

Closed Chest Bypass between the Internal Mammary Artery and the Coronary Artery to the Beating Heart

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Research Question: "What is the best option to perform a closed chest bypass between the internal mammary artery and the coronary artery to beating heart in patients with indication for myocardial revascularization surgery, robotic surgery or minimally invasive surgery by means of the use of a medical device".

Background

Description of condition

Advances in medicine have led to the use of video laparoscopic surgery in all surgical pathologies, both in diseases of appendiceal, biliary, hepatic, inguinal hernias, and colon and rectum surgeries. Also, at chest level with video thoracoscopy in pleural seals, biopsies and pulmonary resections. It is a minimally invasive technique that allows to operate a pathology without opening the patient and having the same advantages in all surgical procedures. Less postoperative pain, quick recovery of the patient, shorter surgical time, good ergonomics for the surgeon and shorter days of hospitalization. This makes us think that with laparoscopic video surgery the beneficiaries were all; both the patient, the surgeon and the health system. On the other hand, at the level of cardiac intervention, in the beginning it was considered as a diagnostic procedure with cardiac cinecoronariography and therapeutic treatments are now being performed in cardiac pathology, with a success rate in a large percentage in median centers and high complexity from all over the world.

For this reason is the proposal of this research that will allow us to perform the first closed chest bypass between the internal mammary artery and the coronary artery to beating heart in two steps: the first is the dissection of the internal mammary arteries by means of video thoracoscopy done by cardiovascular surgeons and the second is the use of a coronary device in performing the anastomosis performed by interventional cardiologists in conjunction with cardiovascular surgeons under direct vision. This project includes robotic surgery as a surgical technique in a comparative sense with the proposed innovative procedure. Does not include MIDCAB and OPCAB.

Three fundamental pillars will be needed for the realization of the same, the first one is a center of high complexity that is the cradle of this project with an animal experimentation laboratory, the second cardiovascular surgeons with guidance in video thoracoscopy or surgery minimally invasive and the third, interventional cardiologists determined to take on new challenges. These three links are fundamental for the realization of this research project. It is also necessary to consider a company or source of financing of the state that allows obtaining instruments of laparoscopy, catheters and manufacture of the device for cardiac surgery.

Description of the intervention

Before undertaking any clinical study in humans, the hypothesis of the animal research project should be demonstrated, especially in the way it works, its feasibility, its safety and reproducibility of the device to perform the closed chest bypass between the internal mammary artery and the coronary artery to beating heart, and then compare it with what exists today.

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When you have an idea "everything is possible", but to demonstrate it you have to start from the beginning. And this is the basis of this research project that will count: with a preclinical stage and then the clinical stage. Once the previous steps are completed, it goes to a regulatory decision period for its later launching of the product for sale and marketing.

Objectives

Primary Objectives:

- 1) To determine the effectiveness of the comparative surgical technique of two procedures, robotic surgery vs minimally invasive surgery by means of a medical device (hybrid surgery).
- 2) Determine which of the two options is most effective for the patient with indication of myocardial revascularization surgery.

Secondary objectives:

- 1) Establish from the study report if there is a clinical association of these procedures with factors such as age, sex and social class.
- 2) To describe patient follow-up results in the literature, with the different treatment alternatives of this pathology in the last 10 years.
- 3) To propose a diagnostic and treatment algorithm in patients with indication of myocardial revascularization surgery.

Methods

Search strategy

Electronic searches will be conducted in the main Pubmed bibliographic databases (from January 2007 to December 2017), MEDLINE (from January 2007 to December 2017), LILACS (from January 2007 to 2017), Embase (from January 2007 to 2017) and Cochrane Collaboration in a 10-year retrospective period prioritizing key words or MeSH terms, advanced search for the combination of terms, abstracts, and complete articles; in the English and Spanish languages, patients of both sexes, over 40 years old, of different social classes and from all the countries of the world without restrictions ("myocardial revascularization surgery", "innovations", "robotic surgery", "minimally invasive surgery" "Benefits", "costs", "disadvantages", "Hybrid surgery" and "technologies"). The year of original publication of the study, year in which the file was included in the database and year in which it was modified, will be taken into account. Inclusion of complete articles of systematic reviews and meta-analysis will be prioritized from the search obtained.

