



Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Project Classification IRG: Healthcare Delivery and Methodologies

Project Classification SS: Health Services Organization and Delivery - HSOD

Project Keyword 1: Healthcare quality, effectiveness, and outcomes; clinical practice guidelines; treatment and prevention outcomes; patient and provider satisfaction; health status and outcomes assessment; evidence-based practice; health-related quality of life; medical decision-making.

Project Keyword 2: Treatment outcome, outcome assessment

Project Keyword 3: Aortic valve stenosis, heart valve prosthesis implantation, transcatheter aortic valve replacement, cardiac surgical procedure

Project Request:

Animals:

Humans:

Clinical trial:

The object/s of this application is/are under patent copyright Y/N:

Operative Units / WP

	INSTITUTION	Department/Division/Laboratory	Role in the project
1	Sicilia	Department of Cardiology, AOU-Vittorio Emanuele - Ospedale Ferrarotto	coordination of project activities, screening of scientific literature, clinical advice, finalization of the research products, drafting of scientific papers
2	University of Oulu, Faculty of Medicine	Department of Cardiothoracic Surgery	contribution to the conception and design of the study protocol, analysis and interpretation of data, clinical advice, finalization of the research products, drafting of scientific papers
3	Istituto Superiore di Sanità	National Center for Epidemiology, Surveillance and Health Promotion	study design, data management, epidemiological and statistical analysis, record linkage, finalization of the research products, drafting of scientific papers

Investigators, Institution and Role in the Project

	Co-PI	Key Personnel	Institution/Org./Pos.	Role in the project	Birth Date
1		Seccareccia Fulvia	Istituto Superiore di Sanità	study design, epidemiological and data analysis coordination, finalization of the research products, scientific papers drafting	05/07/1956
2	X	Capodanno Davide Francesco	AOU-Vittorio Emanuele - Ospedale Ferrarotto/Dept Cardiology /Interventional cardiologist	scientific literature review, clinical advice, finalization of the research products, scientific papers drafting	15/08/1979
3		Barbanti Marco	AOU-Vittorio Emanuele - Ospedale Ferrarotto/Dept Cardiology /Interventional cardiologist	interventional cardiology consultant; data analysis; scientific papers drafting	18/12/1983
4		D'Errigo Paola	Istituto Superiore di Sanità	data management, record linkage, statistical analysis, scientific papers drafting	28/06/1974



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Italian Researcher Abroad - Operative Unit Abroad

Name and Surname: Fausto Biancari
Foreign Institution: University of Oulu, Faculty of Medicine
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Overall Summary

Surgical aortic valve replacement (AVR) represents the gold-standard therapy for severe symptomatic aortic stenosis (AS), whose "benchmark" role was questioned by transcatheter aortic valve implantation (TAVI). This proposal is a rare attempt to analyze a low-to-intermediate risk AS patient population and to compare outcomes of TAVI, both old and new generation devices, with AVR in clinical practice.

As the referral of patients to the most suitable procedure is an emerging issue in health management, this proposal aims to generate a pre-procedural risk scoring method to identify AS patients who may benefit from each of these procedures. This score can lead clinicians and the national health system to take more appropriate actions for increasing quality of care and controlling costs. The linkage between clinical and administrative data will guarantee data on long-term follow-up analyses to define the impact of AVR and TAVI on costs related to re-hospitalizations and survival.

Background / State of Art

The prevalence of aortic valve stenosis (AS) among patients >75 years is around 40%. If untreated, severe AS is associated with poor prognoses. Transcatheter aortic valve implantation (TAVI) is a less invasive alternative to surgical aortic valve replacement (AVR) in high/prohibitive risk patients (1). Contrary to the original guidelines, Europe has largely moved to 'intermediate risk' in clinical practice in the last 3 years (2). Findings from the PARTNER 2 trial demonstrate the non-inferiority of TAVI vs AVR also in patients at intermediate-risk (3). As a signal of the worldwide interest towards this topic, the Food and Drug Administration has recently launched two RCTs of TAVI vs AVR in low risk patients, the PARTNER 3 and Evolut R Low Risk trials. Despite the availability of head-to-head RCTs, there is lack of data on the long-term outcome of TAVI and AVR in low/intermediate risk patients in a real-world setting. Observational outcome studies (OOSs) can be confirmatory of the effectiveness of therapies in more complex patients populations than those enrolled in RCTs. The OBSERVANT I study is an OOS on TAVI and AVR, which showed that, in Italy, TAVI is increasingly performed in patients without contraindications to AVR (4). This shift requires long-term data to evaluate the durability of TAVI compared to AVR in these patients. A new data collection, the OBSERVANT II study, will provide information on the potential benefits of current innovations in transcatheter technology

Hypotesis and Specific AIMS

Hypotesis and Significance:

Comparative analyses made within OBSERVANT I on pairs of patients matched by propensity score show similar 30-day and 1-year mortality rates in Italian patients undergoing either TAVI or AVR (4); a slight diverging trend of the survival curves occurs at 3 years. Our hypothesis is that the "non-inferiority" of TAVI vs AVR will not be confirmed for long-term outcomes, at least when considering the first generation TAVI devices. Conversely, as new technologies and interventional expertise improvements are expected to mitigate these differences (5) we hypothesize that data concerning TAVI



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performed with new generation devices (NGD), collected within OBSERVANT II, would allow the evaluation of the "non inferiority" of TAVI vs AVR, for early, medium and long-term follow-up (FU).

TAVI is proved to be a cost-effective treatment for high-risk patients with AS compared with AVR (6); we hypothesize that TAVI performed with NGD are cost-beneficial in terms of index admission and re-hospitalizations costs, also in an intermediate low-risk patient population.

Pre-operative risk scores used to select patients suitable for TAVI (i.e., EuroSCORE, EuroSCORE II and STS) are not tailored for nonsurgical AS populations. The OBSERVANT studies collect also individual risk factors not included in the available risk calculators. Our hypothesis is that the risk factors collected in OBSERVANT I and II would be suitable to build a valid risk scoring method for the prediction of outcomes in AS patients undergoing TAVI or AVR.

Preliminary Data:

OBSERVANT I collected information on pre-operative, demographic and clinical characteristics on 5707 AVR and 1911 TAVI patients.

The mean Log-EuroSCORE were 6.4% and 14.6%, respectively ($p < 0.001$), confirming a general trend to perform TAVI in patients at intermediate to low surgical risk (7).

Analyses performed on 650 pairs of intermediate-risk patients matched by propensity score, showed 30-day mortality rates of 3.2% for TAVI and 3.8% for AVR patients ($p = 0.546$) and 1-year mortality rates of 13.8% and 13.6% ($p = 0.912$), respectively (4).

