



Belgische Vereniging voor Cardio-Thoracale Heelkunde (BVCTH)
Société Belge de Chirurgie Cardio-Thoracique (SBCCT)
Belgian Association for Cardio-Thoracic Surgery (BACTS)

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Report on the demographics, management and outcome of the surgical treatment for acute type A aortic dissection. A prospective study in Belgian cardiac surgical centers over a one-year period (2008-2009) with a one-year follow-up.

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Introduction

According to its memory of understanding (see annexe 1), the database committee of the BACTS was charged by the Board of the BACTS to obtain and analyse prospective data on the management of acute aortic dissection in our country. This catastrophic aortic disease is amenable to surgical treatment in any Belgian centres with cardiac facilities. Its relatively low incidence was felt compatible with the extra workload imposed to each centre for the participation to this study. It was estimated that between 0 to 10 cases in each centre should satisfy to the inclusion criteria of this study.

In this report, we provide :

- a short overview of the epidemiology, natural history, physiopathology and current management of this disease **(p.2-3)**
- the methodology of the current study **(p. 4)**
- purpose, design of the study **(p.5)**

- We report the descriptive statistics of the available data : **(p.6)**
 - patient demographics,
 - aetiology,
 - diagnosis,
 - surgical management,
 - postoperative complications,
 - immediate outcome,
 - outcome at one year.

- Conclusions **(p.20)**
- Appendix **(p. 21)**
 - . Invitation letter
 - . Questionnaire
 - . MOU



Acute aortic dissection : epidemiology, natural history, physiopathology, classification

Acute dissection of the thoracic aorta is one of the most common dreadful aortic conditions that is encountered in clinical surgical practice.

Its incidence has been reported to be approximately 2.9 per 100,000/year (Meszaros E et al., Chest, 2000). The natural history, owing to its physiopathology, is ominous with a mortality rate considered to be as high as 1% per hour during the first 48H after the onset of symptoms (Lindsay J and Hurst JW, Circulation, 1967 – McCloy RM et al., Circulation, 1965). Appropriate treatment is best provided by a team approach because the aortic dissection process can affect any part of the circulation, and potentially cause a dysfunction of the heart and malperfusion of the brain, the spinal cord, the gastrointestinal tract, the kidneys and the extremities. For acute aortic dissection involving the ascending aorta, emergent or urgent surgical treatment is warranted with the aim to fix the aortic root and replace the ascending aorta.

Even in the current era, the overall mortality remains as high as 20-25% (respectively Prospective Randomised Evaluation of Cryolife Biogluce and International Registry of Aortic Dissection; Hagan Pg et al. for IRAD, JAMA 2000).

Aetiology :

The initial event in this disease is an intimal disruption at any level of the aorta, but most frequently involving the ascending aorta or the isthmic region of the thoracic descending aorta. The disease is not an intimal disease. Endothelial cells and their basement membrane do not possess significant intrinsic tensile strength and their disruption is due to a lack of appropriate mechanical support from the medial layer. The media, in most instances, is abnormal, secondary to genetic structural abnormalities (Marfan disease, Loeys-Dietz syndrome, other connective tissue disorders...) or a degeneration of the media with muscular cells apoptosis and proteoglycans accumulation (cystic medial degeneration typically seen in hypertensive patients). A combination of both presumably genetic or/and mechanical stress factors is reasonable in aortic bicuspidy with dilatation of the ascending aorta.

Other aetiologies involve trauma, iatrogenic complications (cardiac catheter or cardiac surgery) and pregnancy (third trimester, delivery and immediate postpartum).

Miscellaneous causes account for the remaining aetiologies.

Physiopathology:

Acute aortic dissection develops from a tear within the intima of the aortic wall. Blood flows across this entry into a weakened media (usually cystic medial degeneration) splitting the medial layers along the direction of flow and creating a new "false channel" within the aortic media. This new channel progresses downstream and significant pressure-mechanical stress is exerted by the advancing column of blood on the aortic side-branches encountered in its path. Individual branch will either tear (leading to a communication between the false lumen and the original "true" lumen of the aorta) or close off, causing a so called "malperfusion" of the organ supplied by the given arterial branch. The side branches that tear become known as re-entry points or fenestration (Pochettino & Bavaria, Mastery of Cardio-thoracic Surgery, 2007).



Classification :

The prognosis of this disease depends on whether the dissection process involves the ascending aorta and/or the remaining descending thoracic aorta or is exclusively located to the descending thoracic aorta.

According to the Stanford classification, the dissections involving the ascending aorta are type A dissection. The dissections not involving the ascending aorta are type B (Fig 1).

The ominous prognosis of type A acute aortic dissections is linked to local complications that lead to the death of the patient. These are :

1. Cardiac ischemia by compression of the coronary ostia.
2. Tamponnade into the pericardial sac or acute rupture of the ascending aorta into the pericardial sac.
3. Acute left ventricular failure by the development of acute aortic insufficiency.

Other complications linked to malperfusion are obviously possibly associated.

On the contrary, dissection involving exclusively the thoracic aorta, considered as type B (often associated to atherosclerosis – penetrating aortic ulcer), are susceptible to retrograde extension, impending rupture or malperfusion, but are usually best treated with anti-impulse therapy and possibly endovascular treatment.

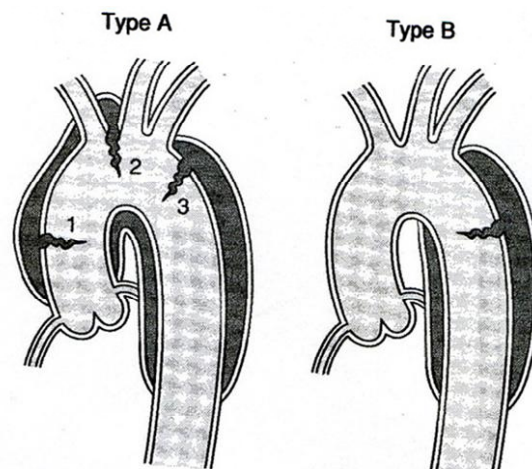


Figure 1 : Stanford classification of aortic dissections



Purpose and methodology of the study

The mission of the database committee within the BACTS, beside data collection is to “create therapeutic or epidemiological studies involving the cardio-thoracic therapy with the intention to improve the quality of care.

This sentence is extracted from the MOU of the database committee (see annexe or available at <http://www.bacts.org/doc/10747>). The database committee proposed, in 2008, a pilot study on acute type A aortic dissection. Acute was defined as a dissection treated within one week following the onset of symptoms. All patients with these criteria arriving alive in OR were to be enrolled.

The goals of this study were to obtain data concerning :

1. the incidence of acute aortic dissection in our country;
2. the proportion of the different aetiologies;
3. the modalities used for diagnosis;
4. the surgical management;
5. the incidence and the type of postoperative complications;
6. the immediate outcome;
7. an estimation of the survival at one year follow-up.

This study was approved by the board of the directors of the BACTS. The participation was obligatory for every Belgian centres within the BACTS.

This obligation is indirectly imposed by the royal decree of February 15, 1999 – College of Cardiac Surgery. This decree imposes to our society to organize projects to improve the quality of care in cardio-thoracic surgery.



Type of the study

- Prospective from June 1, 2008 to May 31, 2009
- - Inclusion criteria : all patients, all centres within the BACTS
acute type A dissection (within one week after the onset of symptoms)
patients arriving alive in OR.
- - Data collection : questionnaire established by the database committee (see appendix)

All the questionnaires from every centres were sent Miss C. Vandeweyer, Database Manager of the BACTS. The data were anonymized and then sent back as excell'spreadsheet to the investigators.

Data analysis : ULg, Department of Biostatistics (Prof. A. Albert, Mrs L. Seidel).
Ad Hoc Committee for the pilot study (MA Radermecker, E de Worm, C Stefanidis).

