
Bando Giovani ricercatori

Presentazione del progetto preliminare / Preliminar Project

Titolo del progetto / Title of the project General anesthesia versus local anesthesia for percutaneous aortic valve implantation: a multi-centre, randomized trial

Tipologia di ricerca / Type of research

Ricerca Valutativa

Area tematiche / Tematic area

1) CARDIOCHIRURGIA/CARDIAC SURGERY

Descrizione preliminare del progetto / Preliminar description of the project

Scopi razionali, specifici e impatto sulla tematica / Rational purpose, and specific impacts on the subject (max 4000 caratteri):

Rapid progress in interventional cardiology has recently seen the rate of percutaneous coronary intervention overtake that of coronary artery bypass surgery. Now attention is directed towards the treatment of valvular heart disease, with exciting developments in balloon and stent technology having the potential to transform the management of many common heart conditions, such as aortic stenosis.

There is no evidence based medicine supporting the use of general or local anesthesia in this setting. It is not clear whether local anesthesia could reduce the need for intensive care unit and hospital costs.

Aortic stenosis is the most common form of valvular heart disease in adults, affecting thousands of patients every year and causing significant morbidity and mortality in case of disease.

Surgical aortic valve replacement is the treatment of choice for a vast majority of patients. Still, old patients with declining overall health status or life-threatening comorbidities, might be excluded from a too high risk surgical therapy. The size of this untreated cohort is expected to increase in the next several years reflecting the aging population and improving therapeutic options in patients with multiple and advanced medical conditions. Prognosis with medical management is poor, and effects of percutaneous balloon valvuloplasty are modest and short-lived. Given the limited therapeutic options in these patients, there has been interest in the development of percutaneous aortic valve implantation (PAVI) techniques. The rationale is that of minimizing the overall surgical trauma by avoiding sternotomy, aortotomy and the use of cardiopulmonary bypass, and by implanting the prosthesis on the beating heart thereby avoiding cardiac arrest.

Six years after the first-in-man, PAVI techniques are undergoing rapid development and dissemination (more than 20 Centres in Italy) and currently represent a dynamic field of research. Optimal strategies for these procedures keep on evolving. Most PAVI procedures have been performed under general anesthesia, but both general and local anesthesia have been reported in previous series. General anesthesia with endotracheal intubation facilitates sheath placement and removal, immobility during valve deployment, periprocedural transesophageal echocardiographic evaluation, eventual surgical repairment of arterial access site and patient management in case of complications. Yet general anesthesia is associated with important potential complications, particularly respiratory, which patients who are unfit for surgical aortic valve replacement may poorly tolerate. On the basis of the EUROSTAR data, high-risk patients attain the most important advantages from minimally invasive anesthetic techniques during endovascular aortic aneurysm repair: mortality, morbidity, hospital stay and ICU admission are significantly lower for regional and local versus general anesthesia. Similar benefits could be expected in high-risk patients undergoing TAVI with local anesthesia. A trend for shorter procedure time, time to ambulation, high-dependency unit stay and overall hospital stay has been observed in our experience. Each of these factors is significant both for patient morbidity and satisfaction, and for hospital efficiency and costs.

A large multicentre randomized trial of general versus local anesthesia will be useful to evaluate whether the choice of anesthetic technique affects the outcome of patients undergoing PAVI, so determining the ideal anesthetic technique for this procedure.

The study will be performed in cardiac surgery operating room or cardiac catheterization laboratory.

The primary endpoint will be the need for intensive care.

Secondary endpoints will be represented by mortality (30 days, 6 months, 1 year), intensive care unit and hospital stay.

Dati del presentatore / Researcher

Nome / Name REMO DANIEL

Cognome / Lastname COVELLO

Qualifica / Role: MEDICAL DOCTOR

Data e luogo di nascita / Date and place of birth: 02/05/1977, ROMA (RM)

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Attuale occupazione / Current Employment: Anesthesiologist and intensive care specialist

DI con cui si preferisce instaurare un rapporto di collaborazione: Fondazione Centro San Raffaele del Monte Tabor [IRCCS].

