

The use of Thunderbeat versus Electrosurgery in the division of the musculoaponeurotic layer of the abdominal wall during laparotomy in major hepatobiliopancreatic surgery

A randomized clinical trial

Final degree project

Hepatobiliopancreatic unit of

Hospital Universitari Doctor Josep Trueta

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Gràcies a tot l'equip de cirurgia hepatobiliopancreàtica de l'Hospital Universitari Doctor Josep Trueta, i en especial al doctor Ernesto Castro, per la gran acollida al servei aquest mesos i per ensenyar-me l'apassionant món de la cirurgia

INDEX

1. ABREVIATIONS	4
2. ABSTRACT	5
3. INTRODUCTION	6
3.1 Abdominal wall	6
3.1.1 Skin	6
3.1.2 Subcutaneous tissue	7
3.1.3 Musculoaponeurotic plane	7
3.1.4 Transversalis fascia	9
3.1.5 Pre-peritoneal adipose layer	9
3.1.6 Peritoneum	. 10
3.2 Laparotomy	. 10
3.2.1 Vertical incisions	. 11
3.2.2 Transverse and oblique incisions	. 11
3.2.3 Abdominothoracic incision	. 13
3.3 Electrosurgery	. 13
3.3.1 Principles of electricity	. 13
3.3.2 Principles of electrosurgery	. 15
3.3.3 Surgical effects of electrosurgery	. 17
3.3.4 Utilities of electrosurgery	. 18
3.4 Thunderbeat	. 19
3.4.1 Principles of ultrasonic energy	. 19
3.4.2 Principles of ultrasonic energy applied in surgery	. 19
3.3.3 Surgical effects of ultrasonic waves	. 20
3.4.4 Utilities of ultrasonic energy in surgery	. 21
3.4.5 Thunderbeat and its utilities	. 22
4. JUSTIFICATION	. 24
5. BIBLIOGRAPRHY	. 25
6. HYPOTESIS	. 29
7. OBJECTIVES	. 29
7.1 Secondary objectives:	. 29
8. METHODS	. 30
8.1 Study design	. 30
8.2 Study population	. 30

8.2.1 Inclusion criteria	30
8.2.2 Exclusion criteria	30
8.3 Sampling and sample size	30
8.3.1 Sampling	30
8.3.2 Sample size	31
8.4 Variables	31
8.4.1 Independent variable	31
8.4.2 Dependent variables	31
8.4.3 Second dependent variables	31
8.4.4 Covariables	31
8.5 Interventions	32
8.5.1 Randomization	32
8.5.2 Instrumentation	33
8.5.3 Approaches	33
8.5.4 Masking techniques	35
8.6 Data collection	36
9. STATISTICAL ANALYSIS	37
10. ETHICAL CONSIDERATIONS	38
11. STUDY LIMITATIONS	39
12. FEASIBILITY	40
13. WORK PLAN AND CHRONOGRAM	41
14. BUDGET	43
15. IMPACT ON THE NATIONAL HEALTH SYSTEM	44
16. ANNEXES	45
Information sheet for participants and Informed consent of the study (English version) \ldots .	45
Information sheet for participants and Informed consent of the study (Catalan version) ϵ	48
Information sheet for participants and Informed consent of the study (Spanish version)	51
Patient data sheet	54
ASA classification	61
GOLD/ATS-ERS spirometric classification	62
Visual analogue scale for pain (VAS score for pain)	63
Analgesic requirements regimen	63
Source of the figures	64

1. ABREVIATIONS

AC: alternating current

ASA: American Society of Anaesthesiologist

BMI: body mass index

COPD: chronic obstructive pulmonary disease

CREC: Clinical Research Ethics Committee

CRP: C reactive protein

CT: computed tomography

DC: direct current

EOM: external oblique muscle

ES: electrosurgery

HBP: hepatobiliopancreatic

IOM: internal oblique muscle

MIT: Minimal Invasive Techniques

NHS: National Health System

PDS I: Polydioxanone I

RM: rectus muscle

SD: standard deviation

TB: Thunderbeat

TM: transverse muscle

VAS: Visual Analogue Scale (for pain score)

2. ABSTRACT

Background	Although the existence, implementation and advantages of the Minimally Invasive Surgeries, some surgeries, as major hepatobiliopancreatic surgeries have to be done via laparotomy due to the complex technique, the difficulty to access to the target area and the anticipated needs. In order to access to the abdominal cavity through the abdominal wall, physicians have at their disposal many devices, such as the traditional scalpel, electrosurgery and ultrasonic scalpel. Recently, a new device, the Thunderbeat, has appeared, claiming to be safer and faster than the other devices in relation with the vessels' sealing and tissues cutting.
Objective	To decrease the dissection time needed to divide the musculoaponeurotic layer of the abdominal wall and to lower the incision blood loss in patients undergoing a major hepatobiliopancreatic surgery via laparotomy using the Thunderbeat instead of the Electrosurgery.
Design	Randomized, controlled, prospective simple-blind clinical trial design will be carried out in Hospital Universitari Doctor Josep Trueta of Girona within the Hepatobiliopancreatic unit.
Participants	Patients facing a major hepatobiliopancreatic surgery via laparotomy as a part of their treatment schedule of his/her hepatobiliary or pancreatic disease, been seen at Hospital Universitari Doctor Josep Trueta of Girona.
Keywords	Major hepatobiliopancreatic surgery; abdominal wall; incision; electrosurgery; Thunderbeat; laparotomy; musculoaponeurotic layer

3. INTRODUCTION

3.1 Abdominal wall

The abdominal wall is an area of the body that delimits the anterolateral part of the abdominal cavity, where the abdominal organs are contained. It goes from the xiphoid process and costal arch to the inguinal ligament, pubic bones and the iliac crest (1). Its functions are to protect the abdominal visceral structures, to stabilize the trunk and to aid trunk movement and posture (2).

This anatomical wall is composed by 6 layers and structures, which simultaneously have more layers and divisions. From the surface inwards, the successive layers are: skin, subcutaneous tissue, musculoaponeurotic plane, transversalis fascia, pre-peritoneal adipose layer, peritoneum (1–3).



Figure 1: Abdominal wall layers

 1)skin, 2) subcutaneous fat, 3) Scarpa's fascia, 4) external oblique muscle, 5) internal oblique muscle, 6) transverse muscle, 7) transversalis fascia, 8) pre-peritoneal adipose layer,
 9) peritoneum, 10) rectus muscle

Note: the sources of all the figures are in the ANNEX

3.1.1 Skin

The skin of the abdominal wall (Figure 1, point 1) is of average thickness, but thinner than the skin of the back, loosely attached to the underlying tissue except at the umbilical region, where is fixed. Naturally, the skin has an elastic traction lines known as Langer's lines (Figure 2). Langer's lines are topological lines of the human body that correspond to the natural orientation of the collagen fibres in the epidermis and dermis (4). Above the level of the umbilical scar, these lines runs almost horizontally, while below that level they run with a slight inferomedial obliquity (3). Nerves and vessels that supply the anterolateral abdomen go parallel to these lines (1).



Figure 2: Langer's lines

3.1.2 Subcutaneous tissue

The subcutaneous tissue, also called superficial fascia, is a movable and soft layer, and it is a rich blood supply to the anterior abdominal wall (Figure 1, points 2 and 3). It comprises two distinct layers (1–3):

- *Camper's fascia*: the outer layer of the subcutaneous tissue. It is a single variably fatty, which thickness varies depending on the nutritional status of the individual.
- *Scarpa's fascia*: is the inner layer of the subcutaneous tissue, composed by fibroeslastic fibres. Even though it runs parallel to the fat layer, it is in the lower abdomen, below the umbilical scar, when it becomes visible, more prominent and better defined.

3.1.3 Musculoaponeurotic plane

This layer is formed by four muscles, their aponeuroses and the fascial lines that the fusions of their fascial layers make (Figure 1, points 4-6 and 10). Three of these four muscles are flat, and the other is a vertical muscle. The three flat muscles are the external oblique, the internal oblique and the transversus. The vertical muscle is the rectus. There is a fifth small muscle present in the 80% of the population called pyramidalis muscle, located in the pelvic portion of the abdominal wall, which adds stabilization to the rectus muscle in this anatomic part (2).

All these muscles maintain intra-abdominal pressure and the position of the viscera. Moreover, they facilitate some physiologic functions such as parturition, vomiting, defecation, urination and coughing. They also promote expiration by depressing and compressing the lower thorax (1).

Muscles and aponeurosis:

Rectus muscle (RM): a paired longitudinal muscle on both side of the midline (Figure 3). Proximally, it attaches to the xiphoid and the costal cartilages of the fifth through the seventh ribs. Caudally, it has two tendons: a medial tendon that is joined to the pubic symphysis and a lateral tendon attached to the pubic crest. This muscle is usually interrupted by three to four transversely running tendinous intersections. Both recti muscles are separated by the linea alba, a fibrous structure running from the xiphoid to the symphysis pubis.

Unlike the flat muscles, the RM does not have an own aponeurosis. However, it has a sheath (Figure 4). This sheath consists of the aponeuroses of the external and internal oblique and transverse muscles, exhibiting two primary patterns of laminations demarcated by the arcuate line of Douglas (midpoint between the umbilicus and the



Figure 3: RM

symphysis pubis). Above this point, this sheath has two layers: the anterior layer, formed by the external oblique aponeurosis and the anterior layer of the internal oblique aponeurosis; and the posterior layer, composed by the posterior layer of the internal oblique aponeurosis and the transverse aponeurosis. Below the arcuate line, all three flat abdominal muscles' aponeurosis form one layer, going anterior of the RM (1-3,5).



- External oblique muscle (EOM): the largest, superficial and thickest of the flat abdominal wall muscles (Figure 5). Its origin are the lower eight ribs, near their costochondral junctions, and it interlocks with slips of latissimus dorsis and serratus anterior. Its fibres run downwards to insert onto the anterior half of the outer lip of the iliac crest. Medially, the muscle ends in a broad aponeurosis, running in front of the rectus abdominis muscle and interdigitates with the contralateral aponeurosis along the vertical midline. In the pelvic area, its aponeurosis folds back upon itself and forms the inguinal ligament between the anterior superior iliac spine and the pubic tubercle. This ligament marks the transition between the abdominal wall and thigh (1-3,5).
- Internal oblique muscle (IOM): the middle muscle of the flat abdominal wall muscles (Figure 6). It lies immediately deep to the external oblique. It originates from the anterior portion of iliac crest, lateral half to two-thirds of inguinal ligament. Its fibres go upwards and medially to attach along the length of the costal margin of the lower fourth ribs, running perpendicular to the external oblique muscle's fibres. These fibres become aponeurotic towards the midline, and contribute to the formation of the linea alba by joining the aponeurosis of the flat abdominal muscle of the same and opposite side. Between the umbilicus and the symphysis pubis, the internal oblique aponeurosis runs as a single layer anterior to the rectus abdominis. Superior to this point, it divides into two layers: the anterior layer, that covers the anterior surface of the rectus muscle at once with the EOM aponeurosis; and the posterior layer, that invests the posterior surface of the rectus muscle altogether with the aponeurosis of the transverse muscle (1–3,5).



Figure 5: EOM



Figure 6: IOM

Transverse muscle (TM): the deeper and thinner of the flat abdominal wall muscles (Figure 7). It assumes a nearly horizontal course deep to the IOM. It has two origins: one is from the anterior three-fourths of the iliac crest and lateral of the inguinal ligament, while the second is from the inner surface of the lower six costal cartilages, where they interdigitate with the fibres of the diaphragm. Its fibres run forwards and medially, closely applied to the inner surface of the IOM. Lateral to the edge of the rectus muscle, these fibres become aponeurotic and meet their counterpart at the linea alba. As the OIM's aponeurosis, the TM's aponeurosis runs anterior to the rectus muscle below the arcuate line. Above that, it goes with the IOM's aponeurosis, posterior to the rectus muscle (1–3,5).