Evaluation of methodological quality

The STROBE statement was used as a quality assessment tool in observational studies.

Gray literature and consultation with experts

An extensive analysis of the gray literature on the subject will be done, information will be sought in national libraries, search by hand, publications in specific areas related to cardiac or cardiothoracic surgery. Three experts from cardiovascular disease in three developed countries (USA, Germany and China) will be consulted through pre-selected interviews with questions oriented to the concept of minimally invasive surgery, accepted terminology, innovations, technology and a better treatment option in surgery of myocardial revascularization (Annex 1). A survey of US, German and Chinese cardiovascular surgeons will be conducted via e-mail on the concept of minimally invasive surgery, accepted terminology, innovations, technology and a better treatment option in myocardial revascularization surgery, and the results are stratified according to the age of surgeons and years of surgical activity (Annex 2). We will try to find as much information as possible to avoid publication bias.

Statistical analysis

Statistical analysis will take into account dichotomous data such as sex, cure of the patient with robotic surgery or minimally invasive surgery using a medical device, which will be evaluated by measures of effect such as relative risk, the ratio of advantages (odds ratio) and the risk difference; and continuous data such as the age to be evaluated with the measurement of measures of central tendency (mean,

median and mode). The analysis of heterogeneity will be performed with the I^2 test and will be complemented with the Forest plot graph that represents the accuracy of each study. But due to the high suspicion of the heterogeneity of the results, a subgroup analysis will be carried out, which will only combine studies that meet certain conditions or characteristics (age, sex and social class), so that they are more homogeneous.

Exposure limits

As it is an unproven scientific innovation for the realization of a closed chest bypass between the internal mammary artery and the coronary artery to beating heart by means of a medical device. A preclinical investigation is going to be carried out that would be the starting point of the research project.

Preclinical research

In the preclinical stage: the research community refers to it as a laboratory period. It often takes physicians years to transform information from this stage into a new treatment, but the proposal in this research project is to use a medical device in animals. Controlling in the periods of 3 (three) months, 6 (six) months to 1 (one) year after the application of the device; evaluating its feasibility, reproducibility, safety, functioning and possible complications that the animal may present. Proposing at all times the respect for the life of the animal, and as a last resort will be made his sacrifice.

Materials and Methods

The proposal is to perform a Bypass or arteriovenous fistula (autologous vein) to closed chest and heart beating in each pig, the total amount required is 5, the Large-White young breed of pigs weighing approximately 30 to 40 kg. The procedure will be carried out in an experimental laboratory that meets the necessary standards requested by the regulatory system.

The animals in the laboratory will be anesthetized to avoid having pain. The pre-surgical preparation of these animals will begin with a sedation of the animal with 2 mg/kg of intramuscular acepromazine; anesthetic induction with thiopental sodium at doses of 6.5 mg/kg intravenous and maintenance with 500 mg thiopental diluted in 500 cm³ of physiological solution at 14 drops per minute; and orotracheal intubation for mechanical ventilation. If necessary, in some cases an orogastric tube will be placed to empty the stomach contents. They will be tied from the animal's legs to the four ends of the operating room table, so that access can be obtained at the level of the thorax and at the level of the femoral artery of the right hind paw.

The surgical technique will consist of replicating in the pig the procedure as it is intended to be performed in humans. The first step in the pig is dissection of the internal thoracic artery by video thoracoscopy. Once the internal thoracic artery is dissected, it is sectioned and a bulldog caliper is placed at its distal end; followed by a Seldinger technique at the level of the right femoral artery, a guidewire catheter with a guidewire 0.14 mm is inserted until it reaches the internal thoracic artery, performed under control of radioscopy and contrast material. The guide wire is placed inside the internal thoracic artery, the catheter is removed and the device is then inserted through the femoral artery to the bulldog caliper. A punctate incision is made in the coronary artery of the heart with a stinging element through video thoracoscopy. The bulldog clamp is released to allow the guidewire to pass through the device, and by video thoracoscopy the guidewire is inserted into the coronary artery, then the device is placed, the device is operated and the anastomosis is performed. Blood losses that may occur with the procedure are evaluated. Radioscopy controls with contrast material are performed.

