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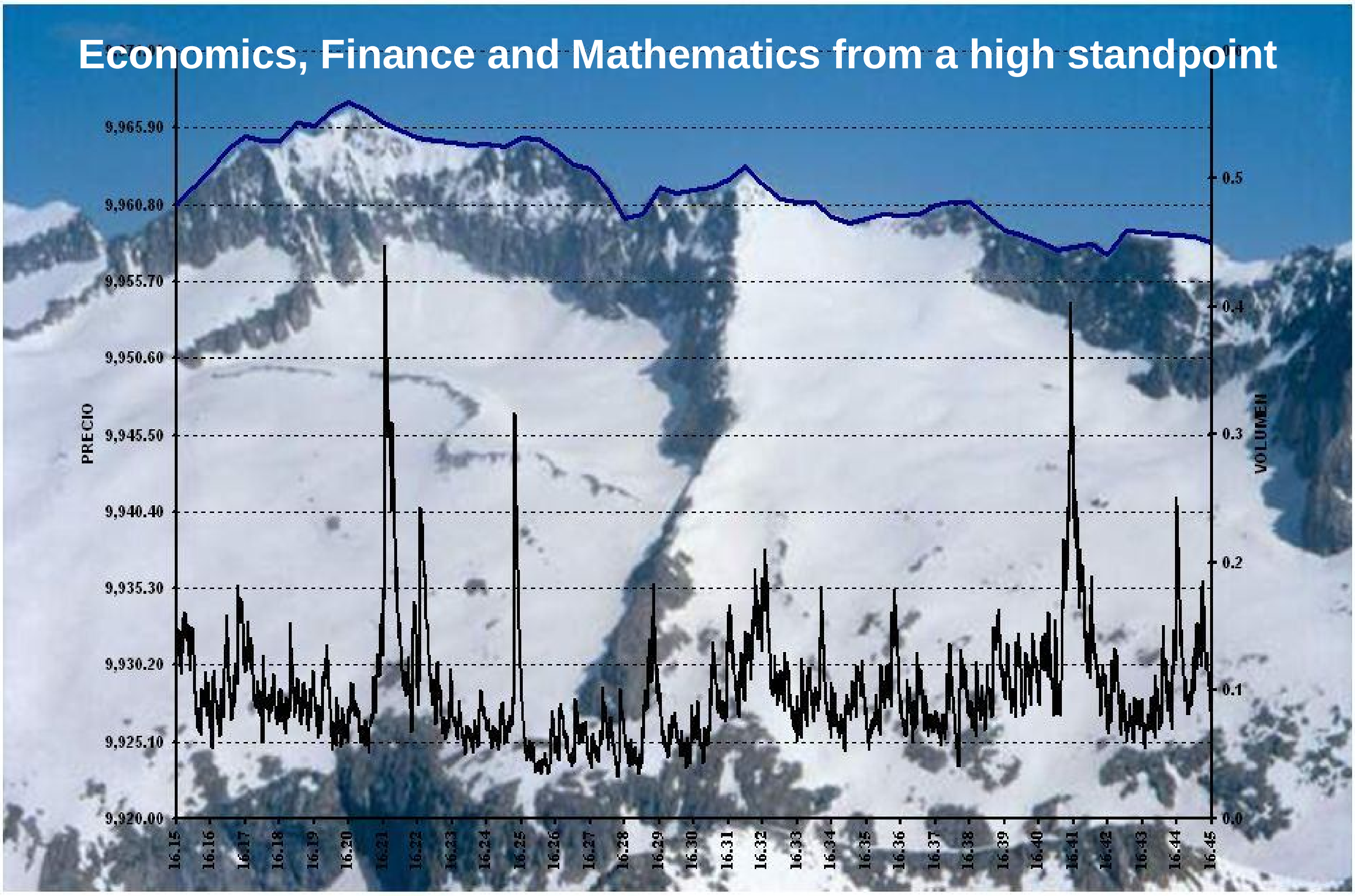

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TITLE

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Key words: Cost-effectiveness. Hernia. Local anesthesia and sedation. Spinal anesthesia. Regional anesthesia. General anesthesia.

Abstract: Primary abdominal hernia is a highly prevalent condition that weighs heavily on human and financial health-care resources (e.g., 1.12% of the total budget of Hospital Virgen de la Luz in 2008). Tension-free hernioplasty is the standard repair procedure, but the anesthetic technique varies, including local anesthesia with sedation (Lsed), regional (Reg), and general (Gen) anesthesia. As the cost-outcome relation of different anesthetic options has never been rigorously examined in our health district, we proposed to identify the most cost-effective anesthetic technique out of three options for primary abdominal hernia repair in terms of clinical outcome and health-care economics. The study sample of 400 patients with primary abdominal hernia in 2008 underwent tension-free hernioplasty using one of three anesthetic techniques: 74 Lsed, 283 Reg, and 43 Gen. The comparability of outcomes was ensured by dividing the sample into homogeneous groups according to the American Society of Anesthesiologists Physical Status classification (ASA 1 and 2) and adjusting for technical complexity, risk factors, and anatomic location. The clinical outcome of hernioplasty with Lsed was significantly better in terms of shorter hospital stay, lower early and intermediate-term complication rate, and shorter time to recovery after discharge. The short-term recurrence rate did not differ between groups. The mean cost per hernioplasty procedure was € 3,270.37 (Lsed), € 4,740.37 (Reg), and € 7,318.44 (Gen). The cost-effectiveness and incremental cost per patient showed the advantage of hernioplasty with Lsed vs. Reg (€ 794.59) and Lsed vs. Gen (€ 704.01), respectively.