Acknowledgement :

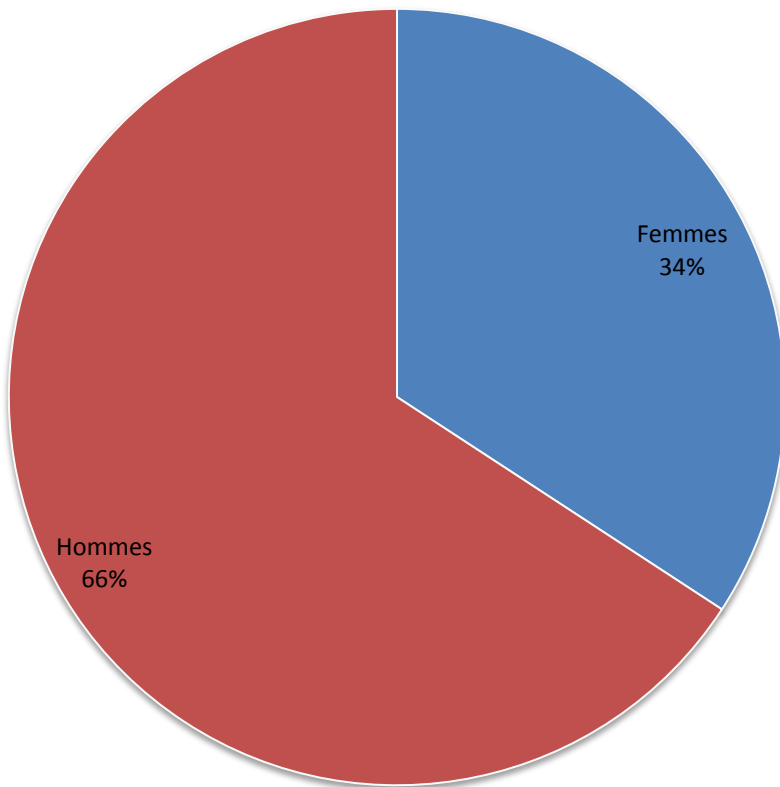
The contribution and collaboration of every Belgian center participating to this study was much appreciated.

The authors and the Database Committee thank Mrs C. Vandeweyer for her important logistic contribution to the study.