Figure 7: TM

Fascial lines

- Lineal alba: is a londitudinally tendinous midline raphe that extends from the xiphoid process to the symphysis pubis and pubic crest, separating both recti muscles. It is the interdigitation of the aponeuroses of the three-py muscles of both sides. As a fibrous structure, it is almost bloodless. It is wider and thicker above the umbilical scar than below. It has a significant role in stabilizing the abdominal wall (1–3,5).
- Semilunar lines: are the lateral borders of the recti muscles. It is a curved groove that extends from the pubic tubercle to the ninth costal cartilage. It is formed by the band of aponeuroses of the flat abdominal wall muscles (1,2,5).

3.1.4 Transversalis fascia

The transversalis fascia is the anterior part of the endo-abdominal fibrous layer that envelops the peritoneum (Figure 2, point 7). It is closely applied to the deep surface of the transverse muscle except below the arcuate line, where the transverse muscle goes anterior to the rectus muscle while the transversalis fascia runs posterior to it, creating the posterior layer of the rectus sheath in this area (1,3).

In the pelvic area, where is thicker and less expansible than in the upper abdominal wall, it contains the deep inguinal ring midway between the anterior superior iliac spine and the symphysis publis (1).

3.1.5 Pre-peritoneal adipose layer

The pre-peritoneal adipose layer (Figure 2, point 8), also known as fascia propria and subserous fascia, is interposed between the transversalis fascia and the parietal peritoneum (3) in the abdomen, and between the peritoneum and the endopelvic fascia in the pelvis. It is a thin connective tissue layer, loose and fatty, especially in the lowest portion, allowing the expansion of the bladder (1).



Figure 8: 1) linea alba, 2) semilunar linea

3.1.6 Peritoneum

The peritoneum is a serous membrane, covered by a layer of mesothelium, saturated by a thin film of serous fluid (Figure 2, point 9). In general, the peritoneum consist of two layer separated by the peritoneal cavity, a virtual cavity. These two layers are the parietal peritoneum and the visceral peritoneum. The parietal layer forms the lining of the abdominal walls and the diaphragm, being its deeper layer. It is loosely attached to the abdominal wall, except in the linea alba and diaphragm, where it becomes denser and firmly adherent (1).

The visceral peritoneum invests the abdominal viscera to various degrees. When it invests an organ completely, it is considered an intraperitoneal organ (for example: spleen, stomach, liver, jejunum and ileum). On the contrary, when it only covers a part of the viscera, generally the anterior or anterolateral face, it is called a retroperitoneal organ, such as the kidney, duodenum, head and body of pancreas and abdominal aorta (1).

3.2 Laparotomy

A laparotomy is a surgical incision of the abdominal wall, made under local or general anaesthesia, with diagnostic or therapeutic purposes. Its meaning comes from the Greek word *lapara* (flank) and the Greek suffix *-tomy* (a surgical cut)(6). Therefore, laparotomy is a way to access to the abdominal cavity and its structures, making a surgical incision through the different layers of the abdominal wall.

There are several ways to go into the abdominal cavity, either to achieve a diagnosis or to perform a therapeutic act. Laparotomy, as mentioned before, is one of these ways. Laparoscopic is the other one. This technology has revolutionized the modern surgical medicine, allowing the access to certain organs and parts that, in the past, required a large incision, with its morbidities and complications (7). Hence, it is known as Minimal invasive techniques (MIT) (8).

Focusing on laparotomy, the choice to do one or another incision depends on the area that needs to be exposed, the nature of the operation (elective or emergency), anticipated needs and the surgeon's experience. It has to keep in mind that the kind of incision may have a strong influence on the occurrence of post-operative wound complications, such as wound infection, wound dehiscence, incisional hernia or pain (9).

A well-planned incision has four essentials elements (4,10) :

- Access to the target area
- Ability to extend the wound
- Preservation of functions of the abdominal wall
- Secure closure

Moreover, to re-enter into the abdominal cavity should be done through the previous laparotomy scar. This act minimizes further loss of tensile strength of the abdominal wall by avoiding the creation of additional functional defects (11).

Another important point is Langer's lines. When an incision is made in the direction of these lines, as in transverse and oblique cut, the wound will heal faster without visible scarring, with less pain and a lower analgesic use (12,13).

The incisions used to the aperture of the abdominal wall can be classified as:

- Vertical
- Transverse and oblique
- Abdominothoracic

3.2.1 Vertical incisions

Vertical incisions include the midline incision and paramedians incisions, both medial paramedian and lateral paramedian incisions (Figure 9).

 Midline incision: in the upper abdomen, it goes from the xiphoid to above the umbilicus. In the lower abdomen, it goes from below the umbilicus to the middle of hypogastric region. As the cut is made through the skin, fat, linea alba and peritoneum, it is almost bloodless, no muscle fibres are divided and no nerves are injured. Extensions can be made linking the two incisions, surrounding the umbilical scar. It provides access to the whole abdominal cavity (including retroperitoneum), and it is especially useful for emergency and exploratory surgery (9,14).



Figure 9: Vertical incisions1) midline incision,2) medial paramedian incision,3) lateral paramedian incision

• *Paramedian incision*: the incision is placed 2 cm lateral to the midline in the medial paramedian incision, and 5 cm lateral to the

middle line in the lateral paramedian incision. Skin, subcutaneous fat, muscle rectus and its sheath, and peritoneum are divided along the length of the wound.

Although these incisions are more bloody than the midline incision, their advantages are that the vertical cut to the right or left of the linea alba provides access to the lateral structures (spleen and kidney), and their closure are more secure because the rectus muscle can act as a buttress between the re-approximated posterior and anterior fascial planes (14). Nowadays, these incisions are in disuse.

3.2.2 Transverse and oblique incisions

Transverse and oblique incisions include:

 Subcostal incision: also known as Kocher incision, it is started at the midline, 2 to 5 cm below the xiphoid, and extends downwards, outwards and parallel to and about 2.5 cm below the costal margin (Figure 10, point 1) (15). When made, it cuts the skin, subcutaneous fat, rectus, internal oblique and transversus abdominis muscles and peritoneum.

On the right side, it affords excellent access to the gall bladder, biliary tract and liver. On the left side, it gives exposure to the spleen and stomach (14). As it is made following Langer's lines, its healing process will has less post-operative complications than vertical incisions.



Figure 10: Transverse and oblique incisions 1) Subcostal incision, 2) J-shape incision

• *J-shape incision*: it is a combination of a vertical and oblique incision. It is made extending a right subcostal incision at the midline to the xiphoid process (Figure 10, point 2). Skin, fat, linea alba, rectus, internal oblique and transversus abdominis muscles and peritoneum are cut in that order when the incision is performed.

It provides excellent access to the liver to perform partial hepatectomy and liver transplant (16). It is mainly used in right hepatectomies.

 Mercedes-type incision: it is a vertical and transverse combined incision. It is defined as a bilateral upper midline transverse subcostal incision with vertical extension to the xiphoid process. When performed, it cuts skin, subcutaneous tissue, linea alba, rectus, internal oblique and transverse muscles, and peritoneum (Figure 11, point 1).

It is useful to expose the upper abdominal viscera and to all the diaphragmatic hiatuses. It is used to perform partial hepatectomies, liver transplant (16) and to repair the diaphragmatic hiatuses (14).

 Extended subcostal incision: also known as Chevron incision and Roof-top incision, it is a double Kocher incision joined in the middle line of the abdomen (Figure 11, point 2). Skin, fat, linea alba, rectus, internal oblique and transverse muscles and peritoneum of both sides are cut when this incision is made. It provides excellent access to the upper abdomen. This is useful in carrying out total gastrectomy, extensive hepatic resections, liver transplantation, pancreaticoduodenectomy

surgery and operations for renovascular hypertension, among others (14,17).

McBurney incision: although its level and length may vary according to the thickness of the abdominal wall and the position of the appendix, this incision is made perpendiculary to the line and point of McBurney (Figure 12 and Figure 13, point 1). When performed, the skin, subcutaneous tissue, internal oblique muscle and peritoneum are cut, sparing the rectus and transverse abdominalis muscles.

It is an excellent choice for appendectomies. It may be used in the left lower quadrant to drainage a diverticular abscess (14).

- Lanz incision: also known as Rockey-Davis incision or Bikini incision, it is a modification of McBurney incision, making it more transversal. It has better cosmetic results (Figure 13, point 2) (14).
- Oblique muscle-cutting incision: also known as Rutherford-Morrison incision, it is an extension of McBurney incision. As its name says, it cut the skin, subcutaneous fat, internal oblique and transverse muscles, and peritoneum (Figure 13, point 3).



Figure 11: Transverse and oblique incisions1) Mercedes-type incision,2) extended subcostal incision



Figure 12: McBurney's line and point



Figure 13: Transverse and oblique incisions

1) McBurney incision, 2) Lanz incision, 3) oblique muscle-cutting incision, 4) open inguinal hernia incision, 5) Maylard incision, 6) Pfannenstiel incision It can be used for a right or left sided colonic resection, caecostomy or sigmoid colostomy (14).

- Open inguinal hernia incision: it is a transverse incision, made two fingerbreadths above the symphysis pubis, lateral to the midline, and it goes to a point about 1 cm upper to the location of the deep inguinal ring (Gregoire incision) (Figure 13, point 4). It cuts skin, subcutaneous fat and the anterior rectus sheath, locating the hernia and going around it. Depending on the situation and extension of the hernia, the incision will be made in one area or another, being the Gregoire incision the most frequent. As its name says, it is used to repair inguinal hernias (18).
- *Pfannenstiel incision:* the incision is made 5 cm above the symphysis pubis. Its length is usually 12 cm, and it cuts skin, subcutaneous tissue, superficial fascia (retracting the rectus muscles) and the peritoneum, avoiding the bladder at the lower end Figure 13, point 6).

It is frequently used by gynaecologist and urologists for its ideal access to the pelvis organs, bladder, prostate and caesarean. As its exposure is limited, it may be used in elective surgeries (19,20). Also, it is very useful in MIT to extract the surgical piece.

Maylard incision: it is performed parallel and above the placement of Pfannenstiel incision. It cuts skin, subcutaneous fat, rectus, external and internal oblique and transverse muscles, and peritoneum, with a length of 18 cm (Figure 13, point 5). It offers a better exposure and access to the pelvic organs than Pfannenstiel incision, without any difference between their post-operative complications (14,21)

3.2.3 Abdominothoracic incision

The abdominothoracic incision converts the thoracic cavity and the abdominal cavity into one, giving and excellent exposure and access to thoracic and abdominal organs. Any of the vertical, transverse and oblique incisions can be easily extended into the right or left chest, becoming and abdominothoracic incision (14).

This incision can be useful in liver surgeries, oesophagus and proximal portion of stomach resections, among others (14).

3.3 Electrosurgery

Since Ancients times, heat has been used to control bleeding using heated rocks or metal objects. During the 1920s, the electricity began to be used in order to heat tissue and control of haemostasis via certain devices. It was on October 1st, 1926, when Dr Harvey Cushing, a neurosurgeon, used a device created by the physicist William Bovie to remove an enlarging, vascular myeloma from the head of a 64-year-old patient successfully, beginning the use of electricity in surgery. Bovie's device was an electrosurgery unit (22,23).