1. Introduction

The aim of cost-effectiveness studies is to satisfy the social need to maximize quality of life using the resources allocated. Effective health policies are needed to improve quality of life and the ultimate objective is to propose cost-effective clinical decisions that optimize the efficient use of public resources. As resources are scarce and rarely enough to satisfy the real health needs and expectations of the community, the best possible results in terms of efficiency and perceived quality must be achieved.

Primary abdominal wall hernia, particularly of the inguinofemoral region, is one of the most prevalent surgical pathologies in the health district of a level II provincial hospital in the Community of Castile-La Mancha (Spain). Primary abdominal wall hernia is responsible for numerous cases on surgical waiting lists and originates many lost workdays among patients of active working age. The annual cost of care for hernial pathology places a heavy burden on public hospital budgets (hernia care consumes 1.12% of the annual budget of Hospital Virgen de la Luz of Cuenca, Castile-La Mancha, Spain). The conjunction of health-care needs and budget constraints has resulted in the design of more efficient and safer methods for providing health services for patients [1-3], with the primary objective of reducing the cost of inefficiency [4] and improving quality of life by reducing postoperative recovery time [5,6], recurrence rates [7,8], and delay in receiving care and resuming work and daily activities [9,7]. In this context, the present study was designed to compare differences in the cost of care for inguinal hernia using a combination of different low-invasive surgical techniques and anesthetic techniques. Objective health results were evaluated in relation to fewer complications, lower recurrence rates, and minimization of the need for postoperative informal care [8,10-13].

The primary objective of this study was to select the most efficient technique for providing the best equivalent outcome using the same amount of resources. The ultimate aim was to improve access to care for the population segment susceptible to receiving local and more personalized care using available resources.

Complementary objectives were:

- Comparison of cost margins for performing complication-free procedures using different anesthetic and surgical techniques.
- Determination of individual costs in relation to hospital structure, the care process, and patient demographic factors.

The final outcome of the study will help clinicians to select the most efficient method for primary abdominal hernia repair based on scientific evidence obtained in our activity setting and will help managers identify the most efficient methods in terms of the cost-effectiveness of health outcomes.

2. Material and Methods

2.1. Study Design, Patients and Data Compilation

The study was designed as an observational, cross-sectional, descriptive cohort study with a prospective longitudinal projection for the evaluation of intermediate-term complications. Follow-up was conducted by visits scheduled one week and two months after surgery.

A dual study of the results was made: 1) A clinical study of short-term recurrence rates, early complications in relation to the surgical and anesthetic techniques, duration of hospitalization, informal care needs after discharge, and time to recovery of daily activity. 2) A cost-effectiveness study of the study groups using direct and indirect costs. Costs were estimated in accordance with international guides [14,15].

A comparative study was made of 400 patients who underwent hernioplasty for primary abdominal wall hernia in the General Surgery Department of Hospital Virgen de la Luz, Cuenca between January and December 2008, inclusively. The patients had been diagnosed of primary abdominal wall hernia in different locations: inguinofemoral, umbilical, epigastric, and Spiegel. Less frequent anatomic locations were excluded.

All patients included in the study underwent either elective or emergency open tension-free hernioplasty, generally using polypropylene mesh attached to tissue with simple interrupted stitches of polypropylene 2/0 suture. The technique varied with hernia location and caliber, and the tension of adjacent tissues. The Lichtenstein, or Rutkow-Robbins, technique was used in femoro-inguinal hernias and subaponeurotic hernioplasty in the rest. Primary closure of the hernia by direct fascial suture was used in some cases in which there was no separation tension on the adjacent tissues. The technical complexity was similar in all cases.

The patients were divided into three groups depending on the anesthetic technique: general anesthesia, spinal anesthesia with anesthetic monitoring, and local anesthesia with superficial sedation. The choice of anesthetic method depended mainly on pre-surgery anesthetic risk factors and on the patient’s own choice.

All patients admitted and treated for primary abdominal hernia in the period from January to December 2008 were included. Patients with abdominal hernia of incisional or traumatic origin, eventration, or non-abdominal hernias were excluded from the study.

We selected 400 cases by reviewing the medical records. Data on the following study variables were compiled: age, gender, date of admission and discharge, pre-surgery risk factors (ASA [American Society of Anesthesiologists Physical Status] anesthetic risk criterion), duration of symptoms in months, type of elective or emergency surgery, type of hernia, surgical technique, anesthetic technique, duration of hospital stay, postoperative complications (urine retention, infection, bruising, post-epidural puncture headache, treatment with platelet aggregation inhibitors or dicumarol agents, general complications), result of outpatient review, recurrence, hospital readmission, reason for readmission, treatment, and duration of the readmission hospital stay.

The study was conducted with homogeneous cases to ensure the comparability of the results by adjusting for previous risk factors (ASA 1 and 2), which left 283 cases (out of the original 400 cases) of similar technical complexity, standardized anatomic location, and surgical technique.

The data were compiled in an Access database and exported to the SPSS version 15.0 program in Spanish for the respective statistical analysis. Since the variables were predominantly qualitative, we used the contingency table model and analysis based on Chi square and its related statistics.

2.2. Calculation of Costs

The economic study was based on the cost of complete care for each case, including direct costs for personnel, drugs, material and hospitalization, and indirect costs, such as structural costs, the patient's and relatives' travel expenses, income lost by the patient and relatives, and informal at-home care after discharge. Intangible costs for diminished quality of life were not taken into account because they were assumed to be minimal. The costs of substituting the patient during temporary sick leave were not considered (TSL).