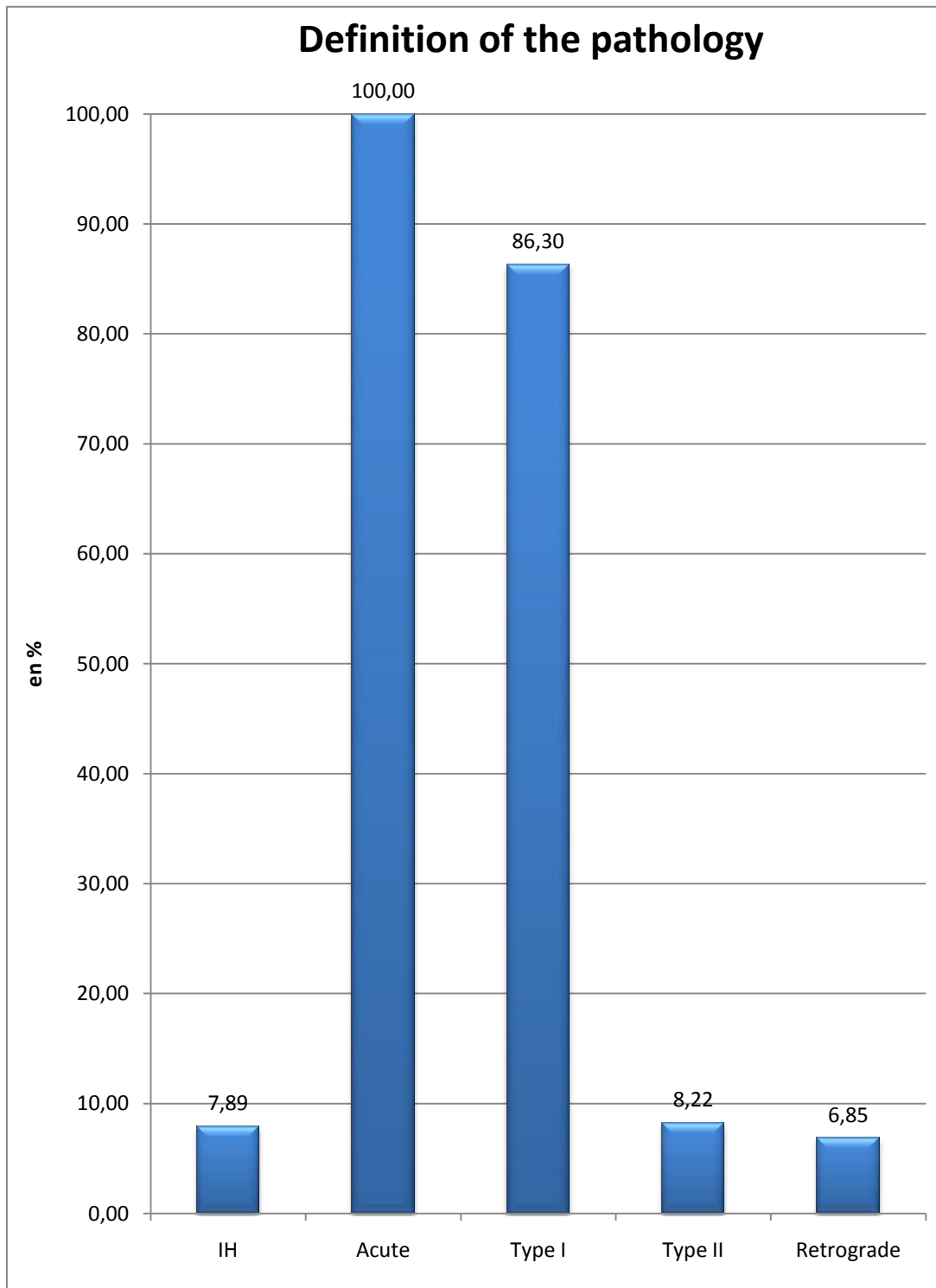
Results

Male/Female
n = 75

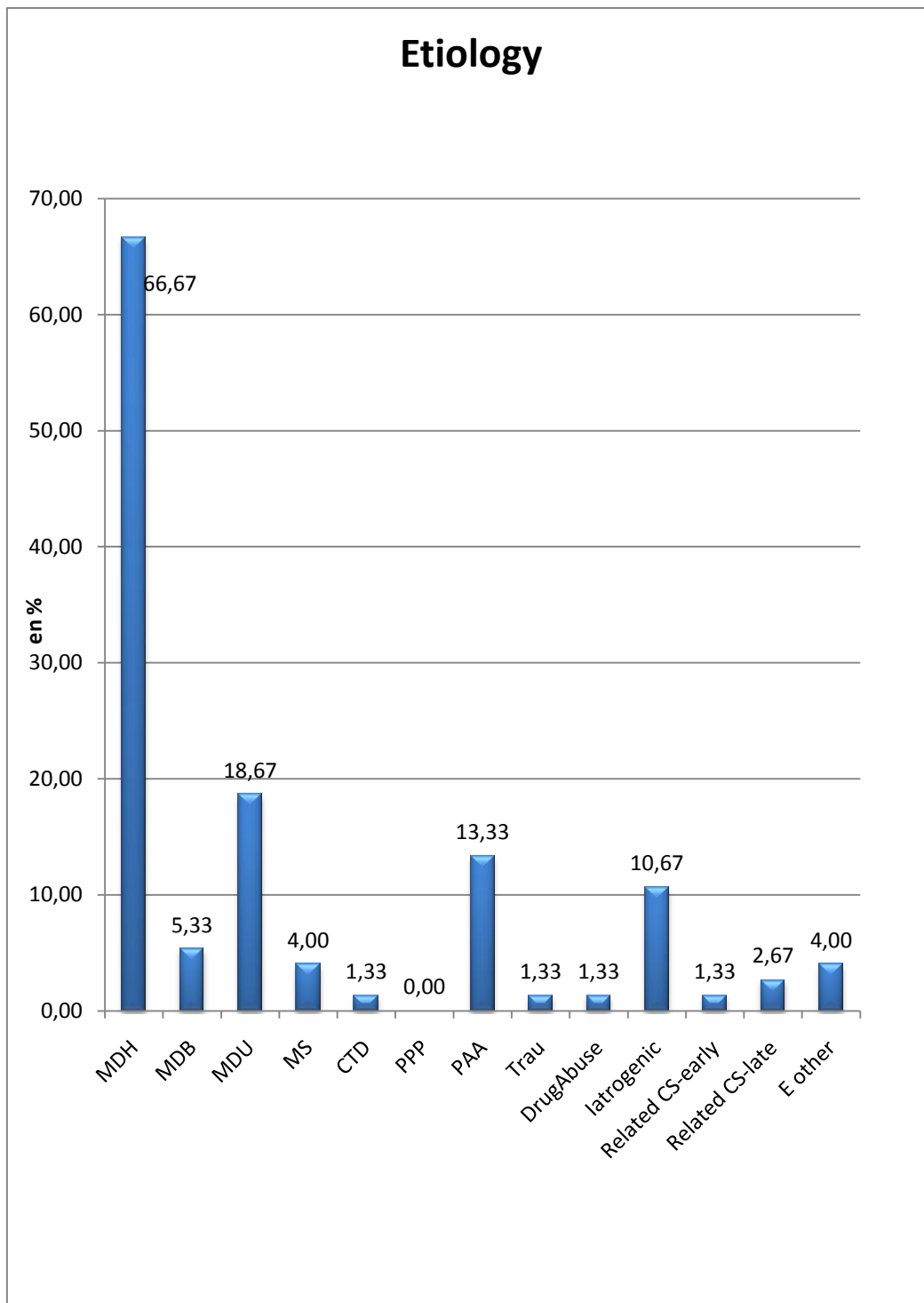




Definition of the pathology



IH = intramural hematoma



MDH : medial degeneration – hypertension

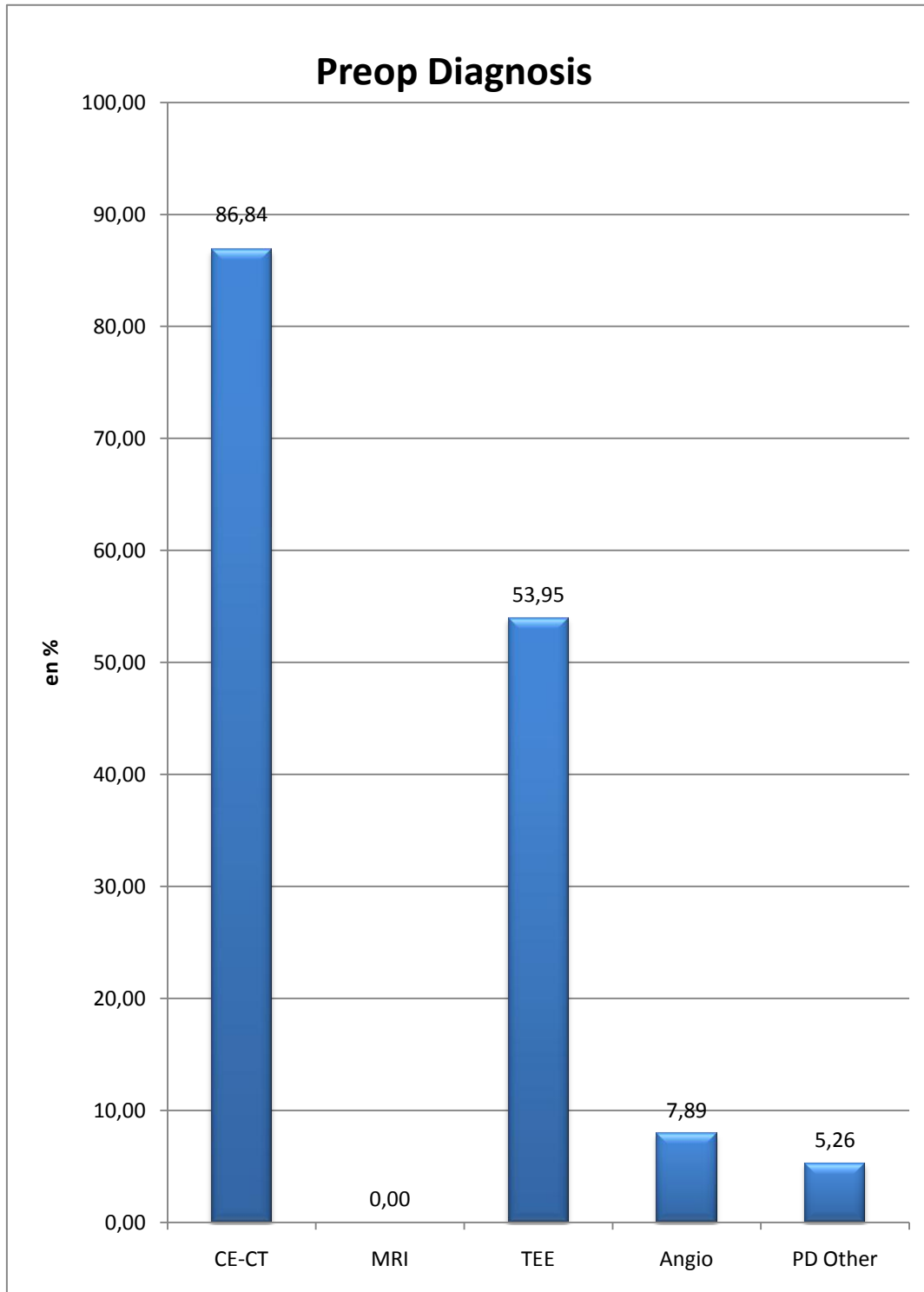
MDB : medial degeneration – bicuspidy