Exploratory analyses indicate an initial diverging trend of the TAVI and AVR survival curves, at 3-year follow up. Other analyses show that some variables not included in the EuroSCORE are strongly associated with the short-term mortality after TAVI (i.e., severe frailty score $OR = 2.1$, NYHA class IV $OR = 2.0$, $p = 0.020$) (8).

The linkage between the OBSERVANT I database and the National Hospital Discharge Records (HDR) resulted in 97% of linked records.

Specific Aim 1:

To assess and compare the medium and long-term outcomes of a population with AS at intermediate/low risk undergoing AVR or TAVI.

Specific Aim 2:

To assess the early, medium and long-term costs related to index admission and re-hospitalizations for AVR and TAVI in a population with AS at intermediate/low risk.

Specific Aim 3:

To derive a new risk scoring method for predicting the outcomes of AS patients after TAVI or AVR.

Experimental Design Aim 1:

OBSERVANTI is an observational multicenter prospective cohort study collecting data on AS patients undergoing AVR and TAVI in Italian hospitals. Patients at low/intermediate operative risk are those assessed to verify the short term "non inferiority" of TAVI vs AVR according to the PARTNER 2A Trial hypothesis (9,10) and will be investigated in our studies to compare the medium- and long-term outcomes in a real-world AS population. To assess the impact of NGD TAVIs on both early and mid- to long-term outcomes, OBSERVANT I will be updated with a new data collection (OBSERVANT II).

As the OBSERVANT studies are not RCTs, clinical characteristics may not be balanced between groups of patients undergoing AVR or TAVI. As already tested in previous analyses (4), a propensity approach will be used to reconstruct a situation similar to randomization. All analyses performed to compare the early, mid and long-term effectiveness of first and



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NGD TAVIs vs AVR, will employ the AVR cohort enrolled in OBSERVANT I as reference. The two OBSERVANT databases will be linked with HDR-TR database (HDR +Tax Register) to retrieve FU data.

Experimental Design Aim 2:

To verify the hypothesis that TAVI performed with NGD are cost-beneficial in a low/intermediate risk population, the early, medium and long-term costs related to index admission and re-hospitalizations for the TAVI population enrolled in OBSERVANT II and for the AVR reference population from OBSERVANT I will be assessed. Information concerning patients' readmissions and life status will be retrieved in the HDR-TR database.

Costs of hospital admissions will be calculated using regional DRGs tariffs. Costs will be updated to year 2016 using the Consumer Price Index and integrated by the costs of the devices obtained from each producing companies.

Demographic and clinical characteristics reported in the OBSERVANT databases will be used to predict patients' cumulative costs within 1 and 3 years.

Experimental Design Aim 3:

Clinical characteristics of patients included in the two OBSERVANT cohorts will be used to generate and validate a new risk scoring method to predict 30-day all-cause mortality after intervention. The new risk score will include risk factors specific for the AS population which have not been considered in currently available risk scores. To allow the referral of patients to the most suitable procedure given their pre-procedural characteristics, a risk score calculator will be implemented in the OBSERVANT website (www.outcomeresearch.it/OBSERVANT).

Picture to support preliminary data:

picture.pdf

Methodologies and statistical analyses:

Study design. OBSERVANT I and II are OOSs including patients admitted to Italian hospitals with a diagnosis of severe AS (aortic valve area<1 cm², maximum aortic velocity>4 m/s, or mean pressure gradient>40 mmHg and NYHA class>=2) and requiring an interventional treatment.

OBSERVANT I was carried out in 2011-2012 and collected clinical data on 7618 patients who underwent either TAVI or AVR. A new data collection on TAVI patients treated with NGD (OBSERVANT II) is scheduled to start in December 2016 and will collect data on consecutive patients operated on during a period of 12 months.

OBSERVANT I and II will be linked with the HDR-TR database to retrieve FU information in terms of readmissions and life status (OBS-HDR-TR database).

The study end points are: 1) all-cause mortality, major adverse cardiac and cerebrovascular events (MACCE) and re-hospitalizations at 30-day, 36 and 60-month (OBSERVANT I only) from intervention; 2) short-, medium- and long-term hospitalization related costs.

Data analysis. AIM 1: Within OBSERVANT I, 650 matched pairs of TAVI and AVR patients were identified (4). Our first hypothesis is that TAVI performed with the first generation devices have a worse performance than AVR in terms of all-cause mortality and in-hospital MACCE at 60 months. Based on the survival curves of the 650 matched AVR and TAVI pairs from OBSERVANT I, we anticipate that 5 years mortality rate could be 44% after AVR and 54% after TAVI. With a power of 80% and one side alpha=0.05, 308 patients with 5-year FU for each procedure should be required to detect this difference (delta=10%). The 650 pairs will allow testing even a more restrictive hypothesis (delta=7%). The second hypothesis is that TAVI performed with the NGD is non-inferior to AVR at early, medium and long term FU. Starting from the 3 years mortality rates of the 650 matched pairs (24.4% after AVR; 28.7% after TAVI), TAVI will be considered non-inferior to AVR if the one-sided 95% upper confidence limit for the treatment difference will be <5% (alpha=0.05). The matched



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pairs required to verify this hypothesis are 279 (power=80%). As in OBSERVANT I the TAVI rate of pairing was 33.9%, OBSERVANT II should enroll 823 new TAVIs.

AIM 2: Devices and hospitalization costs will be estimated using regional DRG tariffs and the devices prices of the producing companies. Readmissions cost will be estimated accounting for the potential censored FU of each patient. The mean cumulative cost within 1 and 3 years will be estimated using the inverse probability weighting (IPW) estimator (11). The censoring distribution will be estimated using the Kaplan-Meier method. In the analysis of cost predictors, the method that account for censored medical costs proposed by Lin (12) will be used.

Factors associated with cumulative cost will be evaluated through the general linear models (GLM), using the survivor function for being censored during FU.

AIM 3: To construct a new risk scoring method for patients with severe AS, a logistic regression model will be estimated on the AVR population of OBSERVANT I and applied on the TAVI patients of the same cohort. Standardized mortality rates (SMR) will be calculated within risk classes identified according to AVR risk quantiles (RQ). SMR will be used to generate a three-class risk score: patients to be referred to TAVI (RQ with SMR significantly <1); patients to be referred to AVR (RQ with SMR significantly >1); patients for whom additional clinical evaluations are necessary to determine the proper therapeutic strategy. The estimated risk score will be updated using the TAVI population enrolled within OBSERVANT II.