Once demonstrated in pigs in a period of 6 months to 1 year that the device works. And stating its feasibility, reproducibility, safety, operation and possible complications. We will only be able to talk about a clinical stage, following the regulatory measures of the place where they are performed. For example: If it is in the US that the FDA approve the application to be able to go to the next stage of the investigation.

Clinical research

Phase I: These studies often last for several months to a year. The proposal is to involve 30 people in a period of 6 months to 1 year. Under the informed consent of the risks and benefits of what a method of experimentation means.

In this clinical investigation the use of the medical device in phase I will be offered to people who do not respond to the standard treatments of coronary disease and that cardiac surgery of myocardial revascularization is not recommended. The treatment administered during this phase aims to improve the myocardial circulation in a shorter surgical time since it is estimated that it would take approximately one hour. The controls would be done with radioscopia and contrast material for evaluation of the bypass. And they will be controlled in the periods of 3 (three) months, 6 (six) months to 1 (one) year after the application of the device; evaluating its feasibility, reproducibility, safety, functioning and possible complications.

Surgical technique in humans

For performing the Bypass surgery between the internal mammary artery and the coronary artery to thorax closed to beating heart: it will consist of two fundamental steps. The first is the dissection of the internal mammary arteries by means of video thoracoscopy performed by cardiovascular surgeons and the second is the use of a coronary device in performing the anastomosis performed by interventional cardiologists in conjunction with cardiovascular surgeons under direct vision. Previously a general anesthesia is needed, the patient's position is in the dorsal decubitus, bladder catheter, a central and an arterial pathway. The left upper limb is then elevated and flexed forward, allowing a greater opening of the thorax, and the stretcher is rotated 45 degrees to the right at the height of the surgeon. Asepsis and placement of the sterile fields are performed, leaving the neck and whole chest free up to the upper abdomen.

The first step in the surgical technique of video thoracoscopy is the visualization of the anterior and middle axillary lines of the left thorax for the placement of the trocars. It would use two working ports and one port for the optics, following the triangulation that the technique demands. The first 8 mm trocar that will have the camera will be placed at the 4th intercostal space left midline axillary line, the other 8 mm trocar will be placed at the level of the 6th left intercostal space on the line axillary anterior and the trocar of 4 mm is going to be placed in level 3^o left intercostal space following the same line previously described.

Instrumentation required:

- 1) A straight camera, 8 mm in diameter and 45 cm in length, with a 2D image with increased color image and white balance.
- 2) A delicate grasper without a zipper of 3 mm in diameter and 45 cm in length.
- 3) A hook for electrocoagulation with a fine tip, 3 mm in diameter and 45 cm in length.
- 4) Three trocars as work ports; two of 8 mm in diameter, one of 4 mm in diameter and a reducer.
- 5) A clipper of 3 mm diameter and 45 cm in length, which will use 2 mm long clips of titanium.

It is performed after local anesthesia in the areas corresponding to the incision, the first trocar to introduce is the 8 mm that will contain the chamber in the 4th intercostal space left mid axillary line. It is incised with cold scalpel on the skin, it is continued by planes and it is entered in pleural cavity, the other two trocars are introduced under direct visualization, first the one of 8 mm in the 6th left intercostal space and the one of 4 mm in the third intercostal left, both in the anterior axillary line. A pneumoinsulfination of 5 mmHg is used and the left internal mammary artery is dissected and then the right one is dissected.

Instrumentals to use:

- 1) Grasper delicate without zipper, 3 mm in diameter by 45 cm in length.
- 2) Hook 3 mm in diameter by 45 cm in length.