MDU : medial degeneration – unknown

MS : Marfan syndrom

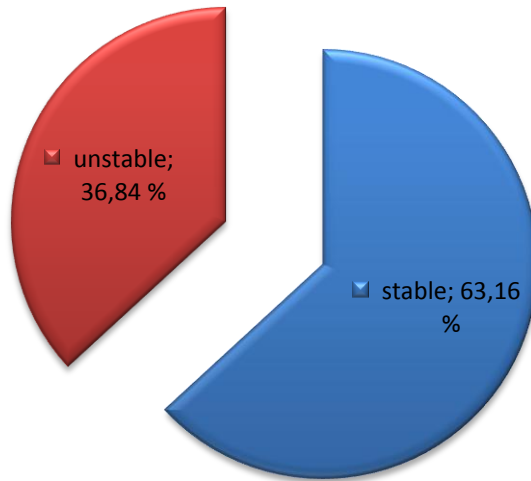
PPP : pregnancy- post partum

PAA : pre-existing aneurysm

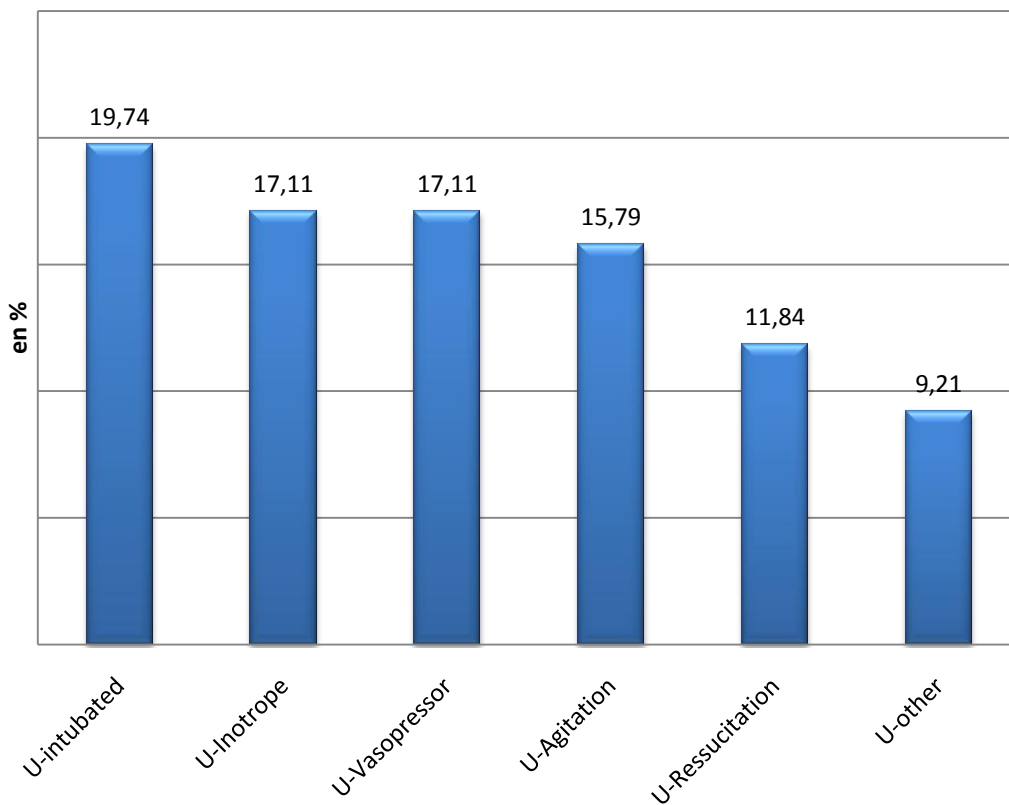


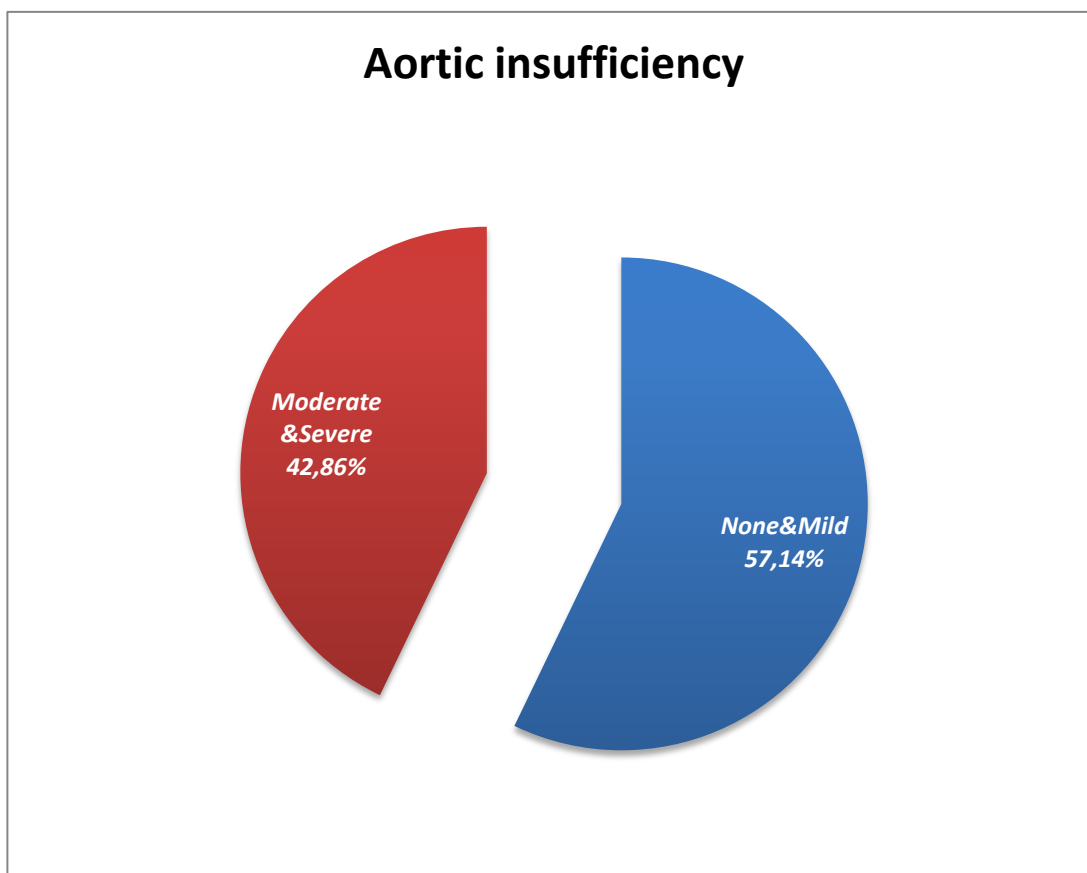
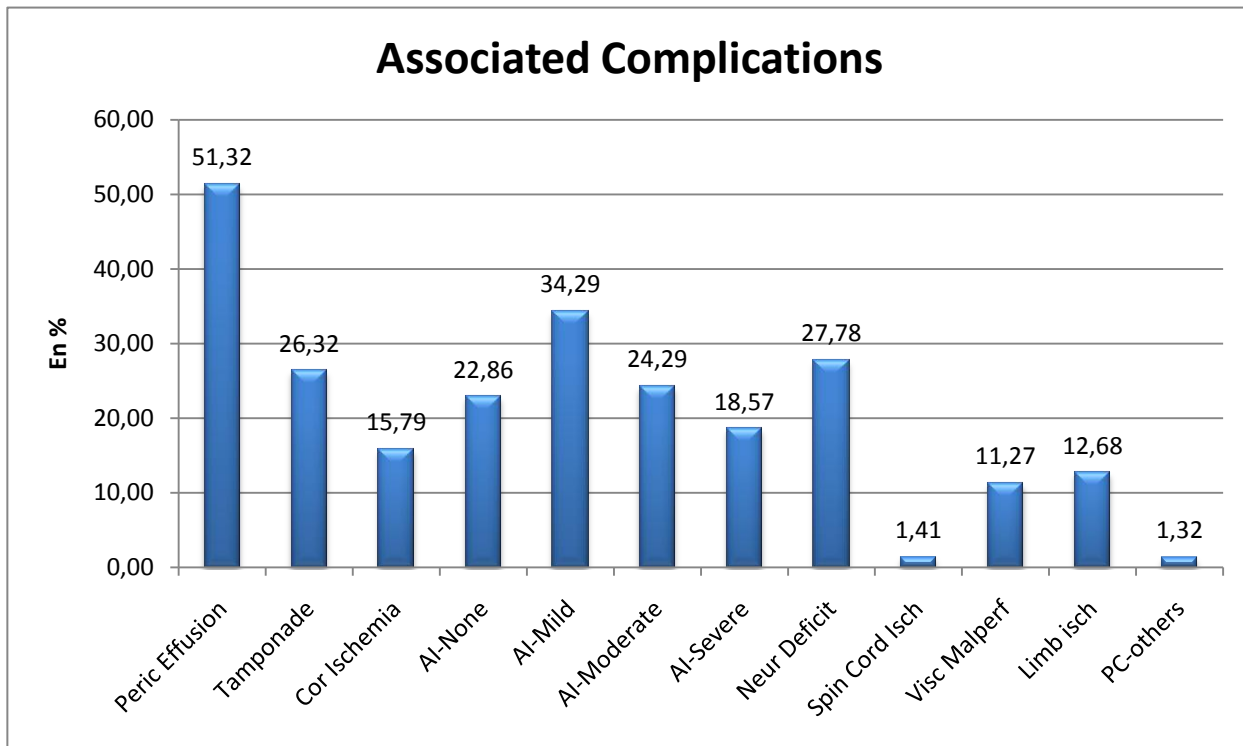