Expected outcomes:

Main: early medium and long-term effectiveness of TAVI compared with AVR for AS in the Italian population at low/intermediate operative risk. As the survival curves built on first generation TAVI devices vs AVR showed a starting diverging trend at 3 years, we expect that such differences would become significant at 5 years of FU. Conversely, results from the data collection on NGD TAVI are expected to show comparable long term survival curves.

Interim: 1) satisfactory enrollment of AS patients in the participating hospitals. This requirement has been verified comparing OBSERVANT I with the HDR-TR database. The same result is expected for OBSERVANT II; 2) goodness of linkage between the two OBSERVANT and the HDR-TR databases. Based on our previous experience, the expected amount of linked data should be at least 95% of the overall OBSERVANT records.

Cost-analysis: costs estimation related to readmissions for TAVI performed with NGD and AVR, at early, mid- and long-term.

Risk score: an on-line risk calculator to stratify risk and to refer AS patients to the most suitable treatment.

Risk analysis, possible problems and solutions:

The same quality assessment arranged in OBSERVANT I will be implemented in OBSERVANT II to evaluate the reliability of the collected data. Hospitals with low quality of recorded data will be excluded from the analysis.

Data from OBSERVANT I were linked with the HDR-TR database achieving 97% of linked records. This result warrants the feasibility of a long-term FU with no drop-outs. At least 95% of linked records are expected in OBSERVANT II. If not, a semi-deterministic strategy with a progressive widening of matching criteria will be used. To avoid over-linkage due to this unspecific strategy, the linked records will be checked one by one.

Cost-estimations analyses can be biased in the presence of incomplete FU. To overcome this problem, the mean cumulative cost within 1-3 years will be estimated using the IPW estimator. As cost data could be positively skewed, factors influencing the cost of readmissions will be investigated evaluating alternative specifications in the GLM, as gamma distribution and logarithmic link function.

As the new risk score cannot be validated due to the lack of a gold standard, validation will be done using an alternative methodology: a predictive risk adjustment model will be estimated in the overall OBSERVANT I population; a new model with the estimated event probability (EEP) and the interaction between type of intervention (AVR or TAVI) and EEP will be built and the corresponding risk curve will be drawn. Three risk score classes will be defined according to the confidence



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bands of the risk curve. If more than 5% of patients do not fall into the same risk score class as determined via the main methodology, supplementary data could be collected to test new risk functions and compute a more reliable risk score.

Significance and Innovation

This proposal is a rare attempt to analyse a low-to-intermediate risk AS patient population and to compare outcomes and costs of TAVI, both old and NGD, with AVR in clinical practice.

The cross-linking with HDR-TR information is an innovative features which assures the feasibility of a long-term FU with no drop outs.

Also, the partnership with an ongoing European multicenter study on AVR, employing the same CRF of the OBSERVANT studies, will allow comparison of the results of NGD TAVI with minimally invasive AVR and sutureless valve prostheses as well.

The costs analysis related to hospital admissions after TAVI and AVR will be a useful and valid tool for the control of the NHS resource allocation.

Finally, the key innovative aspect of this proposal is the derivation of a risk scoring method that will be implemented as an on-line user-friendly score calculator, which will help clinicians to enhance referral of AS patients to the most appropriate treatment.

Description of the complementary and synergy research team

A full professor of cardiology (PI) with well-established experience with TAVI interventions and proven skill in project leading and coordination will ensure the achievement of all the expected goals of the proposal.

A full professor in cardiothoracic surgery (PE), leader of several multicenter studies at European level, well experienced in surgical/methodological issues and scientific paper drafting, will ensure appropriate clinical interpretation of the study findings, guarantee the achievement of some specific expected goals of the proposal, support the development of the pre-procedure score and contribute to the dissemination of results.

A senior epidemiologist with proven experience in comparative effectiveness evaluation will ensure the application of the appropriate methodologies and the critical interpretation of results.

Two senior statisticians with proven experience in record-linkage procedures, data management and statistical analysis of both clinical and administrative data will ensure the achievement of all the expected outcomes.

Two interventional cardiologists and one cardiac surgeon well experienced in clinical/methodological issues, data analysis and scientific paper drafting will guarantee appropriate clinical interpretation of the study findings and contribute to the dissemination of results.

A qualified technician will support all technical activities.

Training and tutorial activities

Training and tutorial activities to disseminate research methodology and findings will be carried out in the form of training workshops.

Participation in seminars, courses and conferences related to the subjects in the study is also planned for the researchers involved in the proposal.



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11. BANG H; Estimating medical costs with censored data. Biometrika 2000; 87:329-43
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Timeline / Deliverables / Payable Milestones

- 18 months. Review of the scientific literature on the project topic. Writing the final version of the study protocols. Finalizing all requirements and procedures for the start of OBSERVANT II. OBSERVANT web-site update tasks. Launch and conclusion of the new data collection. All required administrative databases acquisition. Updating of the OBSERVANT I FU. Check of the consistency and completeness of OBSERVANT II database. Record linkage procedures to generate the OBS-HDR-TR database. Three meetings of the research team.
- 36 months. HDR-TR database update. Quality analysis of the OBS-HDR-TR database. Data analyses. Critical discussion of results. Development, testing and implementation of the on-line risk calculators. Website update. Presentation of the on-line risk calculators to NHS operators. Dissemination of project results through a concluding meeting. Writing of the final report and submission for scientific publication. Three meetings of the research team on the final results.

Milestones 18 month

1. All protocols available
2. 5-year FU of OBSERVANT I available
3. The new data collection completed
4. All required administrative databases available
5. The OBS-HDR-TR database ready to be analyzed



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Milestones 36 month

1. All statistical analyses concluded
 - Long term FU analysis of OBSERVANT I
 - 1 to 3 years FU analyses of OBSERVANT II
 - new risk-score creation
 - cost-analysis
2. The on-line risk calculator available
3. A final project report drawn up

Gantt chart

gant chart.xlsx

Equipment and resources available

Sicily-Coordinating Center (U1): For the fulfillment of all project activities two PCs, a printer, a fax and a share of consumables and supplies will be put at project disposal. A SPSS statistical package will be put at Project disposal for data analysis. As human resources, besides the PI two interventional cardiologists will be directly involved in the study. They will contribute to various phases of the project, with particular reference to the critical interpretation of the results, writing scientific papers, and participation in national and international meetings to present and disseminate study results.

FAUSTO (U2): A PC, a printer, a fax and a share of consumables and supplies will be put at project disposal.

