCUSSION

- Hematomas secondary to detachment of the superficial layers are common in incisional hernia repair with rates up to 18–23%, depending on the study.[1]
- The development of hematomas or seromas delays adhesion of the mesh to the tissues may lead to rejection.[1]
- The use of TISSEEL in hernia repair compared with standard methods of fixation has been demonstrated in open and laparoscopic procedures:
  - Less Pain[1,4,5,9-11,15,19]
  - Enhances wound healing[19,21]
  - Fewer healing complications
  - Shorter hospital stays[1,2,5,8,9,15,19]
  - Better quality of life[2,6,8,12,13-15]
  - Lower cost[1,5,9,12,14,15,19,21]
  - Lower hernia recurrence rate[1,4,9,11,22]
  - Lower frequency of seroma/hematoma[1,2,8,9,11,19,21]
- The cost-savings demonstrated in this model is based on outcomes from one randomized controlled trial in ventral, open hernia repairs.

DISCUSSION (Continued)

- The health resource savings is largely due to the reduction in hospital length of stay.
- Limitations of this analysis:
  - Cost analysis applied retrospectively to a randomized controlled study in Spain may not reflect all costs accurately.
  - More research must be conducted to understand whether the cost advantages associated with utilization of TISSEEL are due to the product itself or to other external factors that may be influencing the difference.
- 80% of the patients in the TISSEEL group were discharged from the hospital without any complications compared with only 54% of the patients in the group without TISSEEL. This analysis has not taken into account the costs of these complications experienced by the patients after discharge.
- Additional observational studies are needed to validate these findings in a real-world US hospital setting.

CONCLUSION

- This budget impact assessment illustrates potential cost-savings of TISSEEL in the prevention of seromas and hematomas in incisional hernia repair with associated dermolipectomy.

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DISCLOSURE

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

- Rosa Fernández-Lobato, MD – Paid consultant for Baxter
- Maurice Bagot D'Arc, MD – Employee of Baxter
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