Preop status



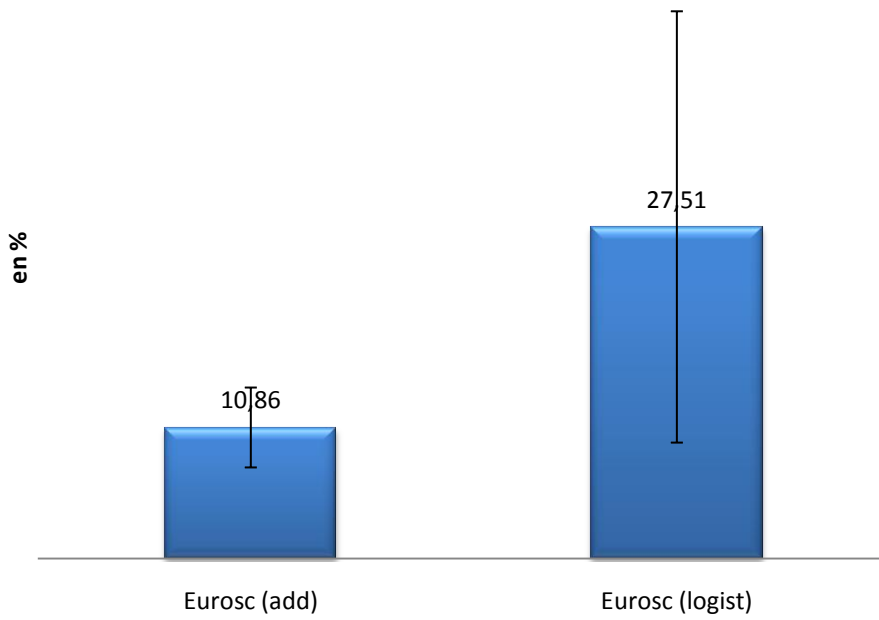
Unstable definition



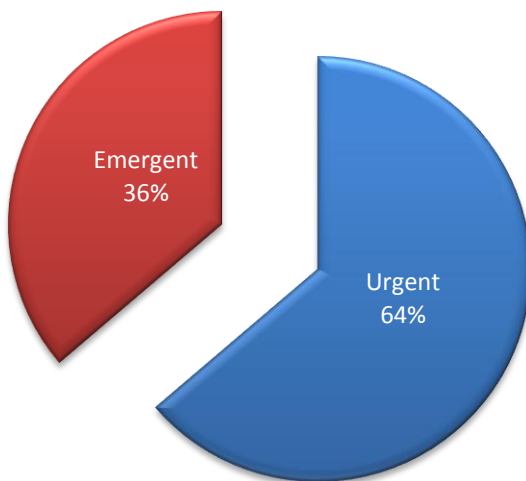




Severity scores



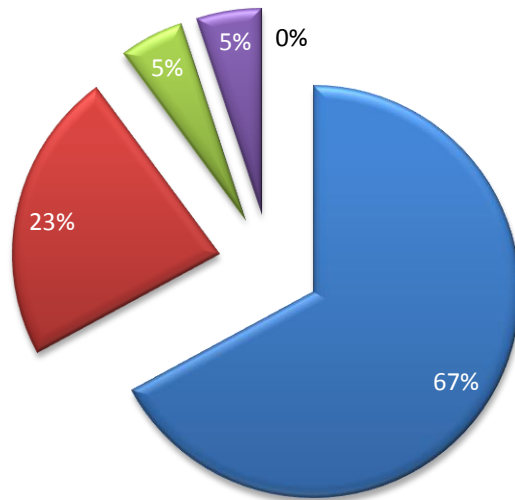
surgery



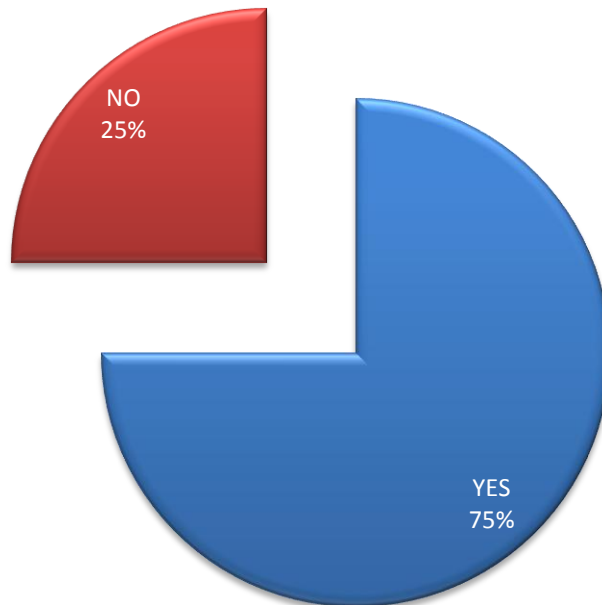


Arterial cannulation

■ AC - femoral ■ AC-subcl axill ■ AC-carotid ■ AC-aortic ■ AC-LV