Istituto Superiore di Sanità (U3): five PCs, two printers, a fax, and a share of consumables and supplies will be put at project disposal. A dedicated portion of a local server for the storage of data will be created. The SAS statistical package will be used for the record linkage procedures, while both the SAS and STATA statistical packages will be put at Project disposal for data analysis. As human resources, a senior researcher will contribute to some phases of the project, with particular reference to the critical interpretation of the results, writing scientific papers, and participation in national and international meetings to present and disseminate study results. Two senior statisticians well experienced in data management and data analyses will contribute to all phases of the project concerning the statistical analysis. A consultant cardiac surgeon will be involved in the study according to specific need of the project phases. A technical assistant will be employed for cooperation in administrative and technical procedures related to project progress.



Ministero della Salute
Direzione Generale della Ricerca Sanitaria
e Biomedica e della Vigilanza sugli Enti

BANDO 2016 PROGETTO COMPLETO

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Translational relevance and impact for the National Health System (SSN)

The proposed research will allow evaluation of the relative performance of AVR and TAVI in low/intermediate risk patients from the real world, thus generating knowledge directly transferable to clinical practice. Findings from this research will help NHS professionals monitor and control the by now documented shift of TAVI toward low-risk patients. The new risk score will provide the NHS with a valid tool for a proper resources allocation. It will support clinicians in the referral of AS patients to the most appropriate therapeutic approach, helping to avoid futile interventions, preventing repeated hospitalizations and re-interventions and enhancing patient quality of life and life expectancy. As the OBSERVANT I was carried out in 2011-12 and its database is immediately usable, an interim version of the new risk score might already be available for a testing period within the first 18 months. The proposed strategy can be easily applied to similar topics concerning therapeutic choices.



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PRINCIPAL INVESTIGATOR PROFILE

Name	Institution	Sicilia
Tamburino Corrado	Department/Unit	Department of Cardiology, AOU- Vittorio Emanuele - Ospedale Ferrarotto
	Position Title	Full Professor of cardiology, Interventional cardiologist, Coordinator of the project activities

Education/Training - Institution and Location	Degree	Year(s)	Field of study
Centre medico-chirurgicale" Parly-Grand-Chesnay, LenChesnay, France	Postdoctoral Research Fellowship	1993	Interventional cardiology
University of Catania	Postgraduate School in Cardiology (50/50 with honors)	1991	Cardiology
University of St. Antoine, Paris, France	Postdoctoral Research Fellowship	1990	Interventional cardiology
University of Pitié - Salpetriere Paris, France	Postdoctoral Research Fellowship	1988	Interventional cardiology
University of Catania	Doctorate in Physiopathology of Metabolism	1988	Health
University of Catania	M.D. (Medical Doctor)	1982	Health

Personal Statement

He is Full Professor of Cardiology and directs the Complex Unit of Cardiology of the Ferrarotto University Hospital in Catania. He cooperates with several foreign universities and clinical centers. He has published over 500 scientific articles. He has introduced in Italy the treatment of severe aortic disease by TAVI. For his proven experience and skills, he will coordinate all the project activities, giving clinical advice. Moreover, he will contribute to the finalization of the research products and to the writing of of scientific papers for the dissemination of the study results.



Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Positions and Honors

Institution	Division / Research group	Location	Position	From year	To year
Ferrarotto Hospital - University of Catania	Institute of Cardiology	Catania	Consultant Cardiologist	1989	1993
Ferrarotto Hospital - University of Catania	Complex Unit of Cardiology	Catania	Associate Professor of Cardiology; Coordinator of Cath Lab	1993	2001
Ferrarotto Hospital - University of Catania	Complex Unit of Cardiology	Catania	Full Professor of cardiology	2001	2016
AOU-Vittorio Emanuele - Ospedale Ferrarotto	Transplantation and Vascular Surgery Department	Catania	Chief	2005	2016
AOU-Vittorio Emanuele - Ospedale Ferrarotto	Cardiology Division and Cardio -Thoracic & Vascular Department	Catania	Head	2005	2016

Grant, Awards and Honors

Official H index: 41.0

Source: Scopus

Scopus Author Id: 7006304483

ORCID ID: orcid.org/0000-0002-4940-9742

RESEARCH ID: -

Awards and Honors:

Sicilian Regional Advisor of the Section of the SIC (1990/93 and 1996/99)
National Counselor of the Italian Group of Studies in Hemodynamics and Interv Cardiology (1992/96, 2005/07)
National Counselor of the SIC (1998/2002)
President of the Italian Society of Invasive Cardiology (2007/09)
Fellow of the ESC
Fellow of the Society for Cardiovascular Angiography and Interventions and the Trustee
Member of the Board of auditors of the journal Cardiology
Member of the Cardiology Commission for the Sicilian Region
President of the Sicilian Regional Committee for the Network of MI

Other CV Informations:

CT introduced in Sicily endomyocardial biopsy and mitral, aortic and pulmonary valvuloplasty, as well as all the alternative procedures to Interventional Cardiology Coronary balloon. Operator of about 20,000 diagnostic and interventional procedures in hemodynamics with particular application in coronary angioplasty and stenting and in the treatment of heart valves diseases.

He was the first in Italy (2007) to perform the implantation of biological aortic valve percutaneously on inoperable patients and in 2008 he made the first mitral clip implant for the treatment of mitral valve prolapse.



Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

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Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Selected peer-reviewed publications of the PI

Valid for PI minimum expertise level									
Title	Publication / Journal	Pag	Vol	Year	DOI	PMID	IF	Cit.	P.*
5-Year Outcomes after Transcatheter Aortic Valve Implantation with CoreValve Prosthesis	JACC: Cardiovascular Interventions	1084-1091	8 (8)	2015	10.1016/j.jcin.2015.03.024	26117458	7.63	12	L
1-year outcomes after transfemoral transcatheter or surgical aortic valve replacement: Results from the Italian OBSERVANT study	Journal of the American College of Cardiology	804-812	66 (7)	2015	10.1016/j.jacc.2015.06.013	26271063	17.759	21	F
Impact of balloon post-dilation on clinical outcomes after transcatheter aortic valve replacement with the self-expanding CoreValve prosthesis	JACC: Cardiovascular Interventions	1014-1021	7 (9)	2014	10.1016/j.jcin.2014.03.009	25234674	7.63	7	L
Percutaneous mitral valve repair with the MitraClip system for severe mitral regurgitation in patients with surgical mitral valve repair failure	Journal of the American College of Cardiology	836-838	63 (8)	2014	10.1016/j.jacc.2013.09.045	24161329	17.759	9	L
Transcatheter aortic valve implantation in patients with mitral prosthesis	Journal of the American College of Cardiology	1841-1842	60 (18)	2012	10.1016/j.jacc.2012.07.037	23099216	17.759	5	L
Transcatheter aortic valve implantation: 3-year outcomes of self-expanding CoreValve prosthesis	European Heart Journal	969-976	33 (8)	2012	10.1093/eurheartj/ehr491	22240494	15.064	173	L
The valve-in-valve technique for treatment of aortic Bioprosthesis malposition: An analysis of incidence and 1-year clinical outcomes from the Italian CoreValve Registry	Journal of the American College of Cardiology	1062-1068	57 (9)	2011	10.1016/j.jacc.2010.11.019	21349397	17.759	56	L
Incidence and predictors of early and late mortality after transcatheter aortic valve implantation in 663 patients with severe aortic stenosis	Circulation	299-308	123 (3)	2011	10.1161/CIRCULATIONAHA.110.946533	21220731	17.047	628	F
Percutaneous coronary intervention versus coronary artery bypass graft surgery in left main coronary artery disease: A meta-analysis of randomized clinical data	Journal of the American College of Cardiology	1426-1432	58 (14)	2011	10.1016/j.jacc.2011.07.005	21939824	17.759	84	L



Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Title	Publication / Journal	Pag	Vol	Year	DOI	PMID	IF	Cit.	P.*
EuroSCORE refines the predictive ability of SYNTAX score in patients undergoing left main percutaneous coronary intervention	American Heart Journal	103-109	159 (1)	2010	10.1016/j.ahj.2009.10.021	20102874	4.332	86	L
Percutaneous mitral valve repair with the MitraClip system: Acute results from a real world setting	European Heart Journal	1382-1389	31 (11)	2010	10.1093/eurheartj/ehq051	20299349	15.064	145	F
Quality of life assessment after percutaneous aortic valve implantation	European Heart Journal	1790-1796	30 (14)	2009	10.1093/eurheartj/ehp171	19443421	15.064	70	L

* Position: F=First L=Last C=Correspondent



Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

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Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

For evaluation CV

Title	Publication / Journal	Pag	Vol	Year	DOI	PMID	IF	Cit.
5-Year Outcomes after Transcatheter Aortic Valve Implantation with CoreValve Prosthesis	JACC: Cardiovascular Interventions	1084-1091	8 (8)	2015	10.1016/j.jcin.2015.03.024	26117458	7.63	12
1-year outcomes after transfemoral transcatheter or surgical aortic valve replacement: Results from the Italian OBSERVANT study	Journal of the American College of Cardiology	804-812	66 (7)	2015	10.1016/j.jacc.2015.06.013	26271063	17.759	21
Impact of balloon post-dilation on clinical outcomes after transcatheter aortic valve replacement with the self-expanding CoreValve prosthesis	JACC: Cardiovascular Interventions	1014-1021	7 (9)	2014	10.1016/j.jcin.2014.03.009	25234674	7.63	7
Percutaneous mitral valve repair with the MitraClip system for severe mitral regurgitation in patients with surgical mitral valve repair failure	Journal of the American College of Cardiology	836-838	63 (8)	2014	10.1016/j.jacc.2013.09.045	24161329	17.759	9
Transcatheter aortic valve implantation in patients with mitral prosthesis	Journal of the American College of Cardiology	1841-1842	60 (18)	2012	10.1016/j.jacc.2012.07.037	23099216	17.759	5
Transcatheter aortic valve implantation: 3-year outcomes of self-expanding CoreValve prosthesis	European Heart Journal	969-976	33 (8)	2012	10.1093/eurheartj/ehq491	22240494	15.064	173
The valve-in-valve technique for treatment of aortic Bioprosthesis malposition: An analysis of incidence and 1-year clinical outcomes from the Italian CoreValve Registry	Journal of the American College of Cardiology	1062-1068	57 (9)	2011	10.1016/j.jacc.2010.11.019	21349397	17.759	56
Incidence and predictors of early and late mortality after transcatheter aortic valve implantation in 663 patients with severe aortic stenosis	Circulation	299-308	123 (3)	2011	10.1161/CIRCULATIONAHA.110.946533	21220731	17.047	628
Percutaneous mitral valve repair with the MitraClip system: Acute results from a real world setting	European Heart Journal	1382-1389	31 (11)	2010	10.1093/eurheartj/ehq051	20299349	15.064	145
Quality of life assessment after percutaneous aortic valve implantation	European Heart Journal	1790-1796	30 (14)	2009	10.1093/eurheartj/ehp171	19443421	15.064	70



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 Direzione Generale della Ricerca Sanitaria
 e Biomedica e della Vigilanza sugli Enti

BANDO 2016 PROGETTO COMPLETO

Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Grant						
Funded Institution / Country	Year	Title	Position in Projects	Fund (€)	Source / Funding Inst.	Att.*
-	-	-	Coordinator	0	-	No

* Attached Certification Letter

Certification letter:



Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Biographical Sketch Contributors 1

Name: Fausto Biancari	Institution University of Oulu, Faculty of Medicine
	Department/Unit Department of Cardiothoracic Surgery
	Position Title Full Professor in Cardiothoracic Surgery, Cardiac Surgeon

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Oulu	Specialist	2004	Cardiothoracic Surgery
University of Helsinki	PhD	2000	Vascular Surgery
University of Roma	Specialist	2000	General Surgery
University of Roma	MD (Medical Doctor)	1993	Medicine

Personal Statement:

Medical Doctor Degree in 1993, PhD in 2000, Specialist in General Surgery in 2000, Specialist in Cardiothoracic Surgery in 2004, Full Professor in Cardiothoracic Surgery: he has large experience in organizing and conducting clinical studies in the fields of cardiac surgery, thoracic surgery, cardiology and vascular surgery. Within the present project, he will contribute to all phases of the project, with particular reference to the conception and design of the study protocol, analysis and interpretation of the data and writing of the articles.