Real costs, extracted by analyzing the Analytical Accounting of Hospital Virgen de la Luz, of the direct costs of personnel, pharmaceuticals, and supplies were used, as well as the real indirect costs of hospitalization in the general surgery ward, operating room, and surgical day hospital. The materials, instruments, and services used were listed by the surgical team of the Outpatient and Short Stay Major Surgery units of the General Surgery Department of Virgen de la Luz Hospital, Cuenca.

The travel expenses of the patient and relatives were calculated using the official rates for travel by civil servants of the Regional Executive of Castile-La Mancha. Travel expenses were adjusted for the distance isochrone between the patient's home and the hospital by highway and the time required to travel between population centers in the health district of Cuenca province. Travel time also was divided into 4 categories ranging from < 30 min to > 90 min (Fig. 1).

Loss of income by the patient during sick leave was calculated using data of the National Institute of Statistics (INE) on salaries (monthly average salary) for the autonomous community of Castile-La Mancha in 2006. Figures were corrected for 2008 by adjusting for the inflation between 2006 and 2008 according to INE statistics for Cuenca.

Finally, we calculated the costs of informal at-home care provided to the convalescent patient during the mean number of days and hours required until recovery of full independence. A personalized survey was made of a sample (n = 80) of patients during an outpatient review visit. Information was compiled on the number of hours a day and number of days during which the patient required assistance from a family member to perform personal tasks, and the person or persons who provided care. The cost of care was calculated using the caregiver's daily wage or the proportional value of the minimum wage in 2008.

The following parameters of the procedures were considered for the comparative econometric study: mean cost of procedure per unilateral or bilateral process, mean cost-effectiveness per day of hospital stay, incremental cost per new patient cared for obtained by comparing the three anesthetic procedures, incremental cost-effectiveness per stay for each unilateral or bilateral procedure, and NNT (number of cases needed to treat to achieve an additional unit of response) to obtain one new case not requiring hospital admission, for each procedure.

A similar study was made of post-discharge complications with admission or without admission; incremental cost per new patient treated comparing the three anesthetic procedures; incremental cost-effectiveness per stay for each procedure, and NNT to achieve one new case free of post-discharge complications per procedure.

The cost-effectiveness ratio was based on days of hospitalization spared with each technique. The incremental cost was the cost of achieving one more complication-free procedure using each anesthetic technique.

3. Results

The 400 cases studied were distributed by gender and physical status: 133 ASA 1 (24 women and 109 men), 149 ASA 2 (37 women and 112 men), 88 ASA 3 (16 women and 72 men), and 29 ASA 4 (8 women and 21 men). These two variables were independent and unrelated with each other according to Chi square analysis (p .049) (Table 1).

Patients were distributed by isochrones of distance from home to the hospital center: Isochrone 1: 146 cases (36.5%), Isochrone 2: 174 cases (43.5 %), Isochrone 3: 78 cases (19.5%), and Isochrone 4: 2 cases (5%) (Fig. 1).

The type of anesthesia practiced according to physical status (ASA) was general anesthesia in 43 cases, local anesthesia and sedation in 74, and spinal anesthesia in 283. Statistical analysis of the two variables (Pearson's Chi square, p .000) ruled out the independence hypothesis and confirmed the relation between them (Table 2)

The relation between type of anesthesia and procedures not requiring a hospital stay or the duration of the hospital stay was: procedure performed without a hospital stay in 63 cases (60 local + sedation, 1 general and 2 regional), with a 1-day hospital stay in 145 (9 local + sedation, 4 general, and 132 regional), a 2-day stay in 63 (4 local + sedation, 10 general, and 49 regional), and a hospital stay of 3 or more days in 129 (1 local + sedation , 28 general, and 100 regional) (Fig. 2). The relation between the type of hernia and duration of the hospital stay was similar (Fig. 3).

Complications that occurred during the hospital stay included 10 cases of acute urinary retention (2 general and 8 regional anesthesia), 12 subcutaneous superficial surgical wound infections (3 general and 9 regional), 29 hematomas (2 local + sedation, 3 general, and 24 regional), 3 episodes of transitory headache after spinal anesthesia, and 12 general complications, including agitation, disorientation, fever, arterial hypertension, acute kidney failure, intestinal occlusion, cardiac fibrillation, shock, and adynamic ileus (3 general and 9 regional anesthesia).

After hospital discharge, complications required a visit to the doctor and/or outpatient nursing in 23 cases: 2 received local anesthesia + sedation, 2 general anesthesia, and 19 regional. The most frequent complications were 10 wound infections, 9 hematomas, 1 local pain, 2 lymphatic secretion, and 1 local swelling.

Readmission was required in 4 cases for surgical wound infection, 1 with general anesthesia and 3 with regional anesthesia. All were treated by local cure.

In the economic study, the total cost of each type of anesthesia was referred to surgical procedures on unilateral hernia and bilateral hernia (Fig. 4). The total cost per procedure and total cost per condition were estimated considering the mean cost of patients from isochrone 2 treated surgically with one of the three anesthetic procedures. Isochrone 2 was the most frequent isochrone of the study and equivalent to the mean cost in the four isochrones studied. The total cost of the procedure without a hospital stay was € 196,222.59 for 60 cases of local anesthesia and sedation, € 9,480.55 € for 2 cases of regional anesthesia, and 7,318.44 € for one patient who underwent surgery with general anesthesia. Among the patients who stayed in the hospital, the largest total cost was € 1,137,690.60 for 240 cases of regional anesthesia.