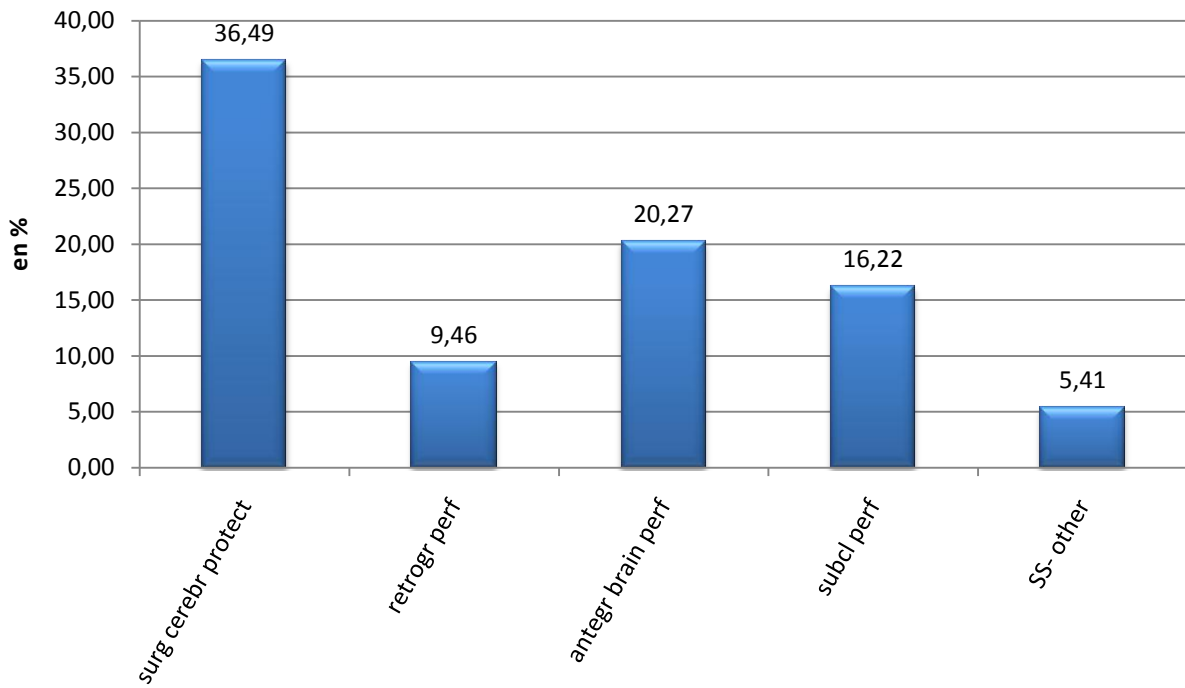


Open distal anastomosis

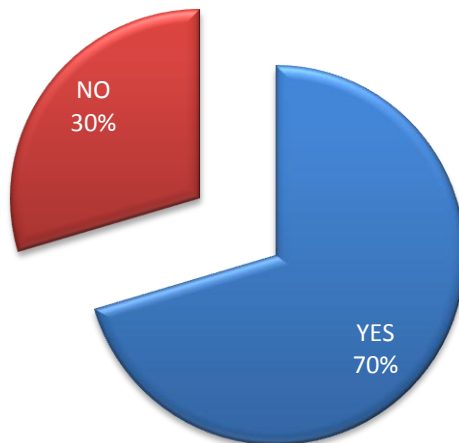


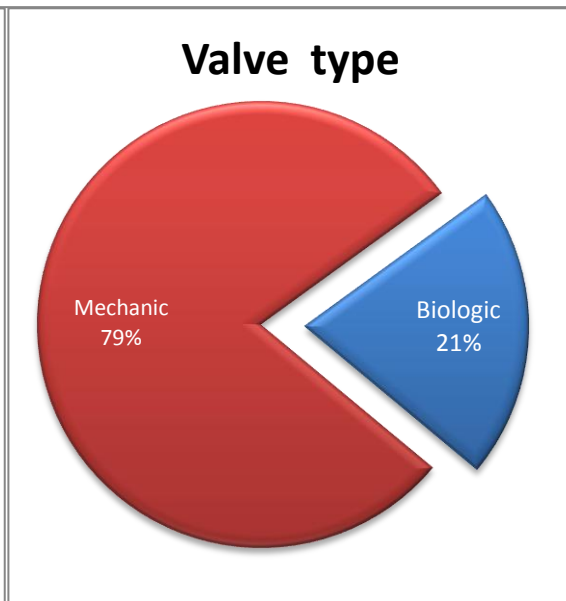
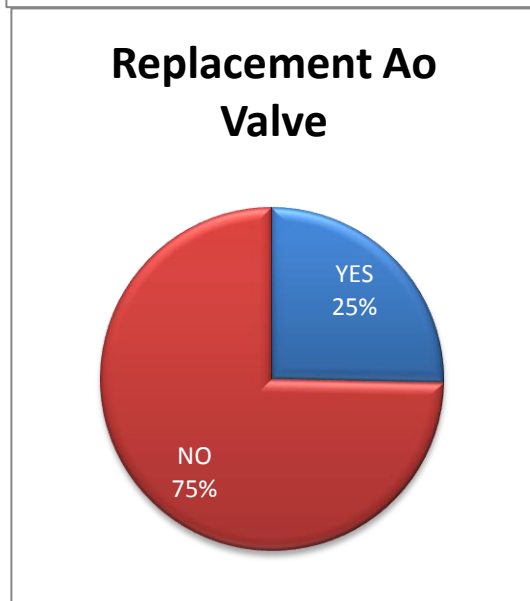
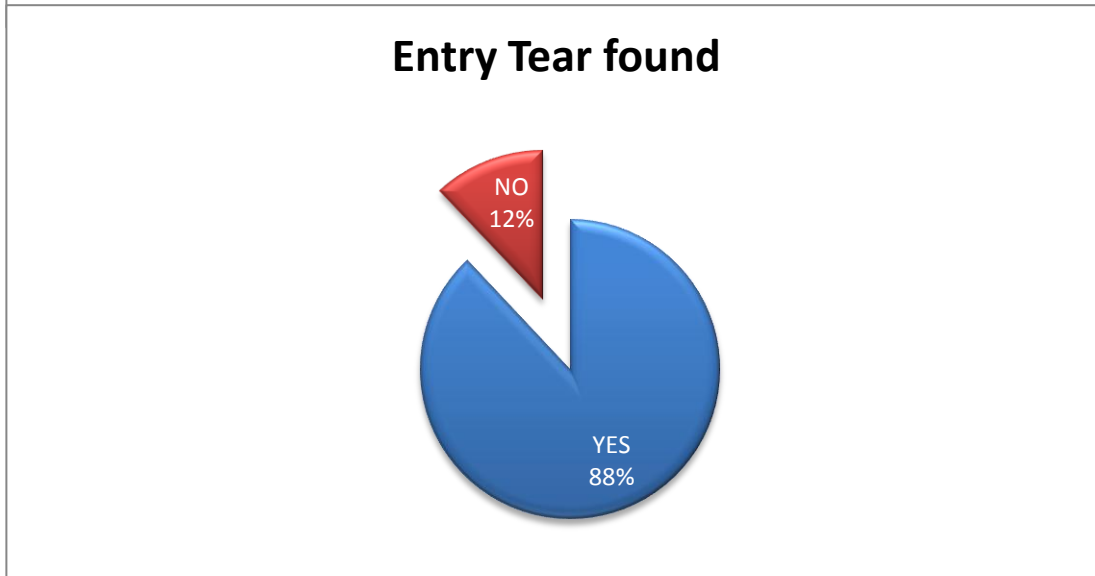
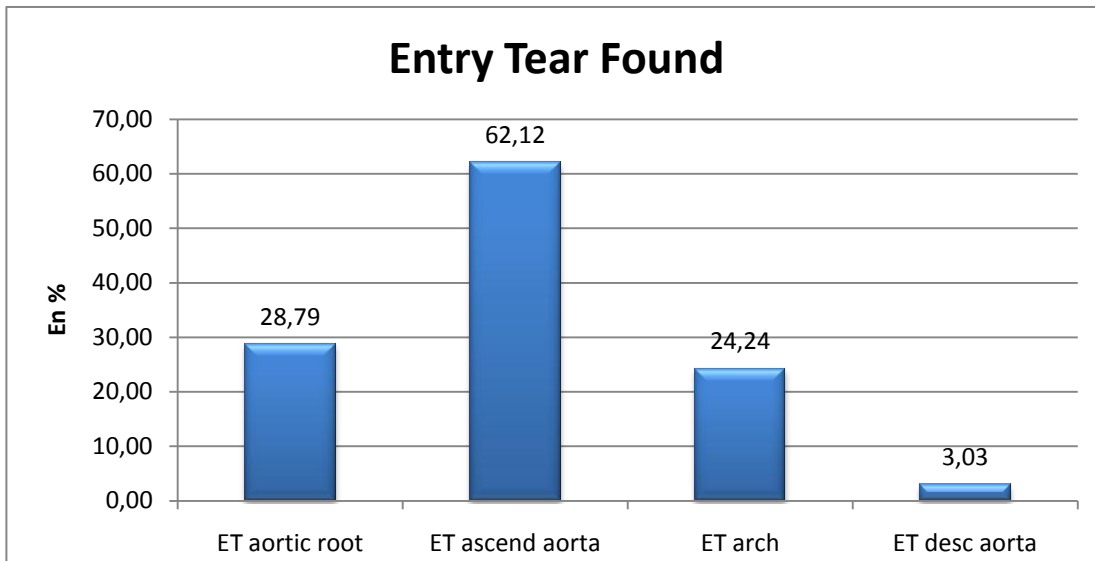