3.3.1 Principles of electricity

Electricity is a form of electromagnetic energy that flows between atoms (24), and electrosurgery is the use of electricity in surgery in order to achieve a specific surgical effect (25).

The basis of electrosurgery begins in physics. Current, resistance and voltage have a direct relationship (26). Current (I), so-called electrical current, is the amount of electricity moving through a conductor over a specific amount of time, and is measured in amperes. Resistant (R), expressed in ohms and also referred to as impedance, represents the property of a conductor that opposes the flow current. Resistance to current is inherent within all human tissues. Voltage (V) is the electromotive force that drives the current through the conductor, and is expressed in volts. In electrosurgery, the conductor is the patient, the resistance are the tissues; while the current and the voltage are given by the electrosurgical generator (23,24,26).

Electricity is governed by Ohm's Law:

$$Voltage(V) = Current(I) \times Resistance(R)$$

Current is directly proportional to voltage and inversely proportional to resistance. Therefore, greater resistance requires greater voltage. If resistance is a fixed variable, greater voltage will create greater current (24). As each kind of tissue (fat, muscle, viscera) has its own basic properties (water content), each one of them will have a determinate impedance (26). Hence, voltage and current will vary according the manipulated tissue and its resistance.

Moreover, there is the definition of power, closely related with the previous equation. Power (W), quantifies the rate of work being done by the electrosurgery unit, and is expressed in watts. It is expressed by the equation:

Power
$$(W) = V \times I$$
 or Power $(W) = I^2 \times R$

In order to maintain the same power through the different tissues' resistances, the electrosurgical generator has to create a greater voltage (24).

The use of the electrical current (I) created by the electrosurgical unit on a tissue during a certain time generates heat (Q, expressed in joules) (27). The transformation of electrical energy into heat (energy) occurs in accordance with Joules' Law, and can be expressed by the following formula:

$$Heat (Q) = \left(\frac{current (I)}{cross - section area}\right)^2 \times resistance (R) \times time$$

The amount of current (I) concentrated at a given point (cross-section area) is the current density. Also, it is apparent from this formula that the heat produced is inversely proportional to the surface area of the electrode. Therefore, the smaller the surface of the electrode in contact with the tissue is, the more localized heating energy is produced (23,28).

Otherwise, there are two types of electrical current: direct current (DC) and alternating current (AC). With direct current, flow is in one direction only, whereas alternating current switches flow in different directions, moving between positive and negative poles (22,24). The polarity switches in sinusoidal waveform rhythmically, and this oscillation per unit of time is the frequency, measured in hertz (Hz) (24) (Figure 14).





Figure 15: applications of different alternating current frequencies

The electricity arrives at households and plugs as alternating current (AC), and does so at 60 Hz. Below 100.000Hz, a contact with those frequencies stimulates muscles and nerves, causing tetanic skeletal muscle contraction and ventricular fibrillation, that ultimately results in death –the so-called Faradic effects (24,26,29). The Faradic effect is overcome by the use of high-frequency AC (above 100.000 Hz). This is based on Morton's observation. In 1881, Morton observed that oscillating current at a frequency of 100.000 Hz could pass through the human body without producing pain, spam, or burn. Ten years later, d'Arsonval showed that AC with a frequency greater than 10.000 Hz could elevated tissue temperature (30). All of these, coupled with Joule's Law, are the reason that modern electrosurgery units use frequency ranges of 200.000 Hz to 5.000.000 Hz (23,29).

3.3.2 Principles of electrosurgery

Electrosurgery is based on the heating effects produced by alternating current electricity on the tissue, and the rate at which tissues are heated will determined the clinical effect (23–26). Often, the term electrocautery is erroneously used as a synonym of electrosurgery. Although both devices use the electricity to achieve a clinical effect, the electric current used in electrocautery is DC. With DC, the current never leaves the instrument, heating it and burning the tissue directly. On the other hand, in electrosurgery, the current used is AC and it passes through and heats the tissue, completing an electrical circuit (22–26,30).

When an oscillating current is applied to tissue, the rapid movement of electrons through the cytoplasm of cells causes the rise of intracellular temperature. Depending of the amount of thermal energy delivered and the time rate of delivery, the observed tissue effect will vary (23,26,27):

- 34-45° C: no visible external changes are seen, but the biologic effect is inflammation and oedema. The thermal damage is reversible
- 45-50° C: cellular processes cease an enzymatic activity is inactivated, without visible external changes.
- 50-80° C: tissue's proteins become denatured, losing their structural integrity. Because of this, coagulation occurs.

- 80-100° C: cytoplasm cell's water is achieving its boiling temperature. The cell is desiccate.
- Above 100^o C: the water of the cytoplasm cell boils, causing its vaporization and destruction. Its clinical effect is the cutting.
- 200^o C: the remaining solid components of the tissue are reduced to carbon (fulguration).

Clinically, coagulation and desiccation are difficult to tell apart, so they are known as coagulation. The clinical effects of thermal damage are: coagulation, cut and fulguration (27).

Due to the electrosurgery unit, these thermal effects can be achieved. An electrosurgery unit (Figure 16) is a closed circuit composed by:

- Generator (Figure 16, point 1): it converts the input of 60 Hz of alternating current (AC) into direct current (DC) and then back to AC with a new higher frequency (between 200.000 Hz and 5.000.000 Hz) (29)
- Active electrode (Figure 16, point 2): the high frequency delivered by the generator goes to the active electrode. This is the surgical tool, the part of the electrosurgery unit that the surgeon will use to achieve the wanted thermal effect (29).



Figure 16: electrosurgery unit 1) generator, 2) active electrode, 3) passive dispersive electrode

• Passive dispersive electrode (Figure 16, point 3): also known as ground plat, is a gel pad

hooked to the patient. The electric energy that entries the patient through the active electrode goes by the tissues and bloodstream to the passive dispersive electrode(28) and return to the electrosurgery generator, completing the circuit (29).

Electrosurgeries units are complete circuits to avoid the possibility for a patient burn. In the absence of a complete circuit, the current will seek other paths to exit the body. Those paths can be an electrocardiogram pad or an intravenous pole in contact with the patient, causing the called burn. Nowadays, this is solved with the passive dispersive electrode. Moreover, if the circuit is opened, the electrosurgical generator will not produce electricity (23).

Electrosurgical generators can apply energy in either a monopolar or bipolar fashion. In monopolar electrosurgery (Figure 16) the current flows from the generator to the active electrode, through the patient, and back to the generator via the passive dispersive electrode. In bipolar electrosurgery (Figure 17), the surgical tool is a pair of forceps where one blade represents the active electrode and the other the passive electrode. Thus, the energy produced by the generator goes from the active electrode to the passive electrode through the bite of tissue between, rather than



Figure 17: bipolar electrosurgery unit

through the body, and returns to the generator. With this system, the gel pad is unnecessary (22–24,26–28).

3.3.3 Surgical effects of electrosurgery

The AC used for electrosurgery is a sinusoidal waveform, and electrosurgery units can produce a variety of wave forms changing the current and voltage in relation to time (Figure 18) (22,24).



Figure 18: waveforms produced by the electrosurgery units

An uninterrupted waveform with low voltage and a delivered current all the time is known as the pure cut mode, while an interrupted waveform with high voltage and a delivered current given only 6% of the time is the so-called pure coagulation mode. Between these two extremes there are the blends modes. There are three blend modes, depending on the time the current goes on. In blend 1, the current is on half of the time; in blend 2 it is the 40% of the time, and in blend 3 only is on the 25% of the time. All these modes allow to cut almost bloodless (22–28). The translation of all these modes to the clinical effects of thermal damage is (Figure 19):

- Cutting (Figure 19, point 1): is achieved by using any of those modes, although it is easily and safest achieved using the cut mode. Holding the electrode slightly away from the target tissue, the current density is higher (there is a small area) and, following the Joule's Law, the tissue's temperature increase rapidly, causing the vaporization of intracellular fluid and the ionization of the gas released. This ionization creates sparks, and all of these produce a clean incision (22–28).
- Coagulation (Figure 19, point 3): it is achieved with any selected waveform, although the best is the coagulation mode. As the electrode touches the tissue surface (a larger area), the current density



Figure 19: clinical effects of thermal damage: 1) cutting, 2) fulguration, 3) coagulation

decrease. Consequently, the tissue is heated more slowly without reaching the boiling point, causing the coagulation (22–28).

• Fulguration (Figure 19, point 2): also known as superficial coagulation or spray coagulation, is achieved with the coagulation mode and holding the electrode slightly away of the tissue. As the coagulation mode use an interrupted waveform, the sparks generated strikes the tissue surface in a widely dispersed and random fashion, creating a zone of superficial coagulation for fast control of bleeding capillary beds or venous bleeding (22–28).

3.3.4 Utilities of electrosurgery

Electrosurgery is undoubtedly some of the most useful and most-often used tools at the surgeon's disposal (23). In the last thirty and forty years, it has been published some articles comparing the use of the traditional scalpel with the electrosurgery. In some reports, the comparison was made to known which of these two surgical tools had the fewer intra and post-operative complication during laparotomy.

Kearns and company published in 2001 a randomized clinical trial comparing these surgical tools during laparotomy, showing that electrosurgery has significant advantages over scalpel on the basis of incision time, blood loses, early post-operative pain and analgesia requirements (31).

In the same year, Franchi and co published a multicentre study and said that, in terms of wound incision complications such as wound infections and superficial wound dehiscence, there was not a statistical significance between the use of electrosurgery and traditional scalpel (32).

More recently, Shamim in 2009 (33) and Prakash and co in 2015 (34), had published a simpleblind, randomized clinical trial, getting the same conclusion as Kearns.

Moreover, Ly and colleagues wrote a systematic review and meta-analysis in 2012, concluding that although electrosurgery is quicker and associated with less blood loss than the traditional scalpel, there are no differences in the rate of wound complication or post-operative pain (35).

The same year, Charoenkwan and co published a review comparing the scalpel versus electrosurgery for abdominal incisions, coming to the conclusion that there are no significant differences between the tools on wounds complication, incision time, blood loss and post-operative pain (36).

In 2015, Aird and co conducted a randomized simple-blind trial comparing the cosmetic outcome of electrosurgery and scalpel for skin incision, saying that in despite of the less post-operative pain achieved with electrosurgery, both tools are cosmetically acceptable, without an increased risk of wound infection in neither of the two tools (37).

In conclusion, it seems that electrosurgery has some advantages over scalpel, such as less wound-time is required; there is less blood loss; and less post-operative pain and analgesia requirements. Regarding wound dehiscences, wound infections and wound hernias, there is not a significant difference between the tools.

3.4 Thunderbeat

The Thunderbeat (TB) (Olympus, Japan) is a surgery tool that integrates both bipolar energy (electricity) and ultrasonic energy. Hence, the basis to understand how TB works lies on electricity and electrosurgery, and on ultrasonic energy.

3.4.1 Principles of ultrasonic energy

There are different kinds of waves depending on the medium in which they propagate: the electromagnetic waves, such as electricity; the mechanical waves, such as sound; and the gravitational waves, related to Einstein's relativity theory. Electromagnetic waves do not require a medium in order to propagate; they can spread through the void. Mechanical waves, on the contrary, required a solid, liquid or gas medium to propagate (38).

Sound waves are a kind of longitudinal mechanical pressure waves that can be propagated in solids, liquids or gases. There is a large range of frequencies of longitudinal mechanical waves, being the audible sound waves the ones with a frequency range between 20 and 20.000 Hz. Below this audible range, waves are called infrasonic waves (earthquake waves), and above that, they are known as ultrasonic waves (39). Therefore, the name of ultrasonic energy is given due to the use of ultrasonic waves.