Profilo dell'investigatore / Profile of the researcher (2000 caratteri): Dr Covello Remo Daniel earned his degrees in Università degli Studi di Roma "La Sapienza" (cum laude) and University of Udine (cum laude), and is currently an anesthesiologist at the Department of Cardiovascular Anesthesia and Intensive Care, Istituto Scientifico San Raffaele, Milan.

He is in charge of the Trans-Catheter Cardiac Valves Therapies Program at the Department of Cardiovascular Anesthesia and Intensive Care, Istituto Scientifico San Raffaele, Milan.

He is member of SIAARTI (Società Italiana di Anestesia, Analgesia, Rianimazione e Terapia Intensiva), EACTA (European Association of Cardiothoracic Anaesthesiologists) and ITACTA (Italian Association of Cardiothoracic Anesthesiologists).

He coordinates the activities of the ITACTA Interest Group named "Anesthesiological management of percutaneous valve replacement" and he was faculty or invited speaker in numerous national and international congresses on this topic.

Sommario e Collaborazioni / Summary and Collaboration (max 2000 caratteri): He is in charge of the Trans-Catheter Cardiac Valves Therapies Program at the Department of Cardiovascular Anesthesia and Intensive Care, Istituto Scientifico San Raffaele, Milan.

He coordinates the activities of the ITACTA Interest Group named "Anesthesiological management of percutaneous valve replacement".

He created a network of collaboration among italian and european intensivists embarked in percutaneous valve implantation program.

He was faculty or invited speaker as an expert on percutaneous valve therapy.

He has been in the Faculty of interventional cardiology and cardiovascular surgery and anesthesia congresses:

-Jim 2008 (Joint interventional meeting, Milan, February 14th-16th, 2008). Course directors: A. Colombo, E Grube, MB Leon, GW Moses, C Di Mario.

-Jim 2009 (Joint interventional meeting, Milan, February 12th-14th, 2009). Course directors: A. Colombo, E Grube, MB Leon, GW Moses, C Di Mario.

-Aortic surgery and anesthesia "How to do it" (Milan, December 11th - 13th, 2008). Course directors: R Chiesa, O Alfieri, A Zangrillo.

He was invited speaker at International Congresses:

-Anesthesiological management of percutaneous aortic valve implantation.

62° Congresso Nazionale SIAARTI (Palermo, October 14th -17th, 2008).

-Periopertive anesthesiological challenges of the unfit patient "ideal candidate" of transfemoral aortic valve implantation.

Aortic surgery and anesthesia "How to do it" (Milan, December 11th - 13th, 2008).

He is a Reviewer for the Journal of Cardiothoracic and Vascular Anesthesia and for HSR proceedings in Intensive Care and Cardiovascular Anesthesia.

Fino a 5 dei migliori lavori scientifici del richiedente, indicando impact factor della rivista su cui è stato pubblicato il lavoro nell'anno di pubblicazione, il numero di citazioni dall'anno di pubblicazione fino all'anno di richiesta del finanziamento e l'indice-h / Up to 5 of the best scientific work of the applicant, indicating the impact factor in the year of publication, the number of citations since the publication until request for financing and the h-index. (max 2000 caratteri): Five best works - Covello Remo Daniel H index: 1

1. Crescenzi G, Covello RD, Landoni G, De Luca M, Fracasso G, Melone M, Serini SM, Bignami E, Rosica C, Zangrillo A. Thoracic epidural anesthesia in valvular cardiac surgery. *Eur J Anaesthesiol* 2008;25:339-340

Impact factor (2007): 1.4

Number of citations: 1

2. Crescenzi G, Rosica C, Marino G, Serini SM, Covello RD, Landoni G. The use of esmolol to treat systolic anterior motion of the mitral valve after mitral valve repair. *Eur J Anaesthesiol* 2008; 25: 342-343