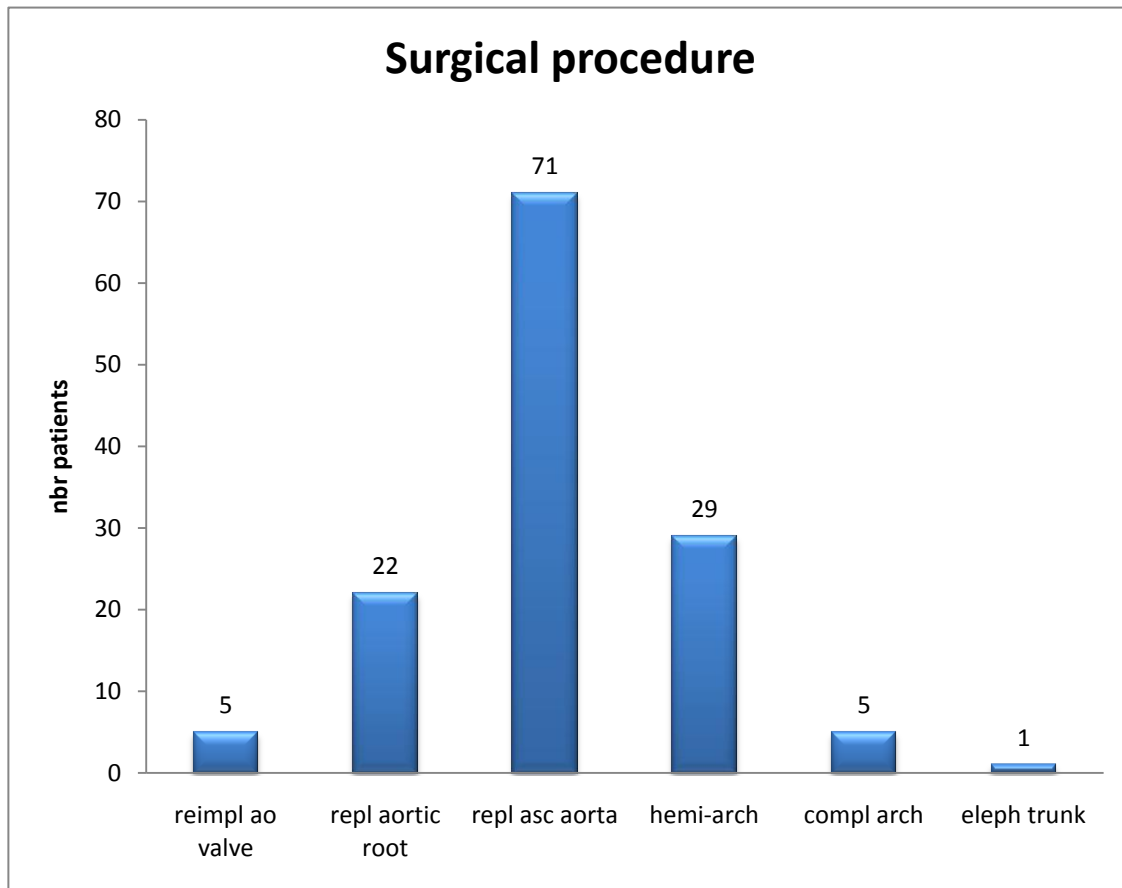
Open distal Anastomosis - cerebral protection