The mean cost per unilateral procedure on a patient from isochrone 2 was: € 3,270.38 with local anesthesia + sedation, € 4,740.38 with regional anesthesia, and € 7,318.44 with general anesthesia (Table 3).

The mean cost-effectiveness per hospital day was: € 2,795.19 for local anesthesia + sedation, € 1,569.66 for regional anesthesia, and € 1,057.57 for general anesthesia (Table 4).

The incremental cost per patient was: general anesthesia versus local anesthesia + sedation, € 4,048.07; regional anesthesia versus local anesthesia + sedation, € 1,470.00; and general anesthesia versus regional anesthesia, €2,758.07 (Table 5).

The incremental cost-effectiveness was: general anesthesia versus local anesthesia + sedation, € 704.01; regional anesthesia versus local anesthesia + sedation, € 794.59; and general anesthesia versus regional anesthesia, € 661.04 (Table 5).

In the case of bilateral hernias, the incremental cost-effectiveness was general anesthesia versus local anesthesia + sedation, € 657.15; regional anesthesia versus local anesthesia + sedation, € 648.65; and general anesthesia versus regional anesthesia, € 661.04.

The NNT for each procedure, or probability of performing the procedure without having to hospitalize one more patient, was:

NNT (local + sedation) = 1/81.8 – 18.91 = 0.0159; NNT = 1.59%

NNT (regional)* = 1/0.7 – 99.29 = -0.01014; NNT* = -1.01%

NNT (general)* = 2.32/97.67 – 99.29 = -0.01048; NNT* = -1.05%

(* number needed to treat for one more patient to require hospitalization)

Post-discharge complications were divided into complications that required re-admission for treatment and complications treated on an outpatient basis.

The isochrone 2 cases yielded the following results:

mean cost of post-discharge outpatient treatment € 321.30 for local anesthesia + sedation, € 1,367.95 for regional anesthesia, and € 776.51 for general anesthesia;

mean cost of post-discharge hospital treatment € 0 for local anesthesia + sedation (no case), € 4,975.73 for regional anesthesia (3 cases), and € 15,089.19 for general anesthesia (1 case).

Incremental costs per patient: general versus regional anesthesia and general versus local anesthesia + sedation were nonevaluable because none of the patients who underwent hernioplasty with local anesthesia + sedation required post-discharge treatment. General anesthesia versus regional anesthesia was € 10,133.46.

Incremental cost-effectiveness: general anesthesia versus regional anesthesia, € 5,066.73.

The NNT for each procedure was calculated to assess the probability of avoiding post-discharge complications in one more patient:

NNT (local+sedation) = 1/(98.64 – 1.35) = 1.027; NNT = 1.03%

NNT (regional) = 1/(96.11 – 3.88) = 0.01084; NNT = 1.08%

NNT (general) = 1/(95.35 – 4.65) = 0.01107; NNT = 1.11%

4. Discussion

In the present context of Spanish health care, universal, public, high-quality care is a permanent goal and mainstay of the welfare state. However, if government budgets are to continue to meet the demands of universal health care, we must seriously evaluate the real needs of the population and work to improve the efficiency of the daily economic decisions made in the health-care setting [7,8,11,12,16]. The sustainability of the system and its capacity to provide satisfactory health-care solutions depends on the efficient use of available resources.

In the general surgery setting, primary abdominal wall hernia is common and consumes a large amount of resources. Moreover, unlike other conditions, it shows no sign of diminishing as overall health status improves. Consequently, it is important to find a way to efficiently treat this pathology. Controversies still exist regarding the most suitable surgical techniques for hernia repair [7,17], but consensus is growing that tension-free techniques yield better results [18-20]. With small variations, tension-free techniques produce major improvement, reducing recurrence rates and early complications, and enhancing quality of life by reducing the time to resumption of daily and work activities.

The same cannot be said of anesthetic techniques. A variety of procedures are used, including local anesthesia with superficial sedation, spinal anesthesia with monitoring, and general anesthesia with a laryngeal mask or intubation [21-26]. Generally speaking, there is no objective reason for choosing one anesthetic technique over another, particularly in the most frequent and lowest risk cases. Selection of the anesthetic technique depends more on the physician’s usual practice than on the patient’s needs; the selection does not substantially modify outcome, but may be related to the cost of the process and, especially, differences in intermediate clinical consequences, including minor complications and avoidable delays in the resolution of the case.

The study reported here aimed to identify the consequences of the use of different anesthetic techniques, calculate the total cost of the procedure by type of anesthesia, and assess the differences in cost-effectiveness relative to factors such as distance from the patient’s home to the reference hospital, or differences between cases with differences in preoperative comorbidity and risk factors in our setting in the surgical activity year 2008 [27]. The results confirmed the experience of other authors [28,29], showing that the surgical technique that best resolves the problem of primary abdominal wall hernia is tension-free repair reinforced with an inert prosthetic material according to the Lichtenstein technique, currently considered the "gold standard" of hernia surgery. The results of the study confirmed the safety of the repair; no case of short-term recurrence occurred and there were few complications during the hospital stay or post-discharge.

In our study group of 282 patients who were either healthy or had mild systemic disease (ASA 1 and ASA 2 physical status), patients undergoing hernioplasty with a local anesthetic technique and sedation required less hospitalization than patients treated with regional anesthesia or general anesthesia (Graphs 2 and 3).