In 1967, Doctor Kelman began to use an ultrasonic phaco-emulsifier to treat cataracts. Since then, this kind of energy is has been used in other surgical specialities, such as to remove CNS tumours, to treat rectal cancer, or in hepatobiliopancreatic surgeries (40). The ultrasonic energy used in surgery has a frequency between 22.000 Hz and 55.500 Hz (39–42).

Ultrasonic surgery is based on the cavitation effect. This effect was first described in 1894 by the British navy. Sir John I. Thornycroft and Sydney W. Barnaby noticed a severe vibration coming from the propeller of the destroyer (ship). They suggested that the source of the vibrations were large bubbles (or cavities) formed by the turning propeller that imploded due to the pressure of the water. Henceforth this effect was known as cavitation. Some years later, in 1917, the navy commissioned Lord Rayleigh to study that effect. He confirmed that the vibration were due to the enormous turbulence, heat and pressure of imploding cavities (bubbles formed in the water) (38).

3.4.2 Principles of ultrasonic energy applied in surgery

In tissues, cavitation is the major factor leading to the cell disruption. In ultrasonic surgery, the ultrasonic waves form bubbles (cavities) in the water content of the cell. Then, these cavities collapse violently inwards, increasing the pressure inside the cell and generating intense heat that raises the temperature of the liquid surrounding the bubbles, boiling it. Thus, the denaturation of proteins and the destruction of the cell it is produced (38–41).

The ultrasonic waves are produced by applying electrical energy to either a piezoelectric or magnetic transducer. With this, the electrical energy is transformed to a mechanical wave of the same frequency, and the tissue can be cut or coagulated. In order to do these clinical effects, there are two kinds of ultrasonic surgical technologies: the ultrasonic cavitational aspirator and the ultrasonically activated scalpel (41).

Ultrasonic cavitational aspirator: is composed of a generator, a handpiece and a functional tip (Figure 20). The generator provides electrical energy to the handpiece, where it is converted to an ultrasonic energy due to a transducer. The ultrasonic energy is conducted via a hollow tube to a tapered hollow tip. This tip has two functions: vibration and aspiration. When the tip vibrates at 23.500-25.000 Hz, the destruction of the cells is caused thanks to the cavitation effect; and the aspiration aspirates the resulting cell debris (41).



Figure 20: ultrasonic cavitational aspirator

In order to work, this device requires a circuit around it filled with saline. This irrigation cools the entire handpiece and provides a medium for the emulsification of the disrupted tissue, helping the aspiration of the cell derbis (40).

The ultrasonic cavitational aspirator is tissue selective because it preferencially breaks cell with a high water content such as adipose tissue. Thus, collagen-rich tissues as nerves or endothelial cells are preserved, having poor coagulation ability. These properties make this device useful in neurosurgery, liver surgery and tumour debulking (41).

• Ultrasonic activated scalpel: is composed of a power supply generator, a handpiece with a transducer and a functional tip (Figure 21). The generator produces electrical energy that goes to the handpiece, where is transformed to ultrasonic energy of the same frequency (23.500-55.500 Hz). These

vibratory waves are conducted to the



Figure 21: ultrasonic activated scalpel

functional tip. This tip can be a scissor blade or a hook blade, allowing to cut and coagulate the tissue (41,42).

As the blade of the scalpel vibrates, the tissue is denaturised by the breaking hydrogen bonds caused by the cavitation effect. This leads to the formation of a sticky coagulum that seals vessels up to 5 mm in diameter. Then, the tissue is cut by the sharp edges of the blade (39,41,42).

The ultrasonic activated scalpel can cut high-protein-density and collagen-rich tissues, such as muscle, peritoneum and fibrous connective tissue; and low-density tissues such as fat and parenchyma. Therefore, it can be used to seal vessels up to 5 mm and cut muscles (42).

3.3.3 Surgical effects of ultrasonic waves

The application of ultrasonic waves on a biological tissue has clinically effects. In this case, these effects are coagulation and cutting (39–41):

• *Coagulation*: the mechanical waves produced by the device are transferred to the tissue due to the tip of the scalpel (Figure 22). The friction produced by these waves is sufficient to break tertiary hydrogens bonds and to heat the intracellular water, denaturing the proteins, leading to the formation of a coagulum.

Thus, ultrasonic devices can coagulated and seal vessels between 3 mm and 5 mm safely (39–41).

• *Cutting*: due to the cavitation effect produced by the ultrasonic waves, bubbles are created in the intracellular water. With the continuous input of mechanical waves and

Blades vibrates 55,500 Hz Blade motion couples with tissue protein Protein hydrogen bonds break & protein disorganizes Protein coagulum seals small coapted vessels Vibrating protein produces secondary heat



Figure 22: coagulation

the implosion of these bubbles, the cell water achieves its boiling point, vaporizing it and resulting in the destruction of the cell. With this, and the sharp edges of the blade, the ultrasonic device cuts tissues (39–41).

3.4.4 Utilities of ultrasonic energy in surgery

Since the introduction of ultrasonic energy in surgery, there has been made multiples articles comparing ultrasonic energy with electrosurgery, both monopolar and bipolar, especially in laparoscopic procedures.

In 2005, Deo and co published a randomized clinical trial comparing the use of harmonic scalpel (ultrasonic energy) and the use of electrosurgery for a pectoralis major myocutaneous flap dissection, and they came to the conclusion that it was feasible to do that surgery using the harmonic scalpel with less operative time, blood loos, drainage volume and morbidity than with electrosurgery (43).

That year, Morino and co published a study comparing the use of ultrasonic and electric dissection in laparoscopic colorectal surgery. In their conclusions, they commented that the ultrasonic device had less intraoperative blood loss than electrosurgery, and that the former was an excellent option to perform those surgeries (44).

In 2008, Pellegrino and company wrote an article comparing the harmonic scalpel and electrosurgery in the treatment of vulvar cancer. They concluded the study saying that the use of harmonic scalpel in that surgery had several advantages, such as decreased operative time and blood loss, without significant differences in postoperative complication (45).

That year, Hubner and colleagues printed a randomized study comparing the use of monopolar electrosurgery, bipolar electrosurgery and ultrasonic device in laparoscopic colorectal surgery with the objective to define which one was better regarding dissection time, blood loss, safety and cost. The results showed that bipolar electrosurgery and the ultrasonic device had less dissection time than monopolar electrosurgery, being equally cost-effective(46).

In 2010, Litta and co published a randomized controlled study comparing harmonic scalpel versus electrosurgery in laparoscopic myomectomy. They concluded that, in those surgeries, the harmonic scalpel was associated with low operative time, low intraoperative blood loss, and low postoperative pain (47).

In conclusion, it seems that ultrasonic devices have less operative time and less blood loss than electrosurgery in general in laparoscopic and laparotomy surgeries, but more trials are required to achieve a conclusion. Regarding post-operative pain and other complications, there is non-consensus.

3.4.5 Thunderbeat and its utilities

TB is a new device created by Olympus in 2012 with the ability to rapidly cut tissue with ultrasonic energy and the ability to create reliable vessels seals with bipolar energy (Figure 23)



Figure 23: energies used in TB

It is composed by an energy platform, a handpiece and a scissor type blade:

- *Energy platform*: is a multifunctional platform that generates both electric energy and ultrasonic energy (Figure 24). Those energies go to the handpiece, where they can be used at the same time or only one (49).
- Handpiece: is a multifunctional pistol shape handpiece (Figure 25). It has two options: Seal (blue button), using only bipolar energy, and Seal & Cut (purple button), using both electric and ultrasonic energy. There are three different levels in both options: level 1, level 2 and level 3, depending on the surgery performed. In level 1 and 2 each energy wave last less than second, while in level 3 it last 1 second (48,50)
- *Blade*: is a scissor type blade (Figure 23). One edge of the blade is the active electrode of the bipolar energy, and the other is the passive electrode. At the same time, these edges vibrate, due to the ultrasonic energy (48).

As it is a device that uses two of the most available and useful energies in surgeries, it has been published some articles comparing the TB with others in order to prove its safety.



Figure 24: energy platform



Figure 25: handpiece

In 2012, Milsom and co compared the use of TB versus other devices that use electric energy or ultrasonic energy, such as Harmonic ACE (Ethicon Endo-Surgery, USA) and LigaSure V (Covidien, USA), in the safety and efficacy of sealing vessels up to 7 mm of diameter. This evaluation was done with 10 female Yorkshire pigs. The results were tat TB was faster than the other devices, having an equal degree of safety and efficacy (51).

That year, a similar article was published by Seehofer and co, comparing the safety and efficacy of TB versus Harmonic (ultrasonic energy) and LigaSure (bipolar energy) used to seal and cut 5 mm vessels in laparoscopic. As the work made by Milsom, this study was performed in pig models. The said that TB had a higher dissection speed than others devices, with the sealing efficacy of bipolar clamps (52).

In 2014, Fagotti and colleagues wrote a randomized study comparing the TB with the electrosurgery during a laparoscopic major gynaecological surgery, performed in 50 women. They concluded that TB was associated with shorter operative time and less operative pain than the electrosurgery in patients with uterine cancer (53).

In 2015, Milsom and co made a prospective trial evaluating the clinical performance of TB in laparoscopic colon surgery. That pilot study had a sample size of 30 subjects undergoing left or right laparoscopic colon resection. At the end of the study, they observed that the TB was successful to dissect tissue in less time and seal vessels safely in a laparoscopic colon surgery (54).

In conclusion, as it has been created three-four years ago, there are fewer articles and publications commenting its effectiveness, some of them using animal population. In despite of these limitations, those studies show TB can dissect tissues with less operating time and can seal vessels with, at least, the same safety as bipolar energy.

4. JUSTIFICATION

Nowadays, some major surgeries have to be done via laparotomy due to the complex technique, the difficulty to access to the point area, the visibility and the surgeons' experience doing laparoscopic surgeries. Some major hepatobiliopancreatic (HBP) surgeries are in this group.

Reviewing some literature in regard to the aperture of the abdominal wall via, we have found that transverse and oblique incisions (i.e. incisions that follow Langer's lines) will heal faster and with less visible scarring, pain and analgesia requirements (4,12,13).

Respecting the aperture of the abdominal wall in major hepatobiliopancreatic surgeries, we have also found that the best incisions to perform those surgeries are the right subcostal incision, the J-shape incision and the extended subcostal incision, allowing an excellent access to those organs but requiring larger incisions (14–17).

Moreover, with the purpose to open the abdominal wall, there are various devices that can be used. These devices are the traditional scalpel, the electrosurgery, the ultrasonic scalpels and, recently, the Thunderbeat. Some studies have been published to determinate which one of these scalpels is the safer and more effective about blood loss, incision time required, wound infections, wound dehiscences, wound hernias, post-operative pain and analgesia requirements.

On one hand, reviewing studies comparing the traditional scalpel with the electrosurgery in surgeries via laparotomy, proving that the latter requires less incision time and has less blood loss, less post-operative pain and analgesia necessities; its safer (31,33–35,37).

On the other hand, assessing published articles comparing the electrosurgery with ultrasonic devises in laparoscopic and laparotomy surgeries, it seems that the ultrasonic scalpel is safer regarding the blood loss and the operative time, but more studies are required (43–47).

Even though some studies have shown that Thunderbeat has less blood loss and less operative time than other devices, those studies have been made using animal population. Furthermore, in the studies performed in humans, none of those opened the abdominal wall using the Thunderbeat; all those results were regarding intraabdominal vessels and tissues (51–54).