Institution	Division / Research group	Location	Position	From year	To year
University of Oulu	Department of Surgery	Oulu, Finland	Full Professor	2015	2016
Oulu University Hospital	Department of Surgery	Oulu, Finland	Consultant	2004	2016

Awards and Honors

Official H index: 33.0

Source: Scopus

Scopus Author Id: 7006099650

ORCID ID: orcid.org/0000-0001-5028-8186

RESEARCH ID: -

Awards and Honors:

Northern Finland Research of the Year - May 2016

Finnish Society for Thoracic Surgery - Nov 2015

Paride Stefanini Prize - Italian Society for Surgery - Oct 2000



Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Biographical Sketch Contributors 2

Name: Seccareccia Fulvia	Institution	Istituto Superiore di Sanità
	Department/Unit	National Center for Epidemiology, Surveillance and Health Promotion
	Position Title	Senior Researcher

Education/Training - Institution and Location	Degree	Year(s)	Field of study
Istituto Superiore di Sanità, Rome, Italy	Trainee	1980	Epidemiology and Biostatistics
University of Rome "La Sapienza", School of Biology, Rome, Italy	Graduated in Biological Sciences	1979	Biological Sciences

Personal Statement:

FS graduated in Biological Sciences in 1979. Her field of interest is mainly the outcome research; she was the coordinator and scientific leader of many national and international projects on this topic. She will contribute to all phases of this proposal, with particular reference to the study design, coordination of the data analysis, critical interpretation of the results, writing of scientific papers representing official outputs of the project and to the participation in national and international meeting to present and spread the results of the study.

Institution	Division / Research group	Location	Position	From year	To year
Istituto Superiore di Sanità	National Centre for Epidemiology, Surveillance and Health Promotion; Department of Clinical Epidemiology and Guidelines	Rome, Italy	Senior Researcher	2013	2016
Istituto Superiore di Sanità	National Centre for Epidemiology, Surveillance and Health Promotion, Department of Cardiac and Cerebrovascular Diseases	Rome, Italy	Senior Researcher	2007	2013
Istituto Superiore di Sanità	National Centre for Epidemiology, Surveillance and Health Promotion; Department of Cardiac and Cerebrovascular Diseases	Rome, Italy	Researcher	1999	2006
Istituto Superiore di Sanità	Laboratory of Epidemiology and Biostatistics, Department of Epidemiological Data Analysis	Rome, Italy	Technical Assistant	1991	1998
Istituto Superiore di Sanità	Laboratory of Epidemiology and Biostatistics; Department of Non-Infectious Diseases	Rome, Italy	Technical Assistant	1985	1990



Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Awards and Honors

Official H index: 27.0

Source: Scopus

Scopus Author Id: 7006166472

ORCID ID: orcid.org/0000-0003-4135-2806

RESEARCH ID: -

Awards and Honors:

Project Leader and member of the Steering Committee in many Italian and European research projects in competitive calls.
Member and Responsible for the Istituto Superiore di Sanità in many Commissions on cardiovascular topics.
Course Director and Teacher in annually institutional (ISS) courses concerning outcome research.
Invited Speaker in several national and international Scientific Meetings
Winner (as UO Responsible) of a grant within the "Bando della Ricerca Finalizzata-Giovani Ricercatori 2009"



Project Title:
Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Biographical Sketch Contributors 3

Name: Capodanno Davide Francesco	Institution AOU-Vittorio Emanuele - Ospedale Ferrarotto/Dept Cardiology /Interventional cardiologist
	Department/Unit Department of Cardiology
	Position Title Associate Professor, Interventional cardiologist

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Catania	PhD	2011	Hypertension and related organ damage
University of Florida	Post-doctoral Associate,	2009	Thrombosis and Haemostasis
University of Catania	Cardiovascular Specialist	2008	Cardiology
University of Catania	MD (Medical Doctor)	2004	Medicine and Surgery

Personal Statement:

He received his MD and PhD from the University of Catania and spent his research fellowship period at the University of Florida in Jacksonville, FL. He has authored more than 300 manuscripts has delivered more than 200 invited lectures around the world. His areas of expertise include interventional cardiology, clinical trials and biostatistics. He is peer reviewer of 20 international journals. Within this project, he will contribute to the screening of scientific publications and the critical interpretation of the results and participate in the writing of scientific papers.

Institution	Division / Research group	Location	Position	From year	To year
AOU-Vittorio Emanuele - Ospedale Ferrarotto	General Surgery and Medical-Surgical Subspecialties	Catania	Associate Professor	2014	2016
University of Catania	Medical and Pediatric Sciences Department	Catania	Researcher	2011	2014
University of Catania	Cardiology	Catania	PhD	2011	2014
University of Florida	Shands-College of Medicine	Jacksonville	Post-Doc	2009	2009
AOU-Vittorio Emanuele - Ospedale Ferrarotto	Cardiology	Catania	Cardiology Fellows	1998	2008



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BANDO 2016 PROGETTO COMPLETO

Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Awards and Honors

Official H index: 34.0

Source: Scopus

Scopus Author Id: 25642544700

ORCID ID: orcid.org/0000-0002-5156-7723

RESEARCH ID: -

Awards and Honors:

- 2016 Most cited article - Eurointervention
- Elite Reviewer Award - Eur Heart J for years 2013, 2014, 2015
- 2012 Scholar in Cardiology - Italian Society of Cardiology, Italy
- 2011 TCT's Thomas J. Linnemeier's Spirit of Interventional Cardiology Young Investigator Award - Columbia Research Foundation, USA
- 2009 Young Investigator Award - Italian Society of Cardiology, Italy
- 2008 Best Thesis Award - Italian Society of Cardiology, Italy
- 2007 Young Investigator Award - Progress in Acute Coronary Syndromes, Italy
- 2006 Young Investigator Award - Italian Society of Cardiology, Italy



Project Title:

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Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Biographical Sketch Contributors 4

Name: Barbanti Marco	Institution AOU-Vittorio Emanuele - Ospedale Ferrarotto/Dept Cardiology /Interventional cardiologist
	Department/Unit Department of Cardiology
	Position Title Interventional cardiologist

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Catania	Post-graduate Research Associate	2015	Cardiology
University of Catania	Postgraduate Diploma	2014	Cardiology
St Paul's Hospital - University of British Columbia, Vancouver, Canada	Clinical/Research Fellowship	2013	Interventional Cardiology
University of Catania	MD (Medical Doctor)	2008	Medicine and Surgery

Personal Statement:

Graduated in medicine in 2008 at Catania University, MB started his training in interventional cardiology in 2010. He obtained a position as a clinical/research fellow at St Paul's Hospital, Vancouver (supervision of John Webb). In July 2014 MB obtained the postgraduate Diploma in Cardiology. He has first authored numerous publications in many first tier. MB will represent a clinical interface of the research team for cardiological issues. He will help in some phases of the data analyses. His experience in scientific paper drafting will contribute to the dissemination of the study results.