The complications observed during admission and post-discharge were mild to moderate in most cases [30,31], but required either prolongation of the hospital stay or longer outpatient treatment. In some cases patients had to be readmitted. Complications and readmission were significantly more frequent in patients treated with regional anesthesia.

The time to recovery in terms of the resumption of daily activities was short, particularly in patients who underwent surgery with less invasive surgical and anesthetic techniques. The mean time to recovery, counting from hospital discharge, was 2.4 days for patients treated with local anesthesia + sedation and outpatient surgery and 3.73 days for patients who received regional anesthesia and had a short hospital stay (less than 72 h) [6,32,33]. Informal care generally was provided by the immediate family, usually caregivers (mother, wife, sisters). Patients who received regional anesthesia and were hospitalized required more care, a mean of 2.5 h per patient (37 min/patient and day) in absolute figures. In contrast, patients who received local anesthesia and were not hospitalized required 47 min (19.5 min/patient and day).

The time to occupational recovery was not a good indicator of recovery in our experience, in contrast with reports by other authors [33,34]. Generally speaking, patients had at least one month of sick leave, regardless of their personal recovery status, because this is the usual practice in primary care for patients requesting sick leave for surgery.

The comparative economic study yielded clear results on the cost effectiveness of different anesthetic techniques. Comparison of the total budget invested in each technique showed that the technique most often used was regional anesthesia, followed by local anesthesia + sedation and general anesthesia. This confirms the findings of other authors [35] and can generally be attributed to the technical ease of operating without having to be concerned about applying a local anesthetic to the surgical field.

The mean cost per procedure with local anesthesia + sedation was lower than with regional or general anesthesia, mainly due to eliminating the expense of a hospital stay as the procedure produced fewer complications during admission and post-discharge. In contrast, the cost per day of stay was lower in patients who underwent general and regional anesthesia, due to the larger number of hospital days.

The incremental cost per patient and the incremental cost-effectiveness in the comparison of techniques showed an advantage for local anesthesia + sedation compared to regional anesthesia and general anesthesia due to a lower cost of care, fewer complications, and shorter hospital stays.

The cost of complications during the hospital stay and after discharge demonstrated that the complications were related to regional and general anesthesia. None of the cases was attributable to local anesthesia + sedation, so cost effectiveness was compared only between regional and general anesthesia, which showed an advantage of regional anesthesia over general anesthesia.

Finally, the NNT indicator (number of cases needed to treat to obtain a certain result) showed a clear advantage for local anesthesia + sedation over regional and general anesthesia in terms of the percentage of new cases in which each technique has to be applied to avoid a hospital stay. NNT to avoid complications in one more case was similar for the three procedures, confirming the infrequency of complications with all three anesthetic techniques in patients with favorable physical status.

In conclusion, the use of local anesthesia and sedation during hernioplasty for primary abdominal wall hernias in different anatomic locations was more effective clinically, required less hospitalization, and had fewer complications and a shorter time to recovery and resumption of daily life activities. Local anesthesia + sedation also was the most cost-effective technique of those habitually used in clinical practice and is recommended as the anesthetic technique of choice for tension-free surgical repair of primary abdominal wall hernia.

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FIGURES

Figure 1. Isochrones of Cuenca province (distance between patient's home and Virgen de la Luz Hospital)