Connecting all of these points, we have that some major hepatobiliopancreatic surgeries have to be done via laparotomy, and the best incisions are the right subcostal incision, the J-shape incision and the extended subcostal incision. Moreover, to open the abdominal wall, the surgeon has at his/her disposal many devices, such as the traditional scalpel, electrosurgery, ultrasonic scalpel and, more recently, the Thunderbeat. About them, electrosurgery is safer than the tradition scalpel, and both ultrasonic devices and bipolar devices seem to improve the required dissection time and to reduce the blood losses in intraabdominal surgeries. As Thunderbeat is a new, there are fewer studies about its safety and effectiveness, none of these regarding the aperture of the abdominal wall.

Thus, we want to determinate which device, whether Thunderbeat or electrosurgery, will have less intra-operation and post-operation complications in major hepatobiliopancreatic surgeries regarding the division of the musculoaponeurotic layer of the abdominal wall.

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*There are some references that do not have any webpage available. This is because those articles were provided by the University's library, the Hospital Universitari Doctor Josep Trueta's library or handed by the hepatobiliopancreatic unit.

6. HYPOTESIS

In this study, the hypothesis to be assessed is: the use of during the division of musculoaponeurotic layer in hepatectomies and pancreaticoduodenectomies via laparotomy will produce fewer intra-operative and post-operative surgical site complications.

7. OBJECTIVES

The main objective of this project is to compare the use of Thunderbeat versus the use of standard electrosurgery in the division of the musculoaponeurotic layer of the abdominal wall and observe which of these procedures will have a lower blood loss of the surgical wound and a decrease of the dissection time needed to access into the abdominal cavity.

7.1 Secondary objectives:

- To compare the pain symptomatology after the surgery
- To compare the number of infections post-surgery
- To compare the number of wounds dehiscences post-operation
- To compare the number of eviscerations through the surgery wound

8. METHODS

8.1 Study design

The study will be a randomized, controlled, prospective simple-blind clinical trial, performed in Hospital Universitari Doctor Josep Trueta.

8.2 Study population

The study population will be patients with a disease that requires a major hepatobiliopancreatic surgery (right or left partial hepatectomy, extended partial hepatectomy or cephalic pancreaticoduodenectomy) between May of 2016 and December of 2018 in Hospital Universitari Doctor Josep Trueta of Girona.

Our study will have two population of study: one group will be known as the Electrosurgery group (ES group) and the other as the Thunderbeat group (TB group).

8.2.1 Inclusion criteria

- Patients with a confirmed diagnosis of resectable hepatobiliary or pancreatic disease due to medical imaging technique
- Patients with ASA II-III (ANNEX)
- Patients who have read, understood and have signed the Informed consent of the surgery
- Patients who have read the Information sheet for participants and have signed the Informed consent of the study (ANNEX)
- Patients aged 18 or older

8.2.2 Exclusion criteria

- Indication of laparoscopic surgery
- Patients with BMI <20 or BMI >40
- Patients with an hereditary coagulopathies
- Patients in treatment with simtrom with an INR > 3 in the last 3 months or/and a platelet count <50,000/mm³
- Patients with chronic obstructive pulmonary disease (COPD) grade III-IV on the GOLD/ATS-ERS spirometric classification (ANNEX)
- Pregnancy

8.3 Sampling and sample size

8.3.1 Sampling

A non-probabilistic consecutive sampling will be performed in this study. All patients aged 18 or older with a resectable hepatobiliopancreatic illness seeing by the Hepatobiliopancreatic unit of Hospital Universitari Doctor Josep Trueta that fulfil the inclusion criteria will be offered to participate in this study.

8.3.2 Sample size

We used the GRANMO application in order to obtain the sample size.

Due to reviewing some literature and based on the clinical experience of hepatobiliopancreatic surgeons of Hospital Josep Trueta, we estimate that the common standard deviation of the time required to open the abdominal wall will be of 192 seconds. So, accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, we need 52 subjects in the Electrosurgery group and 52 in the Thunderbeat to recognize as statistically significant a difference greater than or equal to 119 seconds. We have anticipated that the rate of follow up loses will be 20%.

The incidence of hepatectomies in Hospital Universitari Doctor Josep Trueta is around of 60 per year, of which half of them are performed via laparotomy. Acknowledging this, along with the incidence of pancreaticoduodenectomies is 20 per year, we will need 2 years and a half to reach the 104 participants to confirm or refuse our hypothesis.

8.4 Variables

8.4.1 Independent variable: it will be the use of **Thunderbeat** or **Electrosurgery** during the division of the musculoaponeurotic layer of the abdominal wall in a major laparotomy surgery.

As they are nominal qualitative variables, they will be expressed in percentages

8.4.2 Dependent variables: they will be the **blood loss** (millilitre) per centimetre of incision with the scalpel and the **dissection time** (seconds) per centimetre required to divide the musculoaponeurotic layer.

As they are continuous quantitative variables, they will be expressed in medians

8.4.3 Second dependent variables

All the secondary dependent variables will be related to the post-operative time, considering the post-operative time the period following the surgical operation between the first day post-surgery and 1 year after the surgery.

- *Pain:* it is a continuous quantitative variable. It will be assessed by the Visual Analogue Score (VAS) for pain.
- *Infection:* it is a dichotomous nominal qualitative variable. It will be assessed by yes or not
- *Wound dehiscence*: it is a dichotomous nominal qualitative variable. It will be assessed by yes or not
- *Evisceration:* it is a dichotomous nominal qualitative variable. It will be assessed by yes or not

8.4.4 Covariables

- *Age:* it is a discrete quantitative variable. It will be expressed in years
- *Sex:* it is a dichotomous nominal qualitative variable. It will be assessed by male or female
- *Height:* it is a continuous quantitative variable. It will be expressed in meters (m)
- Weight: it is a continuous quantitative variable. It will be expressed in kilograms (kg)

- *BMI (Body mass index):* it is a continuous quantitative variable. It will be expressed in kg/m²
- *Wound length:* it is continuous quantitative variable. It will be measured in centimetres (cm)
- *Comorbidities:* they are nominals qualitative variables. They will be expressed according their diagnosis
- *Previous abdominal laparotomies surgeries*: it is a dichotomous nominal qualitative variable. It will assessed by yes or not
 - *Previous surgical incision*: it is a nominal qualitative variable. It will be defined according to the kind of incision made.
 - *Previous surgery*: it is a nominal qualitative variable. It will be defined depending on the kind of surgery made.
- *Diagnosis imaging*: it is a nominal qualitative variable. It will be defined according to their imaging features and their suggested diagnosis
- Anatomopathological examination of the piece: it is a nominal qualitative variable. It will be expressed depending on the results of the anatomopathology of the surgical piece and it will define the final diagnosis
- *Major complications of the surgery*: they are nominals qualitative variables. They will be expressed in accordance with their diagnosis
- *Re-intervention:* it is a dichotomous nominal qualitative variable. It will be assessed by yes or not

8.5 Interventions

8.5.1 Randomization

All patients aged 18 or older with a resectable hepatobiliopancreatic illness of the region of Girona seeing by the Hepatobiliopancreatic unit of Hospital Universitari Doctor Josep Trueta that fulfil the inclusion criteria, who are been well informed by the surgeon, have read the Information sheet and have signed the Informed consent, will be eligible for this study.

At the same time the patient is included in the study, we will have to assign him or her to one of the groups randomly in order to avoid a selection bias. As our sample system is consecutive, we will not know all the patients of the study before starting it. Because of that, the used randomization system does not need to know the entire sample before randomizing it. It will be done using a covariate adaptive randomization where a new patient is sequentially assigned to a particular treatment group by taking into account the previous assignments of participants.

Randomization will be done by a statistical specialist using the software SPSS. Doing this, the surgeon will not have access to the randomization sequence, and he or she will know which intervention has to execute by receiving a closed envelope the same day of the intervention.

As the hepatobiliopancreatic unit of Hospital Universitari Doctor Josep Trueta is formed by 6 surgeons, the main surgeon will be also randomized in each intervention in order to decrease inter-surgeon variation.

8.5.2 Instrumentation

In both groups, we will use:

- ES: a monopolar ES device will be used to open the skin and the subcutaneous tissue.
- *Gauzes:* will be used to control the haemostasis and to quantify the blood loss while dividing the musculoaponeurotic layer of the abdominal wall.
- *Chronometer*: will be used to quantify the dissection time required to divide the musculoaponeurotic layer of the abdominal wall.
- Aquamantys: a bipolar electrosurgery device will be used to control the haemostasis.
- *Surgical silk*: will be used to measure the wound length.
- *Meter*: will be used to measure the surgical silk with the same wound length.
- *Polydioxanone I (PDS I):* will be used to close the muscle-aponeurotic plane.
- *Skin staples*: will be used to close the skin of the surgical incision.

8.5.3 Approaches

As explained before, this study will divide the participant population in two groups: the ES group and the TB group.

1st visit

Once the patient clinical situation have been exposed both in the Hepatobiliopancreatic unit committee and the Digestive Tumour Committee of Hospital Universitari Doctor Josep Trueta and a consensus has been achieved about the best treatment of the patient illness, which include a major hepatobiliopancreatic surgery, the surgical team will make an appointment with him or she. In this appointment, the surgeon will explain to the patient the treatment regimen of his/her illness, its surgical approach and complications, and he/she will resolve all the patient doubts. Moreover, if the patient is suitable to be included in our study, the surgeon will inform him/her about the study and will propose him/her to participate in it. After that, the Informed consent of the surgery, the Information sheet for participants and the Informed consent of the study will be given, advising to read all these papers and remarking that all the doubts and concerns that he or she could have the following days will be resolved in the next appointment. At the same time the next appointment is made, the surgeon will make an appointment with anaesthesiology.

Anaesthesiology visit

In this visit, the anaesthesiologist will classified the patient into the different stages of ASA classification. Furthermore, the physician will make a reservation in the blood bank for the day of the surgery with the consent of the patient.

2nd visit

After the appointment with anaesthesiology and with a new computed tomography (CT) made, patient and surgeon will meet again. In this second visit, the patient will bring the Informed consent of the surgery and the Informed consent of the study signed. The surgeon will explain in more detail the surgical approach, which incision they will make to access the target area and some hygienic advices.

Intervention day

The patient will be admitted to the hospital to perform the major hepatobiliopancreatic surgery. That morning, the surgeon team will receive a closed envelope with the group assignment of the patient.

Before the surgery, a nurse will take notes of the anthropometric measures of the patient in the Patient data sheet (ANNEX), and one member of the surgeon team will fill the other parameters of it.

All the patients will receive a general anaesthesia and antibiotic prophylaxis with amoxicillinclavulanic 2 g intravenous each 3 hours during the surgery. If the patient has allergy to penicillin, we will prescribe clindamycin 300 mg or gentamycin 240 mg with metronidazole 500 mg intravenous in the same posology. If we will manipulate the biliary via during the surgery, we will prescribe piperacillin-tazobactam 4/0.5 g intravenous each 3 hours.

ES group

In this group, a monopolar ES (cutting current of 40 W and coagulation current of 45 W) will be used to open all the abdominal wall layers. After all the abdominal wall layers are dissected, the surgeons will prepare the surgical field.

TB group

In this group, a monopolar ES will be used to open the skin and the subcutaneous tissue. Once these layers are dissected, the surgeon will use the TB (Seal & Cut level 1, Seal level 3) to cut the muscular layers with their aponeuroses, the transversalis fascia and the peritoneum. After that, the surgeons will prepare the surgical field.