Institution	Division / Research group	Location	Position	From year	To year
AOU-Vittorio Emanuele-Ospedale Ferrarotto	Department of Cardiology	Catania, Italy	Cardiologist fellow	2014	2016
St Paul's Hospital, University of British Columbia	Department of Cardiology	Vancouver, BC, Canada	Clinical/Research Fellow	2012	2013
AOU-Vittorio Emanuele-Ospedale Ferrarotto	Department of Cardiology	Catania, Italy	Cardiology Resident	2009	2014

Awards and Honors

Official H index: 25.0

Source: Scopus

Scopus Author Id: 26665263900

ORCID ID: orcid.org/0000-0002-4903-5437

RESEARCH ID: -

Awards and Honors:



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BANDO 2016 PROGETTO COMPLETO

Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Best abstract submitted from Canada (ACC 2013, San Francisco)

Best case of the year (TVT 2013, Vancouver)

Winner TCT 2014 Thomas J. Linnemeier Spirit of Interventional Cardiology Young Investigator Award



Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Biographical Sketch Contributors 5

Name: D'Errigo Paola	Institution Istituto Superiore di Sanità	Department/Unit National Centre for Epidemiology, Surveillance and Health Promotion	Position Title Researcher
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Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Bologna and Florence, Bologna	Master in Biostatistics	2003	Biostatistics
University of Rome "La Sapienza", Rome	Degree in Statistical Sciences	1999	Statistic

Personal Statement:

PD is a senior statistician. Her field of interest is mainly the outcome research. She was responsible of UO in a study strictly related to the matter of this project, funded by a grant from Ministry of Health. She will contribute to all phases of the study, with particular reference to the construction and management of the database, to the statistical analysis, to the critical interpretation of the results and to the scientific papers drafting.

Institution	Division / Research group	Location	Position	From year	To year
Istituto Superiore di Sanità	National Centre for Epidemiology, Surveillance and Health Promotion	Rome	Researcher	2000	2016

Awards and Honors

Official H index: 9.0

Source: Scopus

Scopus Author Id: 18233334900

ORCID ID: orcid.org/0000-0002-3174-4278

RESEARCH ID: -

Awards and Honors:

- Winner (as UO Responsible) of the grant GR-2009-1605075
- Winner (as UO Responsible) of the grant RF-2013-02355908
- Winner of the ACCA'S Choice 2013, Acute Cardiac Care 12-14 October, Madrid Spain.
- Winner of the Cardiovascular Research Technology (CRT) Choice 2015, CRT 21-24 February, Washington DC, USA
- Project Leader and member of the Steering Committee in many Italian and European research projects in competitive calls.
- Course Director and Teacher in annually institutional (ISS) courses concerning outcome research.



Project Title:

Comparative effectiveness and costs analysis of AVR and TAVI procedures for severe symptomatic aortic stenosis treatment in the era of new generation devices

Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Expertise Research Collaborators

Selected peer-reviewed publications of the Research Group / Collaborators									
Collaborator	Title	Publication / Journal	Pag	Vol	Year	DOI	PMID	IF	Cit.
D'Errigo Paola	Transcatheter aortic valve implantation compared with surgical aortic valve replacement in low-risk patients	Circulation: Cardiovascular Interventions	Article number e003326	9 (5)	2016	10.1161/CIRCINTEVENTIONS.115.003326	27154298	5.706	1
Seccareccia Fulvia	Transcatheter Aortic Valve Replacement for Severe Aortic Stenosis Patients Undergoing Chronic Dialysis	Journal of the American College of Cardiology	93-94	66 (1)	2015	10.1016/j.jacc.2015.03.598	26139065	17.759	0
Barbanti Marco	Transcatheter aortic valve implantation in failed bioprosthetic surgical valves	JAMA - Journal of American Medical Association	162-170	312(2)	2014	10.1001/jama.2014.7246	25005653	37.684	83
Barbanti Marco	Permanent pacemaker implantation after transcatheter aortic valve implantation impact on late clinical outcomes and left ventricular function	Circulation	1233-1243	129 (11)	2014	10.1161/CIRCULATIONAHA.113.005479	24370552	17.047	46
Barbanti Marco	Predictive factors, management, and clinical outcomes of coronary obstruction following transcatheter aortic valve implantation: Insights from a large multicenter registry	Journal of the American College of Cardiology	1552-1562	62 (17)	2013	10.1016/j.jacc.2013.07.040	23954337	17.759	75
Barbanti Marco	Anatomical and procedural features associated with aortic root rupture during balloon-expandable transcatheter aortic valve replacement	Circulation	244-253	128 (3)	2013	10.1161/CIRCULATIONAHA.113.002947	23748467	17.047	97
Fausto Biancari	Immediate and late outcome of patients aged 80 years and older undergoing isolated aortic valve replacement: A systematic review and meta-analysis of 48 studies	American Heart Journal	477-485	163 (3)	2012	10.1016/j.ahj.2011.12.005	22424020	4.332	53
Capodanno Davide Francesco	Global risk classification and clinical SYNTAX (Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) score in patients undergoing percutaneous or surgical left main revascularization	JACC: Cardiovascular Interventions	287-297	4(3)	2011	10.1016/j.jcin.2010.10.013	21435606	7.63	84



Project Title:

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Project Code: PE-2016-02364619

Principal Investigator: Tamburino Corrado

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Collaborator	Title	Publication / Journal	Pag	Vol	Year	DOI	PMID	IF	Cit.
Capodanno Davide Francesco	Percutaneous coronary intervention versus coronary artery bypass graft surgery in left main coronary artery disease: A meta-analysis of randomized clinical data	Journal of the American College of Cardiology	1426-1432	58(14)	2011	10.1016/j.jacc.2011.07.005	21939824	17.759	84
Capodanno Davide Francesco	Usefulness of SYNTAX Score to Select Patients With Left Main Coronary Artery Disease to Be Treated With Coronary Artery Bypass Graft	JACC: Cardiovascular Interventions	731-738	2 (8)	2009	10.1016/j.jcin.2009.06.003	19695541	7.63	98

Grant

Funded Institution / Country	Year	Title	Position in Projects	Fund (€)	Collaborator	Source / Funding Inst.	Att.*
La Fondazione Istituto Neurologico Casimiro Mondino	2016	Idiopathic Normal Pressure Hydrocephalus (iNPH), parkinsonism and dementia: improving the accuracy of diagnosis and the patient care to reverse the symptomatology Neurodegeneration, Phenotypes and Outcome Measures	Collaborator	380920	D'Errigo Paola	Italian Ministry of Health; http://www.salute.gov.it/imgs/C_17_pagineAree_4357_listaFile_itemName_1_file.pdf	Yes
Istituto Superiore di Sanità	2011	TAVI versus traditional approaches in treating severe symptomatic aortic stenosis	Collaborator	226350	D'Errigo Paola	Italian Ministry of Health; http://www.salute.gov.it/imgs/C_17_bandi_63_listaFile_itemName_0_file.pdf	Yes
Emilia Romagna Region	2011	Quality of life, cognitive abilities and costs of transcatheter aortic valve implantation and surgical aortic valve replacement	Collaborator	540000	Seccareccia Fulvia	Italian Ministry of Health; http://www.salute.gov.it/imgs/C_17_bandi_63_listaFile_itemName_0_file.pdf	Yes

