



Ospedale
di Circolo
Fondazione
Macchi



Facoltà di Medicina
e Chirurgia

Cardiac Surgery Unit

Head: Prof. Cesare Beghi

Object: Investigation of suspected misconduct

The present letter is in response to the investigation of suspected misconduct. The accusations refer to the paper "*Relationship between atrial histopathology and atrial fibrillation after coronary bypass surgery* (J Thorac Cardiovasc Surg 2006;131:1364-72)".

According to your request, based on un-coded data:

Question #1 – The early material (n=55).

Effectively ID#1 accounts for the same patient. The only difference is the left ventricular ejection fraction (37% vs 60%). The correct value is 37%. Possibly the value 60% refers to an echocardiographic examination preoperatively done in another hospital. Admitted patients generally are subjected to an internal echocardiography, this is a common practice in many hospitals.

Question #2 – The early material (n=55).

Effectively patients with the ID#18 and ID#51 present a longer ventilation time than ICU time. This error is also present in the un-coded dataset, possibly due to column (ICU time-ventilation) inversion during data input.

Question #3 – The updated material (n=70).

The coded method used the initials of surname and name. These identical initials relate to 25 different persons (2 AA; 4 BM; 3 CA; 2 LA; 2 MA; 3 MG; 3 MM; 2 RG; 2 SG; 2 TM).

Question #4 – The updated material (n=70).

The updated material with 70 patients reasonably contains 55 patients from the early material.

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Question #5 – The updated material (n=70).

The data with a ventilation time exceeding the ICU time is also present in the original un-coded dataset. A column (ICU time-ventilation) inversion seems to be occurred during data input. It cannot be excluded that for a minority of patients, the reason is that some subject could have been transferred to another ICU (general intensive care unit or cardiologic intensive care unit) due to the contingent need of beds in the thoracic ICU.

Question #6 – The updated material (n=70).

The data is not unusual. Patients undergoing elective uncomplicated cardiac operations are extubated at 7 to 7.30 am and transferred to cardiac surgery ward from around 8.30 am to 9 am.

Question #7 – The updated material (n=70).

For each coded patient corresponds a histopathological analysis and with the un-coded dataset it is possible to retrieve it.

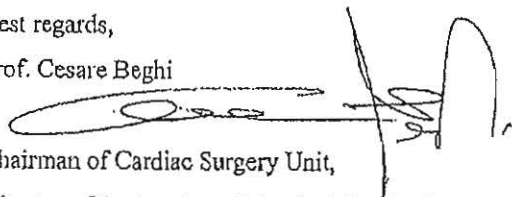
In addition, the manuscript "*Relationship between atrial histopathology and atrial fibrillation after coronary bypass surgery* (J Thorac Cardiovasc Surg 2006;131:1364-72)" exactly matches to another manuscript co-author's PhD thesis, which was deeply analysed and formerly discussed by the involved Professors of University of Insubria during its preparation, analysis and dissertation (academic year 2004-2005) without finding data irregularities.

The present document is addressed to the committee appointed to investigate the suspicious only.

Varese, 19th April 2012

Best regards,

Prof. Cesare Beghi



Chairman of Cardiac Surgery Unit,

Director of Postgraduate School of Cardiac Surgery

Ospedale di Circolo e Fondazione Masechi, Varese

Università dell'Insubria, Varese e Como



Ospedale
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Facoltà di Medicina
e Chirurgia

Cardiochirurgia

Direttore: Cesare Beghi

Object:

Investigation of suspected misconduct – supplementary request

We've appreciated our involvement in the present investigation, aimed to clarify the issue about the suspected misconduct on the paper by Mariscalco and colleagues (J Thorac Cardiovasc Surg 2006; 131:1364-1372).

We expect that this issue could be definitively concluded above all considering that University of Insubria and Faculty of Medicine have never questioned the validity of the above paper and study.

Concerning the supplementary requests:

Sensitive personal data are strictly regulated in our Country by a specific act (Decreto legislativo 30 giugno 2003, n.196 – D.Lgs 196/2003). Patient Identity/information are coded and cannot be traced by unauthorised. Providing for each single patient information such as data of operation, involved surgeon or histological report, will generate a combination of parameters specific enough to easily identify name, surname, address, social status, social card number, etc. for every one of them.

Nevertheless, considering the entire cohort of patients and the supplementary request:

a) Data of operation

All patients were affected by critical coronary artery disease without cardiac valve involvement. Year 2002-2003: a total of 43 patients were operated on isolated coronary artery bypass grafting with and without cardiopulmonary bypass (CPB). Age of the patients: 64.9 ± 8.9 years; 20 subjects were affected by preoperative acute myocardial infarction and 7 had a left main stem stenosis. All patients received a median of 2 grafts (range: 1 to 4 grafts). For patients operated on CPB (cCABG group, conventional coronary artery bypass grafting), median aortic-cross clamp time was 54 minutes (range: 15 to 110 min) and median CPB time was 85 minutes (range: 32 to 164 min). Median of total bleeding was 800 mL (range: 540 to 1300 mL). No intra-operative mortality was observed.

Year 2004-2005: a total of 27 patients were operated on isolated coronary artery bypass grafting with and without CPB. Age of the patients: 65.4 ± 8.1 years; 19 subjects were affected by

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preoperative acute myocardial infarction and 4 had a left main coronary artery disease. Patient group received a median of 2 grafts (range: 1 to 4 grafts). For patients operated on CPB (cCABG group), median aortic-cross clamp time was 45 minutes (range: 28 to 72 min) and median CPB time was 71 minutes (range: 43 to 102 min). Median of total bleeding was 450 mL (range: 220 to 860 mL). Similarly, no intra-operative mortality was registered.

b) Surgeons involved

Andrea Sala, MD, Prof (co-author)

Sandro Ferrarese, MD, PhD (co-author)

Andrea M. Musazzi, MD, PhD

Vittorio Mantovani, MD, PhD

Giuseppe P. Cozzi, MD (co-author)

Other surgeons are omitted because they moved from Varese Hospital.

- c) The histological report includes the identity (name/surname) of each patient and is not identifiable just by a code. A specific format for the histological report was realised for the study, listing name/surname, code and histological observations. That reports list in a semiquantitative scale (multiple choices) histological data/observations of the atrial appendage tissue with reference to myocytes (degree of vacuolization - vacuole density and size -, hypertrophy, atrophy, lipofuscin content, nuclear derangement) and interstitial tissue (oedema, mononuclear exudates, fibrosis, fibroelastosis, arteriolar hypertrophy), respectively.
The histological diagnosis/observations can be retrieved for each patient from the corresponding rows/columns of the excel dataset.

Varese, 27 June 2012

Best regards,

Professor Cesare Begli

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