Both groups

In both groups, the skin and the subcutaneous tissue will be dissected with a monopolar ES, and the haemostasis done will be not counted. During the aperture of the musculoaponeurotic layer of the abdominal wall, gauzes and the Aquamantys will be used to control the haemostasis. Those gauzes will be weighted before and after being used in order to know the different weigh and determined the blood loss in each procedure. At the same time, a nurse will calculate the time required since the beginning of the division of the musculoaponeurotic layer of the muscle abdominal wall until the surgical fields are ready, using a chronometer. After the incision is made, the wound length will be measured using a surgical silk and a meter. All these data will be collected in the Patient data sheet.

In hepatectomies, the incisions made will be a subcostal or a J-shape incision, according to the patient's BMI and the surgery indication.

In pancreaticoduodenectomies, the incision made will be an extended subcostal incision. Firstly, the surgeon will make a subcostal incision. Secondly, the surgical team will search signs of carcinomatosis and take biopsies in a positive case. Finally, the surgeon will extend the incision to complete the extended subcostal incision. Once the surgical intervention have been finished, the surgeons will close the muscleaponeurotic plane with PDS I, an antibacterial suture. After that, they will close the skin with skin staples.

Hospitalization

After the surgery, the patient will be hospitalized for 7-10 days at least, depending on his/her necessities and requirements.

The first day of his/her hospitalization, a nurse will pass each 8 hours to assess the patient's pain with the VAS score for pain and his/her analgesic requirements will be fulfilled (ANNEX). Henceforth, the VAS score will be passed at once every day of his/her hospitalization.

Moreover, the nurses and the doctors will observe the wound incision, the patient condition and the analytics parameters looking for infections signs, such as wound tumefaction, colour and temperature; fever or an increase of leucocytosis or CRP.

All these parameters will be collected in the Patient data sheet by nurses and doctors.

Clinical follow-up

The clinical follow-up will be performed one week after discharge and then one, three, six and twelve months after surgery. On these appointments, the patient will come with a CT and an analytical test made in order to control the illness. With these, and the inspection of the wound scar, the surgeon will observe any signs of post-operative complication such as dehiscence, evisceration or incisional hernia.

Moreover, in the case the patient has a drain post-surgery, the follow-up of it will be every week until its removal.

On those dates, the anatomopathological examination of the surgery piece will be done, and it will be collected, with any post-surgery complication, in the Patient data sheet.

8.5.4 Masking techniques

As a simple-blind study, the patients will be blinded. The patient will not know in which group is allocated, and will continue blinded until the publication of the study. As the surgeon is the one who will perform the surgery, he or she cannot be blinded. For this reason, the main surgeon will kwon which device he/she will be use the same day of the intervention.

The VAS pain score will be passed by a nurse alien to the study group in order to minimize the bias of simple blind.

The statistical analysis of the data recorded will be done by an external statistician who will not know in which group each patient was, so he/she will be masked too.

8.6 Data collection

The data will be collected from the clinical and surgical medical records, analytic tests, anthropometric measures, imaging techniques and anatomopathological results of the surgical piece. All these parameters will be collected using the Patient data sheet (ANNEX).

In order to preserve the patient confidentiality, a code will be given to each patient.

Schedule of the approaches

PANCREATICODUODENECTOMY													
WEEKS	-6	-5	-4	-3	-2	-1	0	1	2	12	24	36	48
1 st visit													
Anaesthesiology visit													
2 nd visit													
Intervention day													
Hospitalization													
Follow-up*													

НЕРАТЕСТОМУ														
WEEKS	-12	-10	-8	-6	-4	-2	0	1	2		12	24	36	48
1 st visit														
Anaesthesiology visit														
2 nd visit														
Intervention day														
Hospitalization														
Follow-up*														

*if the patient has a drain post-surgery, the follow-up of it will be done every week until its removal

9. STATISTICAL ANALYSIS

In order to do the statistical analysis, we will use the 20.0 SPSS package.

In the univariate analysis, the results will be expressed as percentages for categorical variables and as mean +/- standard deviation (SD) or median for continuous variables depending on whether or not they are normally distributed.

In the bivariate analysis, Mann–Whitney U test will be used for the comparison between the nominal qualitative independent variable and all the continuous quantitative dependents variables, whether main or second dependent variable. Chi-Square test will be used for the comparison between the independent and the *infection, wound dehiscence* and *evisceration* second dependents variables, as they are qualitative variables.

In the multivariate analysis, we will use a type of probabilistic statistical classification model such as logistic regression adjusted for all the covariables or possible confusion variables.

We will considerate all variables statistically significant if p value <0.05.

10. ETHICAL CONSIDERATIONS

In order to execute this study, the Comitè Ètic d'Investigació Clínica (CEIC) from Hospital Universitari Doctor Josep Trueta will evaluate it. The study may be initiated only after receiving their approval. Moreover, this trial will be registered in AEMPS webpage with EudraCT application.

This study has been designed following the Ethical Principles for Medical Research Involving Human Subjects stated by the World Health Association (WMA) in the Declaration of Helsinki.

It will be performed in agreement with the Spanish laws related to clinical trials: "Ley 29/2006 de 26 Julio, de garantías y uso racional de los medicamentos y productos sanitarios" and "Ley 14/2007 de 3 de Julio, de investigación biomédica".

To respect the principle of autonomy, all the patients must read and understand the Information sheet for participants and sign the Informed consent of the study (ANNEX). They will enter this study voluntarily, and they have the right to withdraw of it in any moment with no impact on the health care they receive. If this happens, their collected data regarding the study will be eliminated and none of that will be used.

All the collected data in regard of this trial will be keep strictly confidential, ensuring the compliance of the "Ley orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal". An identification number will be used instead of the patient's name to maintain confidentially of personal data.

Nowadays, ES is one of the most used devices to open the abdominal wall in abdominal surgery. Moreover, bipolar energy is one of the safest methods to coagulate and seal vessels. Regarding the ultrasonic energy, there are some articles showing a clear advantage over ES about the time needed to dissect tissues. Although TB is relatively new, the fewer articles and clinical trials made till the date suggest that it is faster dissecting tissues and at least equally safer sealing vessels than the ES and/or ultrasonic energy devices. Because of all these literature support, we believe that it is ethical to compare the ES and the TB.

11. STUDY LIMITATIONS

One limitation in our study is the impossibility of making a triple-blinding, as the surgeon will know which device he/she will use the day of the intervention. To overcome a detection bias, both patient and statistician will not know in which group each participant will belong. Moreover, all participants will have an assigned code to preserve the patient confidentiality and to avoid a detection bias.

In order to minimize an information bias, all the data will collected by the same way and using the Patient data sheet.

Another limitation may be the sample size. In our study, we have two dependent variables (blood loss and time required to divide the musculoaponeurotic layer). In order to calculate our sample size, we used the time dependent variable instead of the blood loss dependent variable. Using one or another in order to calculate it is indifferent; the only difference may be the number of participants obtained.

As we are carrying out a study about a surgical intervention, all 6 hepatobiliopancreatic surgeons of Hospital Universitari Doctor Josep Trueta will be randomized in order to avoid inter-surgeon variation and a procedure bias.

One important point to take into account is the loss of patients follow-up. Those loses can be due to a decision of the patient to withdraw of the study, a missing appointment during the clinical follow-up and death. In the first case, all the data collected regarding our study will be eliminated and none of it will be used in the results. In the second case, the hospital will try to contact him/her via phone or text message during the following days and make a new appointment. In the last case, the data collected belonging to the deceased patient only will be used if this scenario happens after the closing of the database.

As our study will be performed in Hospital Universitari Doctor Josep Trueta and not in a national scale, it may be difficult to extrapolate to another regions or countries. With the purpose to compensate this, our study will randomize the participants, will be simple-blinded and all the data will be collected using the Patient data sheet.

12. FEASIBILITY

This clinical trial will be carried out at Hospital Universitari Doctor Josep Trueta of Girona between May of 2016 and December of 2018. Before its star, we will organize various meetings with all the professionals involved explaining our objectives, the importance of recording all data and how to collect it using the Patient data sheet. We will hire a statistical specialist to randomize the study population and to do the statistical analysis and a clinical research associated to create a database.

The hospital will provide all the necessary means regarding personnel salaries, surgeries and their material, and the consecutives visits with participants.

In a year, there are approximately 60 patients who will be diagnosed of a hepatobiliary illness which treatment includes a surgical intervention. For the complexity of the surgery and for the patient features, half of those interventions will be performed via laparotomy. Moreover, around 20 patients will be diagnosed of pancreatic disease which treatment encompasses a surgical procedure. Acknowledging these, we expect to include about 45 patients per year. To achieve the 104 participants needed to confirm or refuse our hypothesis, the recruitment time will be 32 months.

13. WORK PLAN AND CHRONOGRAM

Personnel of the research team

Investigators: HBP team (HT)

Collaborators: nurse staff (NS), statistical specialist (SS), clinical research associated (CRA)

Study stages

Our study will be divided in 4 stages:

- Stage 1: Coordination (6 months)
 - Activity 1: Protocol design. The HT will determinate the objectives of the study and a protocol of it will be prepared.
 - Activity 2: Obtaining the ethical approval from the Clinical Research Ethics Committee (CREC). The HT will present the protocol of the study to the CREC of the hospital.
 - *Activity 3*: Informative meeting. The HT will explain all the objectives to the rest of the research team. The chronogram of the study will be done.
- Stage 2: Data collection (48 months)
 - Activity 4: Database creation. The CRA will perform this activity.
 - Activity 5: Recruitment of the participants. The patients who meet the inclusion criteria and no exclusion criteria will be include in the study. They will be randomly assigned to one of the study groups.
 - Activity 6: Intervention. The HT will perform the surgery.
 - Activity 7: Follow-up. The HT will meet every patient during one year through control visits every 3 months
 - Activity 8: Data collection and database creation. All the research team will collect the data in the Patient data sheet. After that, the data will be introduced in a database.
 - Activity 9: Control and closure of the database. The CRA will be responsible for maintaining a good quality of the data introduced in the database. Once all data is collected in the database, the CRA will closure it.
 - Activity 10: Research team meetings. Meeting with all the research team will be done time to time.
- Stage 3: Data analysis and interpretation of the results (6 months)
 - Activity 11: Statistical analysis. The SS will perform this activity.
 - Activity 12: Interpretation and discussion of the results. The HT will interpret and discuss the results obtained by the SS
- Stage 4: Publication and dissemination of the research finding (12 months)
 - Activity 13: Publication of the results. Articles will be submitted to a surgical journal
 - Activity 14: Dissemination of the findings. The HT will attempt to assist to HPB conferences.

			2015-16		20	16			20:	17			20	18			202	19			20	20			20	21	
	ACTIVITIES	PERSONNEL	Nov-Jan	Feb-Apr	May-Jul	Aug-Oct	Nov-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec																
Ч	Protocol design	HT																									
Ю	CEIC	HT																									
STA	Meeting with the team	All personnel																									
	Database creation	CRA																									
	Patients recruitment	HT																									
ЭЕ 2	Intervention	HT, NS																									
TAG	Follow-up	HT																									
S	Data collection	HT, NS																									
	Database	CRA																									
	Research team meetings	All personnel																									
m	Statistical analysis	SS																									
STAGE	Interpretation and discussion of the results	HT																									
GE 4	Publication of the results	HT																									
STA	Dissemination of the findings	HT																									

14. BUDGET

The appointments and surgeries will not be included in the budged because they are part of the National Health System.

We will hire a statistical specialist in order to randomize and code the participants in each group and to the statistical analysis. The estimated salary will be $40 \in$ per hour and he or she will do approximately 30 hours. Thus, the estimated cost will be $700 \in$.