- 3) Clipper.
- 4) Plastic bulldog clip 3 mm in diameter by 4 mm in length.

The dissection of the left internal mammary artery is by delicate dissection of the same in the direction of caudal to cephalic with the grasper and the hook, and placing clips in all the collaterals that are visualized. Once the dissection is completed, a bulldog clamp is placed at the caudal end of the artery and sectioned.

The parietal pleura is then dissected and inserted into the anterior mediastinum. Semiology is performed with the camera, visualizing our objectives as a rectangular box, in the superior view we would have the posterior aspect of it thymus, in the inferior face the anterior face of the heart, in the front the parietal pleura of the right lung, in the union of the parietal pleura with the sternum, the right mammary artery is searched and it is dissected in the direction of caudal to cephalic, clips are placed in the collaterals and a bulldog caliper in its distal third. After dissection of both the right and left internal mammary artery, the opening of the pericardium with electrocoagulation is decided and the level of the obstruction is sought according to the surgical plan obtained by the cinecoronariography.

The second step of the surgical technique is carried out by interventional cardiologists and cardiovascular surgeons. The first perform a right femoral access with the placement of a 6 F introducer, then a 0.35 mm guidewire is inserted followed by a mammary guide catheter for the right or left mammary artery, under control by radioscopia and contrast material. Once the guide catheter is placed in contact with the mammary artery, the guidewire is removed 0.35 mm and a guidewire 0.14 mm is inserted to the end of the artery, which is occluded with the Bulldog clamp at its distal end; then the guide catheter is removed and the device is inserted until reaching the bulldog clip. At the moment the guidewire is seen with the thoracoscopic video device in the dissected internal mammary artery. Cardiovascular surgeons then perform a punctate incision of 1 mm diameter in the affected coronary artery, releasing the bulldog clamp and inserting the guidewire into the coronary artery orifice under direct vision. The device is then lowered and actuated, and the anastomosis is achieved. Under direct vision of the cardiovascular surgeons through video thoracoscopy, it is visualized that there is no leak in the anastomosis, a test of the internal mammary artery is carried out using a guiding catheter to evaluate the perfusion of the anastomosis.

Phase II: Clinical trials at this stage provide physicians with more information about the safety of the treatment and how well the device works. These studies also look at whether the new treatment is effective in coronary heart disease and we can know if the treatment is working. And demonstrate if it is safe as standard treatment in myocardial revascularization.

Phase II clinical studies take approximately 2 years. And 100 patients will be included, of which they will be divided into two groups: "group A" will have 50 patients who do not respond to the standard treatments of coronary disease and that is not recommended cardiac surgery of myocardial revascularization and group B of 50 patients, if cardiac myocardial revascularization surgery is recommended. To whom also by protocol will be made to sign the informed consent, explaining the risks and benefits of a procedure in an experimental stage. Everyone is going to have the same surgical technique. The controls would be done with radioscopia and contrast material for evaluation of the bypass. And they will be controlled in the periods of 3 (three) months, 6 (six) months to 1 (one) year after the application of the device; evaluating its feasibility, reproducibility, safety, operation and possible complications.

Phase III: In this phase, the two possible treatments, robotic surgery and minimally invasive surgery through the medical device will be assigned to different people who have indication of myocardial revascularization surgery. This phase of treatments is intended to include standard treatment as compared to innovative standard treatment.

Phase III clinical trials will include 1000 patients. It will continue with the same rules of the protocol. The goal is to determine if the new treatment is better than the standard treatment or if it has fewer side effects. They will be randomized. These studies include patients of different ages, ethnic backgrounds, and both sexes. This will help to apply the results to a large number of people.

Once the research shows that the treatment works well, the regulatory body may be asked to approve, for example: the FDA. If the data obtained in clinical trials comply with FDA regulations, the FDA will approve treatment for a specific use.

Values and Strengths of the Study

The advantage of this research protocol is that, by combining the information from various studies, they have sufficient statistical power to be able to answer our research question.

Ethical Considerations

The Research Protocol has conflicts of interest.

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