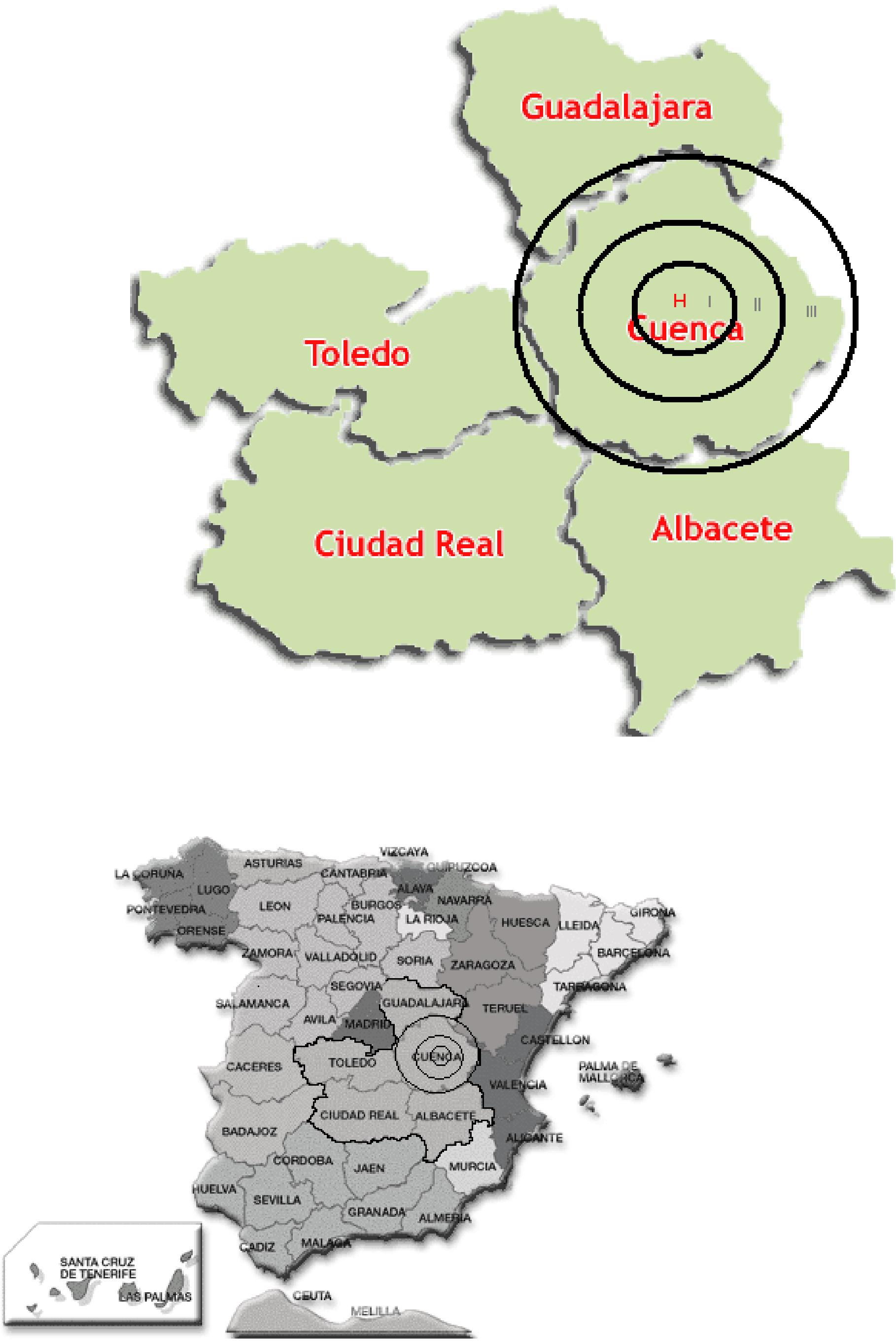

Figure 2. Box diagram of the number of days of hospitalization required for hernioplasty with different types of anesthesia