We will hire a Clinical researcher associated with the purpose to create a database and to do the data quality control. The estimated salary will be $30 \in$ per hour and approximately 90 hours will be needed (assuming 2 hour per month per 45 months). Thus, the estimated cost will be 2.700 \in .

	Cost	Quantity	Total				
PERSONNEL COST							
Statistical Specialist	40€/h	30h	700€				
Clinical researcher associated	30€/h	90h	2.700€				
			SUBTOTAL: 3.400€				
MATERIAL							
Paper	30€	1	30€				
			SUBTOTAL: 30€				
PUBLICATION							
Article publication	1.500€	1	1.500€				
Inscription to National meetings of <i>Spanish</i> association of Surgeons	700€	1	700€				
Accommodation	600€	1	600€				
			SUBTOTAL: 2.800€				
			TOTAL: 6.230€				

15. IMPACT ON THE NATIONAL HEALTH SYSTEM

Although the existence and the implementation of the Minimally Invasive Surgeries in our National Health System (NHS), some major HBP surgeries have to be done via laparotomy. If the results are relevant and our hypothesis is validated, there will be an evident impact both on the NHS and on patients.

Regarding the NHS, the use of Thunderbeat will decrease the time required to divide the musculoaponeurotic layer of the abdominal wall, and will do it with less blood loss. In any surgery, the operation time and the amount of blood needed to replace the losses define an important part of the surgery total cost. In major HPB surgeries, which they can last between 5 and 9 hours, every little input is very grateful.

Furthermore, during the hospitalization and follow-up there will be fewer post-operation complications. If patient has less pain in the wound area, he or she will require less analgesic drugs, decreasing the amount of analgesic-drugs used in the hospital every year. Depending on the patient and his/her features, it may reduce the hospitalization time. During the follow-up, if there are fewer dehiscences and/or eviscerations, he or she may not have to endure another surgical intervention. All of these may reduce the hospital cost per year.

In regard of the patients, the most apparent benefit will be the decrease of the pain. It may also reduce his/her time in the hospital until discharge and another surgery. Furthermore, if there are fewer dehiscenses and/or evisceration, the patient will not undergo another surgical intervention, with all its personals cost. All of these may improve their quality of life.

Moreover, if our hypothesis is validated, Thunderbeat could be used in others surgeries to open the muscular-aponeurotic plane.

16. ANNEXES

Information sheet for participants and Informed consent of the study (English version)

INFORMATION SHEET FOR PARTICIPANTS

Title: THE USE OF THUNDERBEAT VERSUS ELECTROSURGERY IN THE DIVISION OF THE MUSCULOAPONEUROTIC LAYER OF THE ABDOMINAL WALL DURING LAPAROTOMY IN MAJOR HEPATOBILIOPANCREATIC SURGERY

We write to inform you about a clinical trial that will take place in this centre. You are invited to participate in this study and we ask you to consider whether you want to join or not. It is very important that you read and understand why they are doing this study and all that this implies. Please read the following information and, if in doubt, we will resolve it delighted.

Voluntary participation

The participation in this clinical trial is voluntary. If you decide to participate, you will be asked to sign a consent form. If at any given time along it you want to leave the study, you may do so without specifying the reason and without affecting your health care.

The study doctor will answer any questions that may arise.

Description of the study

The main objective of this study is to compare two types of scalpels at the time of the aperture of the muscles abdominal wall and see which one produces less blood loss during the incision and which gains access to the abdominal cavity in less time. In addition, we also want to compare which of these causes less post-surgical complications (pain wound, dehiscence and evisceration the surgical wound).

The two scalpels to compare are the electrocautery, which is routinely used to perform this action, and Thunderbeat, a new surgical instrument that appears to be as safe as electrocautery and could fulfil the main objective of the study.

This study is a clinical trial with two groups of patients. In the first group, known as ES group, the surgical incision will be performed with electric scalpel; while in the second group, known as TB group, it will be done with the Thunderbeat. Once you form part of the study, you will be randomly assigned to a group. You will not know in which group you are to avoid possible bias in the results.

Your medical care throughout the study will be the same regardless of which group you belong. The only difference is whether the incision made in the muscle abdominal wall is done with a scalpel or other. Visits with the different specialists, diagnostic tests and post-surgical follow-up will be exactly the same as if you decide not to participate or withdraw from the study.

Responsibility

If you participate in this study, you must attend all scheduled visits. If you encounter further questions or concerns, please inform the staff so they could be resolved.

Confidentiality

All information gathered during this trial will be kept confidential at all times ensuring compliance with the provisions of Ley orgánica 15/1999, de 13 de diciembre, on the protection of personal data.

The data collected will be identified by a numerical code, and only the researchers and collaborators will have access to this information. Your identification will not be decoded.

Thank you for your attention.

Try to keep this information sheet about your participation in this study until it is completed.

Any questions, feel free to ask.

If you want to participate in the study, sign the consent of the study.

INFORMED CONSENT OF THE STUDY

Title: THE USE OF THUNDERBEAT VERSUS ELECTROSURGERY IN THE DIVISION OF THE MUSCULOAPONEUROTIC LAYER OF THE ABDOMINAL WALL DURING LAPAROTOMY IN MAJOR HEPATOBILIOPANCREATIC SURGERY

- I have read the Information sheet for participants and the Informed consent form. I understand that I can keep a copy of both.
- I understand what I will be ask to do during the study and I have had enough time to think about what the study will mean to me.
- I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
- I give permission for the study's members to have access to my clinical history with verifying purposes and to my study's records always ensuring the compliance of the Organic Law 15/1999 of 13 December on the Protection of Personal Data.
- I consent voluntarily to participate as a participant in this research.

Participant	Investigator
Name	Name
ID	ID
Sign	Sign

Girona, ______ of _____ of 20

Information sheet for participants and Informed consent of the study (Catalan version)

INFORMATION SHEET FOR PARTICIPANTS

TÍTOI: THE USE OF THUNDERBEAT VERSUS ELECTROSURGERY IN THE DIVISION OF THE MUSCULOAPONEUROTIC LAYER OF THE ABDOMINAL WALL DURING LAPAROTOMY IN MAJOR HEPATOBILIOPANCREATIC SURGERY

Li escrivim per informar-li sobre un assaig clínic que es durà a terme en aquest centre. Vostè està convidat a participar en aquest estudi i li preguem que consideri si en vol formar part o no. És molt important que vostè llegeixi i entengui per què s'està realitzant aquest estudi i tot el que implica. Si-us-plau, llegeixi detingudament la següent informació i, si té algun dubte, nosaltres li resoldrem encantats.

Participació voluntària

La participació en aquest assaig clínic es voluntària. Si vostè decideix participar-hi, se li demanarà que firmi un full de consentiment. Si en un moment donat al llarg d'aquest vostè desitja abandonar l'estudi, ho podrà fer sense cap necessitat d'especificar el motiu i sense que això afecti en la seva atenció mèdica.

El metge de l'estudi li contestarà qualsevol dubte o pregunta que li pugui sorgir.

Descripció de l'estudi

El principal objectiu d'aquest estudi és comparar dos tipus de bisturís en el moment de l'apertura de la musculatura de la paret abdominal i observar quin dels quals produeix menys pèrdues hemàtiques durant la incisió i amb quin s'aconsegueix accedir a la cavitat abdominal en menys temps. A més a més, també es vol comparar quin d'aquests provoca menys complicacions post-quirúrgiques (dolor de la ferida, dehiscències i evisceracions per la ferida quirúrgica).

Els dos bisturís a comparar són el bisturí elèctric, que és el que s'utilitza de rutina per dur a terme aquesta acció, i el Thunderbeat, un nou instrument quirúrgic que sembla ser igual de segur que el bisturí elèctric i que podria complir amb l'objectiu principal de l'estudi.

Aquest estudi consisteix en un assaig clínic amb dos grups de pacients. En el primer grup, conegut com a ES group, la incisió quirúrgica es realitzarà amb el bisturí elèctric; mentre que en el segon grup, conegut com TB group, aquesta serà realitzada amb el Thunderbeat. Una vegada vostè entri a formar part de l'estudi, serà assignat a un grup aleatòriament. Vostè no sabrà en quin grup pertany per tal d'evitar possibles biaixos en el resultats.

La seva atenció mèdica al llarg de l'estudi serà igual independentment de quin grup formi part. L'única diferència serà si la incisió feta a la musculatura de la paret abdominal es realitza amb un bisturí o amb un altre. Les visites amb els diferents especialistes, proves diagnòstiques i seguiment post-quirúrgic serà exactament el mateix que si vostè decidís no participar o abandonar l'estudi.

Responsabilitat

Si decideix participar en aquest estudi, haurà d'assistir a totes les visites programades. Si li sorgeixen nous dubtes o inquietuds, haurà d'informar al personal per tal de poder-les resoldre.

Confidencialitat

Tota la informació recopilada durant aquest assaig clínic es mantindrà confidencial garantint en tot moment el compliment de les disposicions de la Llei Orgànica 15/1999, de 13 de desembre, sobre la protecció de dades de caràcter personal.

Les dades recopilades seran identificades amb un codi numèric, i només els investigadors i col·laboradors tindran accés a aquesta informació. La vostra identificació no serà descodificada.

Moltes gràcies per la seva atenció.

Intenti mantenir aquest full d'informació fins que la seva participació en aquest estudi hagi finalitzat.

Qualsevol dubte, no dubti en preguntar.

Si decideix participar en l'estudi, firmi el consentiment de l'estudi.

INFORMED CONSENT OF THE STUDY

Títol: THE USE OF THUNDERBEAT VERSUS ELECTROSURGERY IN THE DIVISION OF THE MUSCULOAPONEUROTIC LAYER OF THE ABDOMINAL WALL DURING LAPAROTOMY IN MAJOR HEPATOBILIOPANCREATIC SURGERY

- He llegit el Full d'informació per al pacient i el Formulari de consentiment informat. Entenc que podré conservar una còpia d'ambdós.
- Entenc què se'm sol·licitarà que faci durant aquest estudi i he tingut temps per a pensar en la implicació que té l'estudi per mi.
- He parlat sobre l'estudi amb el metge o el personal de l'estudi i han respòs a les meves preguntes de forma satisfactòria.
- Entenc que la decisió de participar o no en l'estudi depèn de mi, que puc canviar d'idea més endavant i que, independentment de la meva decisió, la meva atenció mèdica i els meus drets legals no es veuran afectats.
- Dono permís al personal de l'estudi perquè consultin la meva història clínica amb finalitats de verificació de dades i la meva informació recopilada en l'estudi. Sempre en conformitat amb la Llei Orgànica 15/1999, de 13 de desembre, sobre protecció de dades de caràcter personal.
- Accepto voluntàriament participar en aquest estudio d'investigació.

Participant	Investigador
Nom	Nom
DNI	DNI
Firma	Firma

Girona, ______ de _____ de 20

Information sheet for participants and Informed consent of the study (Spanish version)

INFORMATION SHEET FOR PARTICIPANTS

Título: THE USE OF THUNDERBEAT VERSUS ELECTROSURGERY IN THE DIVISION OF THE MUSCULOAPONEUROTIC LAYER OF THE ABDOMINAL WALL DURING LAPAROTOMY IN MAJOR HEPATOBILIOPANCREATIC SURGERY

Le escribimos para informarle sobre un ensayo clínico que se llevará a cabo en este centro. Usted está invitado a participar en este estudio y le rogamos que considere si quiere formar parte o no. Es muy importante que usted lea y entienda por qué se está realizando este estudio y todo lo que implica. Por favor, lea detenidamente la siguiente información y, si tiene alguna duda, nosotros se la resolveremos encantados.