Impact factor (2007): 1.4

Number of citations: 1

3. Covello RD, Maj G, Landoni G, Maisano F, Michev I, Guarracino F, Alfieri O, Zangrillo A. Anesthesiological management of percutaneous aortic valve implantation. *J Cardiothorac Vasc Anesth* 2009 in press

Impact factor (2007): 0.9

Number of citations: 0

4. Bove T, Monaco F, Covello RD, Zangrillo A. Acute renal failure and cardiac surgery. *HSR Proceedings in Intensive Care and Cardiovascular Anesthesia* 2009 in press

5. Covello RD, Landoni G, Michev I, Bignami E, Ruggeri E, Maisano F, Montorfano M, Alfieri O Colombo A, Zangrillo A. Percutaneous aortic valve implantation: the anaesthesiologist perspective. *HSR Proceedings in Intensive Care and Cardiovascular Anesthesia* 2009 in press

Fino a 5 dei lavori scientifici del richiedente sull'argomento oggetto della richiesta, indicando impact factor della rivista su cui è stato pubblicato il lavoro nell'anno di pubblicazione, il numero di citazioni dall'anno di pubblicazione fino all'anno di richiesta del finanziamento e l'indice-h / Up to 5 of the scientific work of the applicant on the subject of the request, indicating the impact factor in the year of publication, the number of citations since the publication until request for financing and the h-index(max 2000 caratteri): Five works on the subject of the request - Covello Remo Daniel H index: 1

1. Covello RD, Maj G, Landoni G, Maisano F, Michev I, Guarracino F, Alfieri O, Zangrillo A. Anesthesiological management of percutaneous aortic valve implantation. *J Cardiothorac Vasc Anesth* 2009 in press

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2. Covello RD, Landoni G, Michev I, Bignami E, Ruggeri E, Maisano F, Montorfano M, Alfieri O Colombo A, Zangrillo A. Percutaneous aortic valve implantation: the anaesthesiologist perspective. *HSR Proceedings in Intensive Care and Cardiovascular Anesthesia* 2009 in press

3. Zangrillo A, Ruggeri L, Covello RD. "Anesthesiological management of percutaneous aortic valve implantation" in *ETI Book (Endovascular Therapy International)* 2009 in press

4. Michev I, Colombo A, Denti P, Montorfano M, Covello RD, Zangrillo A, Alfieri O, Maisano F. The Buddy-Balloon technique: a method to facilitate retrograde crossing of the SAPIEN THV valve. *TCT (Trans-Catheter Cardiovascular Therapeutics symposium)* 12th -17th October 2008, Washington, USA

5. Covello D, Maj G, Landoni M, Crivellari M, Bignami E, Zangrillo A. Anesthesiological management of percutaneous aortic valve implantation: a focus on challenges encountered and proposal of solutions. *Comunicazione Libera, 62° Congresso SIAARTI, 14-17 Ottobre 2008, Palermo, Italia. Minerva Anesthesiol.* 2008;74(suppl.2 al n.10):7-8

Fino a 5 dei più recenti lavori scientifici del richiedente , indicando impact factor della rivista su cui è stato pubblicato il lavoro nell'anno di pubblicazione, il numero di citazioni dall'anno di pubblicazione fino all'anno di richiesta del finanziamento e l'indice-h / Up to 5 of the recent scientific work of the applicant, indicating the impact factor in the year of publication, the number of citations since the publication until request for financing and the h-index(max 2000 caratteri): Five recent works - Covello Remo Daniel H index: 1

1. Bove T, Monaco F, Covello RD, Zangrillo A. Acute renal failure and cardiac surgery. *HSR Proceedings in Intensive Care and Cardiovascular Anesthesia* 2009 in press

2. Covello RD, Maj G, Landoni G, Maisano F, Michev I, Guarracino F, Alfieri O, Zangrillo A. Anesthesiological management of percutaneous aortic valve implantation. *J Cardiothorac Vasc Anesth* 2009 in press

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