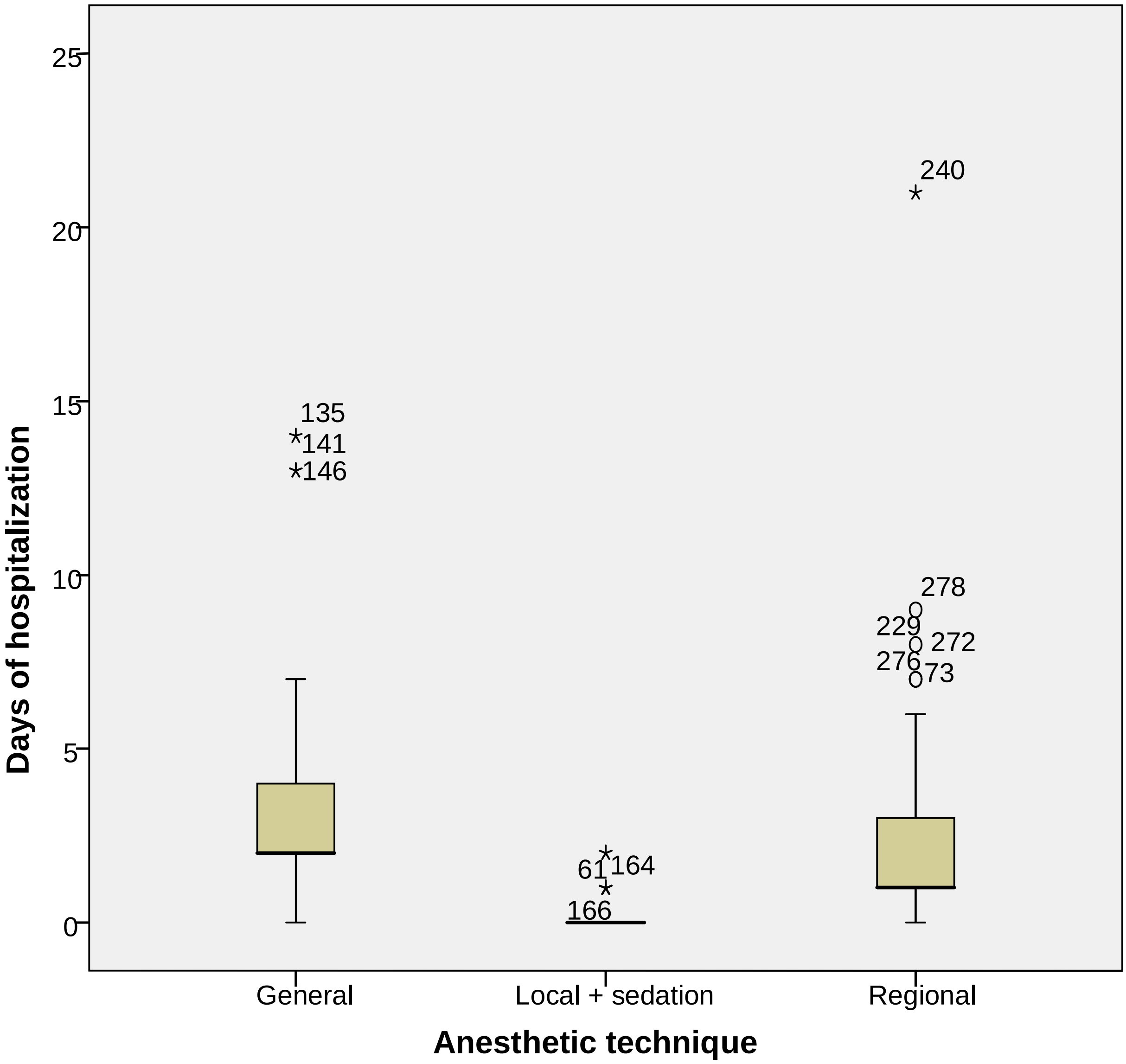

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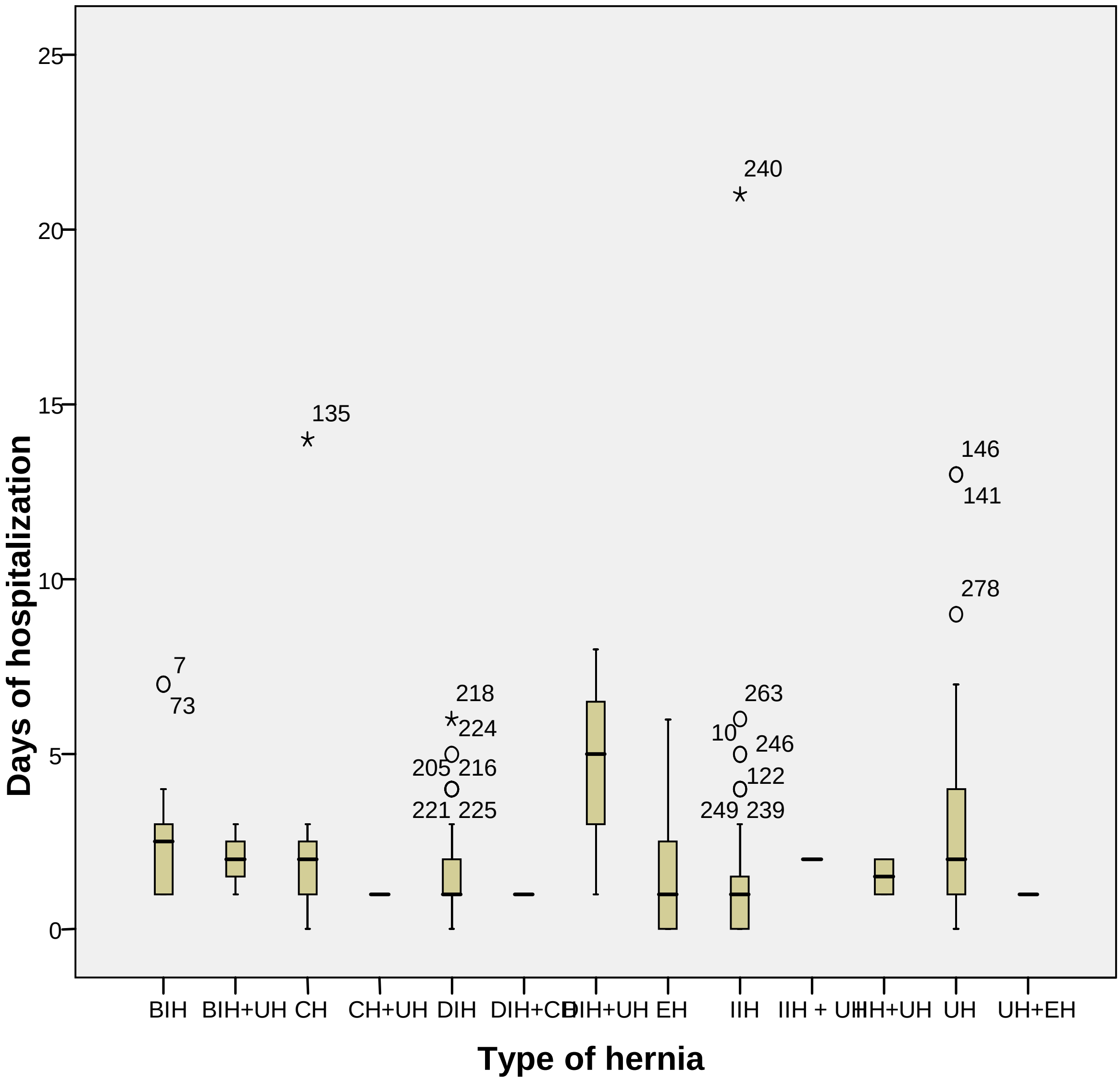
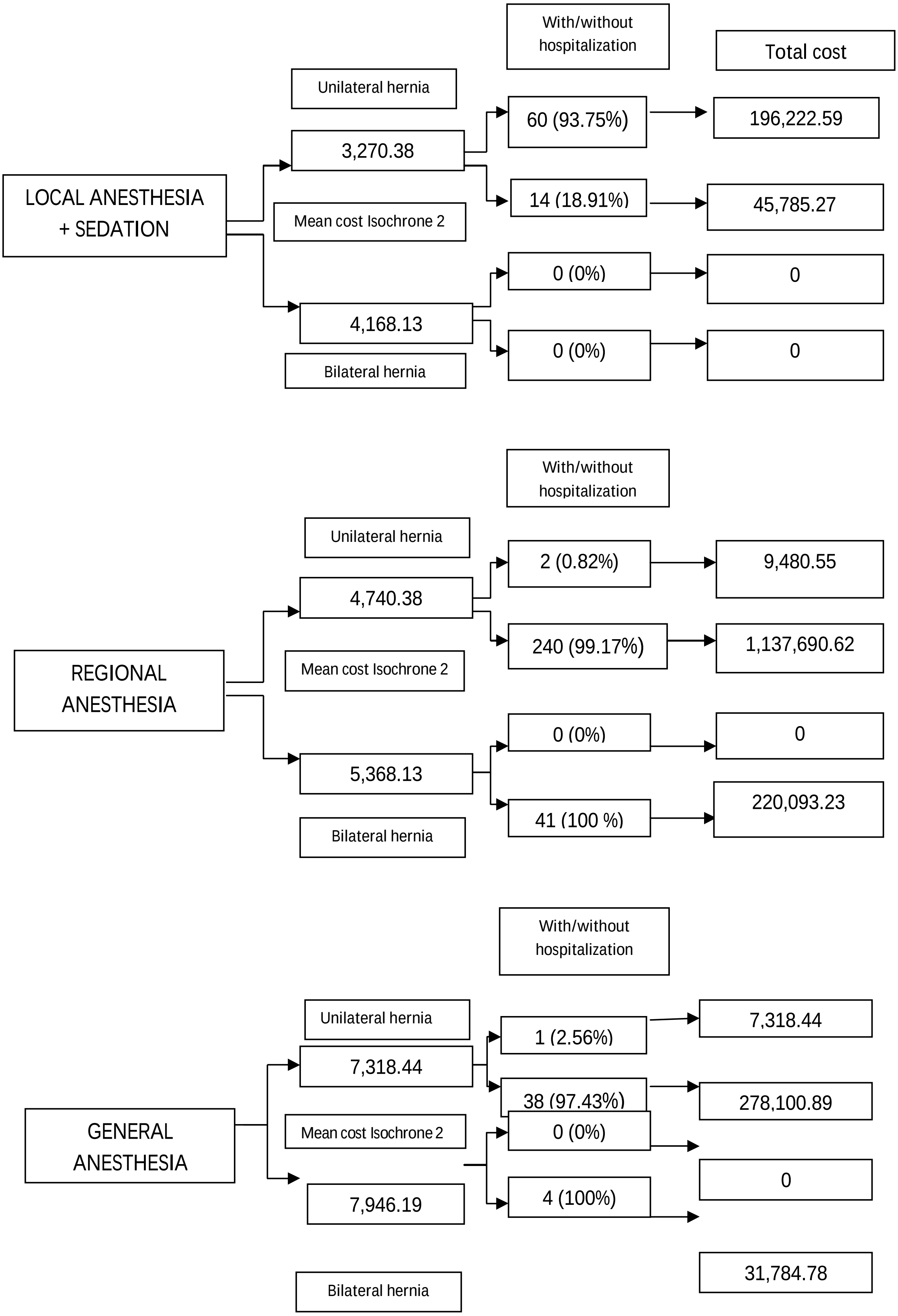
Figure 3. Box diagram of the number of days of hospitalization required for hernioplasty on different types of hernia