Participación voluntaria

La participación en este ensayo clínico se voluntaria. Si usted decide participar, se le pedirá que firme una hoja de consentimiento. Si en algún momento dado a lo largo de éste usted desea abandonar el estudio, lo podrá hacer sin necesidad de especificar el motivo y sin que ello afecte a su atención médica.

El médico del estudio le contestará cualquier duda o pregunta que le pueda surgir.

Descripción del estudio

El principal objetivo de este estudio es comparar dos tipos de bisturís en el momento de la apertura de la musculatura de la pared abdominal y observar cuál de ellos produce menos pérdidas hemáticas durante la incisión y con cúal se consigue acceder a la cavidad abdominal en menos tiempo. Además, también se quiere comparar cuál de estos provoca menos complicaciones post-quirúrgicas (dolor de la herida, dehiscencias y evisceración por la herida quirúrgica).

Los dos bisturís a comparar son el bisturí eléctrico, que es el que se utiliza de rutina para llevar a cabo esta acción, y el Thunderbeat, un nuevo instrumento quirúrgico que parece ser igual de seguro que el bisturí eléctrico y que podría cumplir con el objetivo principal del estudio.

Este estudio consiste en un ensayo clínico con dos grupos de pacientes. En el primer grupo, conocido como SE group, la incisión quirúrgica se realizará con el bisturí eléctrico; mientras que en el segundo grupo, conocido como TB group, ésta será realizada con el Thunderbeat. Una vez usted entre a formar parte del estudio, será asignado a un grupo aleatoriamente. Usted no sabrá en qué grupo pertenece el fin de evitar posibles sesgos en los resultados.

Su atención médica a lo largo del estudio será igual independientemente de qué grupo forme parte. La única diferencia será si la incisión hecha en la musculatura de la pared abdominal se realiza con un bisturí o con otro. Las visitas con los diferentes especialistas, pruebas diagnósticas y seguimiento post-quirúrgico será exactamente el mismo que si usted decide no participar o abandonar el estudio.

Responsabilidad

Si decide participar en este estudio, deberá asistir a todas las visitas programadas. Si le surgen nuevas dudas o inquietudes, deberá informar al personal a fin de poderlas resolver.

Confidencialidad

Toda la información recopilada durante este ensayo clínico se mantendrá confidencial garantizando en todo momento el cumplimiento de las disposiciones de la Ley Orgánica 15/1999, de 13 de diciembre, sobre la protección de datos de carácter personal.

Los datos recopilados serán identificados con un código numérico, y sólo los investigadores y colaboradores tendrán acceso a esta información. Su identificación no será decodificada.

Muchas gracias por su atención.

Intente mantener esta hoja de información hasta que su participación en este estudio haya finalizado.

Cualquier duda, no dude en preguntar.

Si decide participar en el estudio, firme el consentimiento del estudio.

INFORMED CONSENT OF THE STUDY

Título: THE USE OF THUNDERBEAT VERSUS ELECTROSURGERY IN THE DIVISION OF THE MUSCULOAPONEUROTIC LAYER OF THE ABDOMINAL WALL DURING LAPAROTOMY IN MAJOR HEPATOBILIOPANCREATIC SURGERY

- He leído la Hoja de información para el paciente y el Formulario de consentimiento informado. Entiendo que podré conservar una copia de ambos.
- Entiendo lo que se me solicitará que haga durante este estudio y he tenido tiempo para pensar en lo que el estudio implica para mí.
- He hablado sobre el estudio con el médico o el personal del estudio y han respondido a mis preguntas de forma satisfactoria.
- Entiendo que la decisión de participar o no en el estudio depende de mí, que puedo cambiar de idea más adelante y que independientemente de lo que decida, mi atención médica y mis derechos legales no se verán afectados.
- Otorgo permiso al personal del estudio para que consulten mi historia clínica con fines de verificación de dados y mi información recopilada en el estudio. Siempre en conformidad con la Ley Orgánica 15/1999, de 13 de diciembre, sobre protección de datos de carácter personal.
- Acepto voluntariamente participar en este estudio de investigación.

Participante	Investigador
Nombre	Nombre
DNI	
ואט	DINI
Firma	Firma

Girona, ______ de _____ de 20

Patient data sheet

PATIENT INFORMATION	
Name:	Surname:
Code:	Date of birth:
Email:	Tel:
Day of intervention:	Sex: 🗌 MALE 🗌 FEMALE

ANTHROPOMETRIC MEASURES								
Height (m):	Weight (kg):	BMI:						

PERSONAL ANTECEDENTS:	
ALLERGIES:	
REGULAR MEDICATION :	
Drug name	Posology

COMORBILITIES:		
Diabetes	Hypertension	
Dyslipidaemia	Alcoholism	
Tobacco	COPD	
Pulmonary failure	Renal failure	
Arrhythmia	Cardiac failure	
Hepatitis B virus	Hepatitis C virus	
Alcoholic liver cirrhosis	HIV virus	
Non-alcoholic liver cirrhosis	Biliary illness	
Chronic pancreatitis	Coagulopathies	
Digestive tract illness	Inflammatory bowel disease	
Primary cancer	Metastatic cancer	
Active chemotherapy	Immunosuppressive illness	
Others:		

PREVIOUS ABDOMINALS	SURGE	ERIES:	VES		🗌 NOT	
If the answer is yes, which kind of incision was made:						
Midline incision		Paramedian incision		Right subcostal incisior	ו 🗌	
Left subcostal incision		J-shape incision		Extended subcostal incision		
McBurney incision		Lanz incision		Oblique muscle-cutting incision	3	
Open inguinal hernia incision		Pfannenstiel incision		Maylard incision		
Other:						

If the answer is yes, what kind of surgery was:								
Oesophagus surgery		Stomach surgery		Spleen surgery				
Hepatic surgery		Biliary surgery		Pancreatic surgery				
Small intestine surgery		Cecum surgery		Ascending colon surgery				
Transverse colon surgery		Descending colon surgery		Sigma surgery				
Rectus surgery		Hernia surgery		Urologic surgery				
Gynaecologic surgery		Others						
Comments:								

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ANALITICAL PARAMETERS:	
Blood count	
Haematites	
Haematocrit	
Haemoglobin	
MCV	
RDW	
Neutrophil	
Lymphocytes	
Platelet	
Biochemical analysis	
Sodium	
Potassium	
Urea	
Creatinine	
Glucose	
Albumin	
Total bilirubin	
Direct bilirubin	
Indirect bilirubin	
GOT	
GPT	
GGT	
Alkaline phosphatase	
Amylase	
Lactic acid	

Coagulation	
РТ	
РТТ	
INR	
Fibrinogen	
Tumour marker	
Ca 19.9	
CEA	
Others:	

DIAGNOSIS IMAGING:

ANATOMOPATHOLOGICAL DIAGNOSIS:	

ASA :				IV	V
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SURGICAL PROCEDURE:								
Kind of intervention:								
Right hepatectomy		Left hepatectomy		Pancreaticoduodenectomy				
Extended right hepatectomy		Extended left hepatectomy			•			
Comments:								
Kind of incision:								
Right subcostal		J-shape subcostal		Extended subcostal				
Comments:								
Kind of scalpel:		Thunderbeat		Electrosurgery				

THUNDERBEAT	
Time open abdominal wall:	Wound length:
Previous gauzes weight :	Posterior gauzes weight:
Blood loss:	
Total time procedure:	
Comments:	
ELECTROSURGERY	
Time open abdominal wall:	Wound length:
Previous gauzes weight	Posterior gauzes weight:
Blood loss:	
Total time procedure:	
Comments :	

RE-INTERVENTION :	YES	
If the answer is yes, explain the motive		

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POST-SURGERY COMPLICATION										
Pain										
VAS score										
1 st day 2 nd day 3 rd day 4 th day 5 th day 6 th day 7 th day 8 th day	1 1 1 1 1 1 1 1	2 2 2 2 2 2 2 2 2 2 2	3 3 3 3 3 3 3 3 3 3	4 4 4 4 4 4 4 4	5 5 5 5 5 5 5 5 5	6 6 6 6 6 6 6	7 7 7 7 7 7 7 7	8 8 8 8 8 8 8 8	9 9 9 9 9 9 9 9	10 10 10 10 10 10 10 10
9 th day 10 th day	1 1	2 2	3	4 4	5 5	6 6	7 7	8 8	9 9	10 10
Extra require	ement:		3			☐ YES			5	
Hospitalizati	on days:	:								
Extra days ho	ospitaliz	ation:				YES				
If the answe	r is yes,	how many:								
Infection										
Signs of infe	ction					YES				
If the answe	r is yes, v	which ones	:							
Tumefaction			Oed	ema			↑ te	emperatu	re	
Erythema			Supp	ouration			ºC:			
↑RCP			∕↑lyı	mphocytes			↑ la	ctic acid		
Others:										
Comments:										

Dehiscence	YES	
Evisceration	YES	

RE-INTERVENTION :	YES	
If the answer is yes, explain the motive:		

Drainage post-surgery	YES	
If the answer is yes:		
Discharge day:	Removal day:	

ASA PS Classification	Definition	Examples, including, but not limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	<u> </u>

ASA classification

*The addition of "E" denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

GOLD/ATS-ERS spirometric classification

Category/Severity stage	FEV1/FEV	FEV1 (%)
Normal (healthy patients)	0.8	≈100
l: mild	<0.7	≥80
II: moderate	<0.7	50 to <80
III: severe	<0.7	30 to <50
IV: very severe	<0.7	<30

0-10 VAS Numeric Pain Distress Scale No Moderate Unbearable pain pain pain 2 3 5 9 0 1 4 6 7 8 10

Visual analogue scale for pain (VAS score for pain)

Analgesic requirements regimen

The first day post-surgery, the patient will be hospitalized with bupivacaine-adrenalinefentanyl 5-6 mL via epidural each hour, with a gradually decrease of its dose. If he or she has nausea or vomits, we will prescribe ondansetron 8mg.

Henceforth, we will prescribe paracetamol each 8 hours via oral alternating with metamizole in the same posology. If the patient's pain requirements are not fulfilled with this regime, we will add pethidine 50 mg subcutaneous each 6 hours.

Source of the figures

Figure 01:

http://teleanatomy.com/General%20Anatomy/Introduction%20to%20Anatomy%203rd%20Edi tion/Fascia_files/image006.jpg

Figure 02: https://commons.wikimedia.org/wiki/File:Spaltrichtungen.gif

Figures 03, 05-08: Prometheus: texto y atlas de anatomia. Tomo I

Figure 04: <u>https://s-media-cache-</u> ak0.pinimg.com/736x/5f/54/f8/5f54f813520cff012f25224b702e1deb.jpg

Figures 09-11, 13: figure of internet + hand-made

Figure 12: <u>http://drugline.org/medic/term/mcburneys-point/</u>

Figure 14: http://www.220-electronics.com/media/images/hertz-cycle.gif

Figures 15-19: Massarweh NN, Cosgriff N, Slakey DP. Electrosurgery: History, principles, and current and future uses. J Am Coll Surg. 2006;202(3):520–30.

Figure 17: http://www.ramalaser.com/know/RFsurgery/Electrosurgery.htm

Figures 20: <u>http://www.aiimsnets.org/review_seminar/cusa/1.pdf</u>

Figure 21: <u>http://www.google.com/patents/US6174309</u> + <u>http://www.mybwmc.org/sites/all/modules/adam/graphics/images/en/19445.jpg</u>

Figure 22: Lee SJ, Park KH. Ultrasonic energy in endoscopic surgery. Yonsei Medical Journal. 1999. p. 545–9.

Figures 23-25: Inc. Olympus America. Tissue management system. USA; 2014. p. 1–31.