* Attached Certification Letter (Y/N)

Certification letter: Grants certification letters.pdf



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Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Proposed total budget (Euro)

Costs	Budget Year 1	Budget Year 2	Budget Year 3	TOTAL BUDGET	Co-Funding	List of costs proposed for funding to the moh
1 Staff salary	139.500,00	139.500,00	139.500,00	418.500,00	418.500,00	
2 Researchers contracts	76.000,00	76.000,00	73.000,00	225.000,00	0,00	225.000,00
3a Equipment (leasing)	11.000,00	7.000,00	7.000,00	25.000,00	0,00	25.000,00
3b Supplies	5.000,00	4.000,00	2.500,00	11.500,00	0,00	11.500,00
3c Model costs	0,00	0,00	0,00	0,00	0,00	0,00
4 Subcontracts	0,00	0,00	0,00	0,00	0,00	0,00
5 Patient costs	0,00	0,00	0,00	0,00	0,00	0,00
6 IT services and data bases	30.000,00	10.000,00	10.000,00	50.000,00	0,00	50.000,00
7 Travels	18.000,00	19.000,00	18.000,00	55.000,00	0,00	55.000,00
8 Publication costs	0,00	2.000,00	2.000,00	4.000,00	0,00	4.000,00
9 Training and Dissemination	0,00	2.000,00	2.500,00	4.500,00	0,00	4.500,00
10 Overheads	45.000,00	0,00	0,00	45.000,00	0,00	45.000,00
11 Coordination costs	6.000,00	6.000,00	18.000,00	30.000,00	0,00	30.000,00
Total	330.500,00	265.500,00	272.500,00	868.500,00	418.500,00	450.000,00

Report the Co-Funding Contributor:

The Department of Cardiology, Azienda Ospedaliero Universitaria Policlinico-Vittorio Emanuele-Ospedale Ferrarotto, the Istituto Superiore di Sanità, and the Regional Health Authority of Lazio will be the co-funding contributors through the salary of the respective permanent staff involved into the project.

In particular, the Department of Cardiology, Azienda Ospedaliero Universitaria Policlinico-Vittorio Emanuele-Ospedale Ferrarotto, will contribute with 500 h/year of a Full Professor of Cardiology and 750 h/year of an interventional cardiologist; the University of Oulu will contribute with 500 h/year of a full professor in Cardiothoracic Surgery; the Istituto Superiore di Sanità will contribute with 500 h/year of a senior epidemiologist researcher, 350 h/year of a senior statistician and 350 h/year of an administrative technician.



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Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Budget Justification

1 Staff salary	A Full Professor of Cardiology (500h/year); a cardiologist (750h/y); a professor in cardiothoracic surgery (500h/y); a senior epidemiologist (500h/y), a senior statistician (350 h/y); a cardiac surgeon (50 h/y); an administrative technician (350h/y)
2 Researchers contracts	One 2 years and 11 months research contract for Unit 1 activities; one 3 years research contract for Unit 3 activities
3a Equipment (leasing)	Costs to create and maintain portions of local servers for the data storage (Unit 3). Two PCs and a printer through a leasing contract for three years (Unit 1 and 3)
3b Supplies	Toners; paper; pen-drives, CDs and DVDs for data storages; other consumables and supplies useful for the project activities (Unit 1 and 3)
3c Model costs	-
4 Subcontracts	-
5 Patient costs	-
6 IT services and data bases	Two 3 years SAS statistical package licenses (Unit 3) and 2 STATA statistical package license (Unit 1 and 3). Set-up, up-date and maintenance of a dedicated Web-site and implementation of the score calculator (Unit 3)
7 Travels	Travels costs and living expenses of all the researchers involved in the proposed study for the participation to meetings concerning project activities (Unit 1 and 3)
8 Publication costs	Costs for dissemination of results through scientific publication (Unit 1 and 3)
9 Training and Dissemination	Costs for dissemination of results through the participation to national and international congresses (subscription fees, travels costs and living expenses) (Unit 1 and 3)
10 Overheads	General indirect costs
11 Coordination costs	Costs for the organization of working group meetings, conference calls and final congress (CME, conference room, catering, etc..) (Unit 1)



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Applicant Institution: Sicilia

Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Proposed budget distribution (Euro)

Costs	Unit 1 Total Budget	Unit 1 costs MOH funding	Unit 2 Total Budget	Unit 2 costs MOH funding	Unit 3 Total Budget	Unit 3 costs MOH funding
1 Staff salary	231.000,00		52.500,00		135.000,00	
2 Researchers contracts	111.000,00	111.000,00	0,00		114.000,00	114.000,00
3a Equipment (leasing)	5.000,00	5.000,00	0,00		20.000,00	20.000,00
3b Supplies	6.000,00	6.000,00	0,00		5.500,00	5.500,00
3c Model costs	0,00	0,00	0,00		0,00	0,00
4 Subcontracts	0,00	0,00	0,00		0,00	0,00
5 Patient costs	0,00	0,00	0,00		0,00	0,00
6 IT services and data bases	2.000,00	2.000,00	0,00		48.000,00	48.000,00
7 Travels	40.000,00	40.000,00	0,00		15.000,00	15.000,00
8 Publication costs	2.000,00	2.000,00	0,00		2.000,00	2.000,00
9 Training and Dissemination	2.000,00	2.000,00	0,00		2.500,00	2.500,00
10 Overheads	22.000,00	22.000,00	0,00		23.000,00	23.000,00
11 Coordination costs	30.000,00	30.000,00				
Total	451.000,00	220.000,00	52.500,00	0,00	365.000,00	230.000,00

Legend

Unit 1: Sicilia

Unit 2: University of Oulu, Faculty of Medicine

Unit 3: Istituto Superiore di Sanità



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Project Type: Italian researcher abroad/Progetti con ricercatore italiano

Principal Investigator Data

Cognome: Tamburino

Nome: Corrado

Codice fiscale: TMBCRD58E21C351H

Documento: Carta d'identità, Numero: AR0601449

Data di nascita: 21/05/1958

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Qualifica: Professore

Struttura: Ospedale Ferrarotto

Istituzione: Azienda Ospedaliero Universitaria Policlinico-Vittorio Emanuele