BIH: bilateral inguinal hernia. UH. umbilical hernia. CH: femoral hernia. DIH: direct inguinal hernia. IIH: indirect inguinal hernia. EH: epigastric hernia.

FIGURE 4. FLOW CHART OF COST-EFFECTIVENESS STUDY OF THE SURGICAL TREATMENT OF PRIMARY ABDOMINAL WALL HERNIA USING THREE DIFFERENT TYPES OF ANESTHESIA



TABLES

Table 1 Relation between gender and ASA physical status (anesthetic risk)

Contingency Table: GENDER × ASA Physical Status							
			Physical Status				**Total**
			ASA 1	**ASA 2**	**ASA 3**	**ASA 4**	**0**
GENDER	**W**	**0**	**24**	**37**	**16**	**8**	**85**
	M	**1**	**109**	**112**	**72**	**21**	**315**
Total			**133**	**149**	**88**	**29**	**400**
Pearson's Chi-square (p 0.000)							

Prepared by authors.

Table 2. Relation between ASA physical status (anesthetic risk) and anesthetic technique

Contingency Table: Type of Anesthesia × Physical Status								
		Anesthetic Risk					**Total**
		0	**Low risk**	**Medium risk**	**High risk**	**Very high risk**	**0**
Type of anesthesia	**General**	1	15	12	9	6	43
	Local + sedation	0	47	23	3	1	74
	Regional	0	71	114	76	22	283
Total		1	133	149	88	29	400
Pearson's Chi-square (p 0.000)							

Prepared by authors.

Table 3. Mean cost per patient (€) of hernioplasty (including procedure, anesthesia and other direct costs and indirect costs)

	Local + sedation (74 cases)		Regional (283 cases)		General (43 cases)	
By distance	Mean cost hernia	Mean hospital stay	Mean cost hernia	Mean hospital stay	Mean cost hernia	Mean hospital stay
Isochrone 1	**3,180.38**	1.17	**4,650.38**	3.02	**7,228.44**	6.92
Isochrone 2	**3,270.38**		**4,740.38**		**7,318.44**	
Isochrone 3	**3,360.38**		**4,830.38**		**7,408.44**	
Isochrone 4	**3,450.38**		**4,920.38**		**7,498.44**	

Table 4. Mean cost-effectiveness per day of hospitalization (€)

By distance	**Local + sedation**	**Regional**	**General**
Isochrone 1	**2,718.27**	**1,539.86**	**1,044.57**
Isochrone 2	**2,795.19**	**1,569.66**	**1,057.58**
Isochrone 3	**2,872.12**	**1,599.46**	**1,070.58**
Isochrone 4	**2,949.04**	**1,629.26**	**1,083.59**

Table 5. Incremental cost and incremental cost-effectiveness (€) of hernioplasty performed using three different anesthetic techniques

	General vs. Local + sedation	Regional vs. Local + sedation	General vs. Regional
Incremental cost	**4,048.07**	**1,470.00**	**2,578.07**
Incremental cost-effectiveness	**704.01**	**794.60**	**661.04**