Antegrade reperfusion

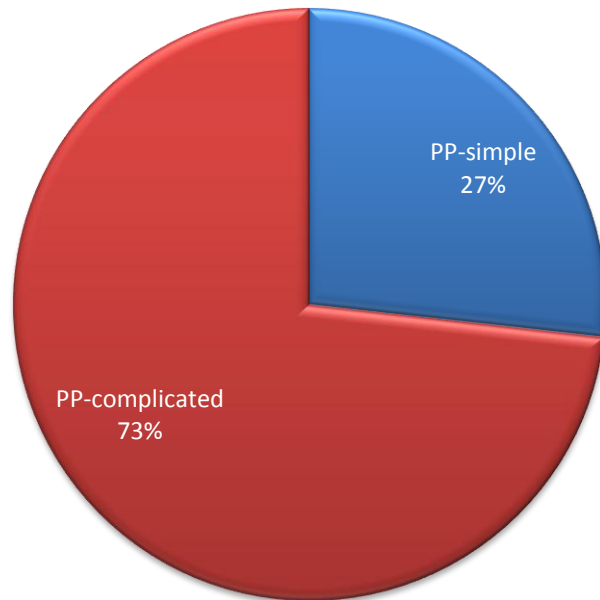




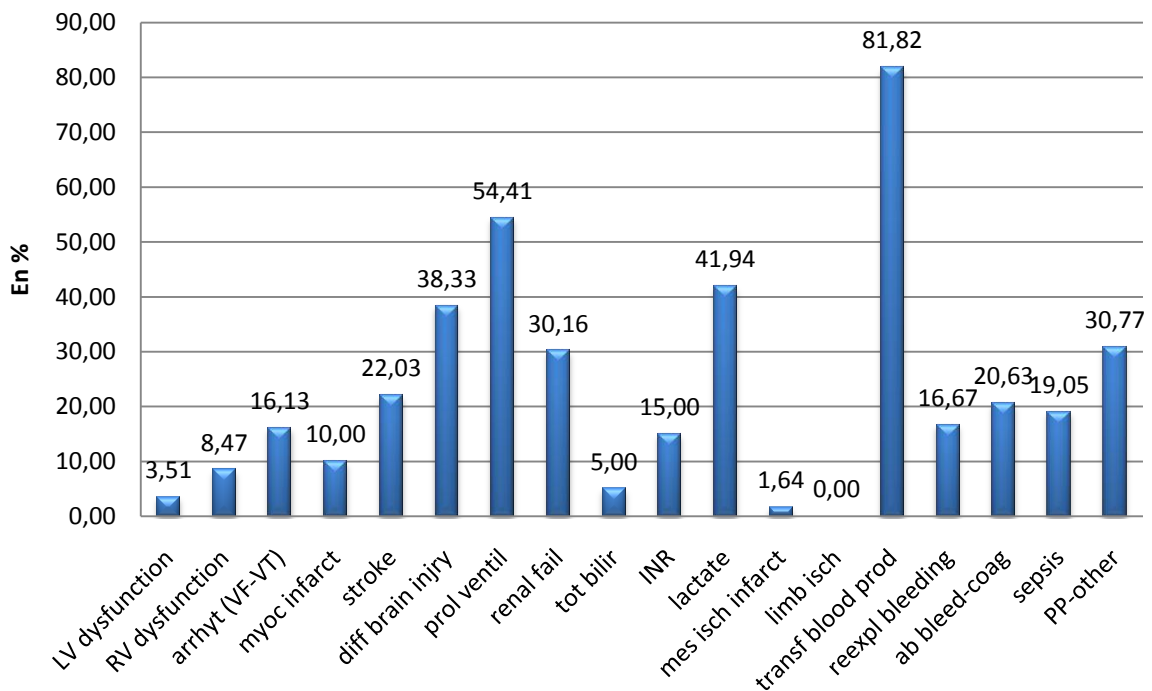




Post-op period

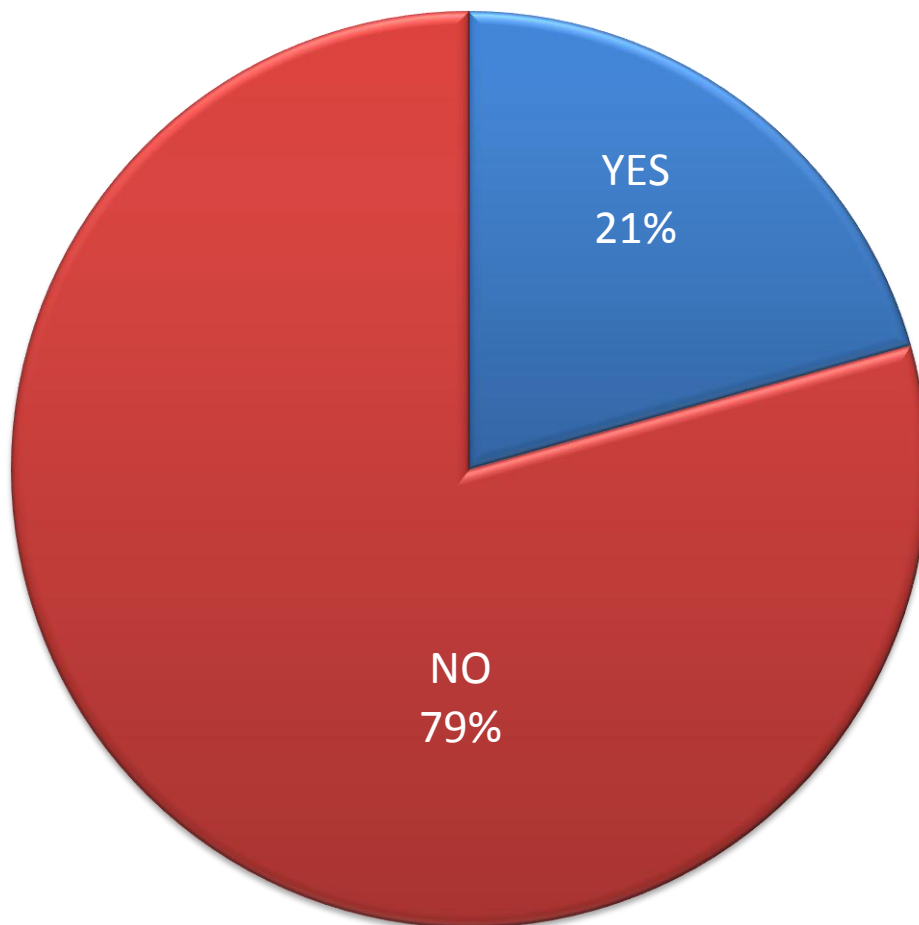


Post-Operative Period : complications



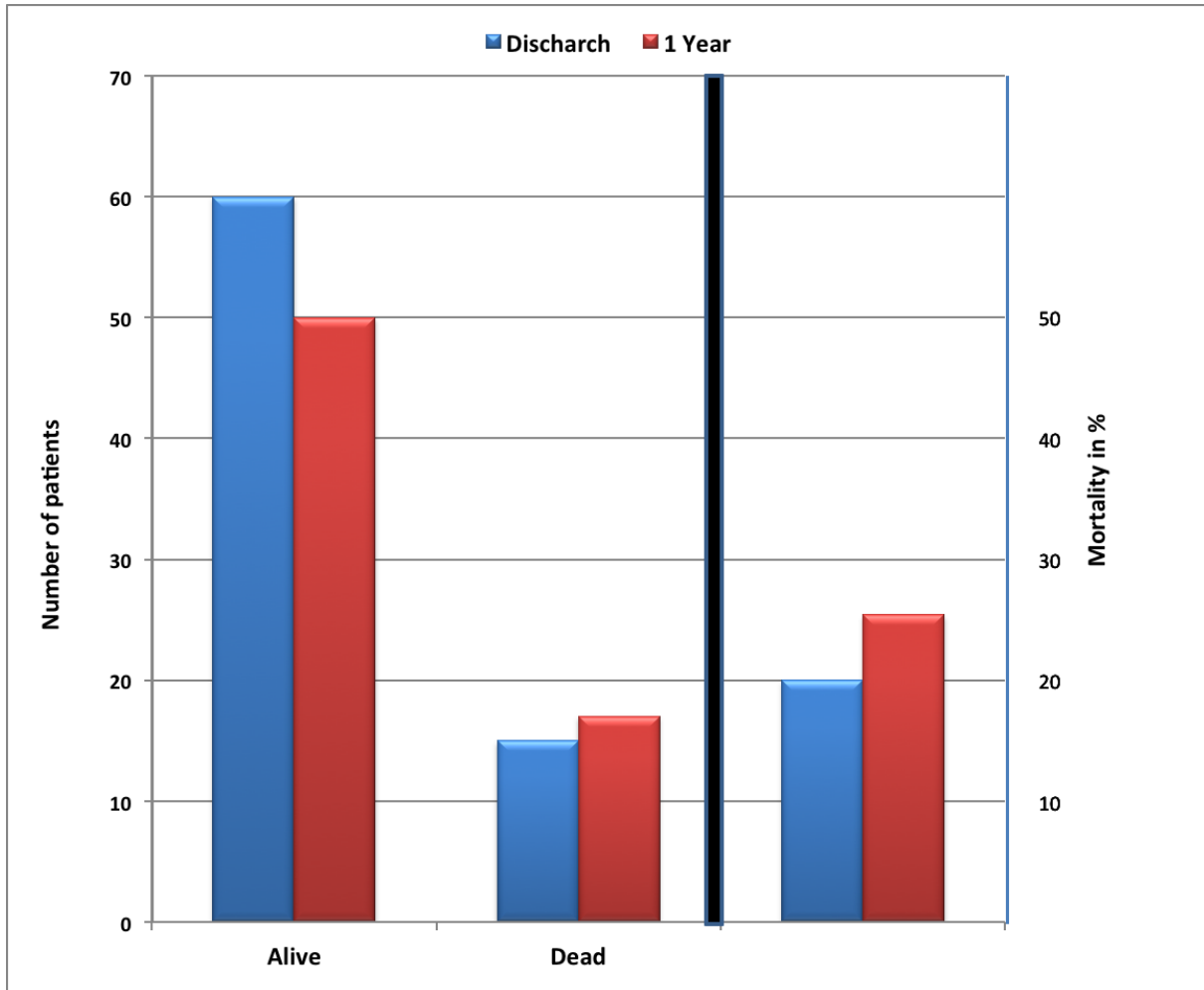


Abnormal bleeding-coagulopathy





Follow – up





Conclusions

This prospective study over a one year period (2008-2009) highlights the profile and clinical presentation of patients undergoing surgery for acute type A aortic dissection in Belgium. This study was able to collect the information of 75 patients treated within a week after the onset of symptoms of acute aortic dissection. It therefore involved a specific subset of patients suffering from acute aortic dissection.

Three specific points need to be emphasized :

- Most cardiac surgical centres endorsed this study. It is our estimation that this cohort represents probably +/- 85% of the cases of acute aortic dissection in Belgium over one year.

- To the best of our knowledge, this is the first time in the Belgian cardiac surgical community that demographic data are associated to an exhaustive definition of the disease, pathology, patients' conditions and are related to outcome evaluation. This last aspect was assessed by the description of the postoperative complications, in-hospital mortality and survival at one year.

- A crude in-hospital mortality of 20% is within the range of published results from the literature. Statistically, for an observed proportion of 20%, 15 events in a population of 75 give a 95% confidence interval of 11 to 30%. Whilst most reports from the literature consider "acute" dissection as a disease treated within the first fifteen days or three weeks after the onset of symptoms, our study specifically focused on the patients in the early phase of the disease who are at higher risk of mortality from the pathology, and therefore also at higher risk for surgical complications and mortality. This is illustrated by the high percentage of unstable patients, associated complications and elevated scores for surgical risk. In the latest IRAD report (Trimarchi et al. J Thorc Cardiovasc Surg, 2010), the operative mortality was 21.2% below 70 years of age and 30.8% observed in a cohort of 776 surgically treated type A aortic dissections.



Appendix

- Invitation letter
- Questionnaire
- Other didactical documents (MOU from the Database Committee)



Pilot Project for a Nation wide Prospective Registry on Type A Acute Aortic Dissection (2008)

Acute Aortic Dissection (AaoD) is probably the most devastating manifestation of various diseases involving the aortic wall (sharing in common the anatomopathological hallmark of Erdheim's disease or basophile degeneration of the media). It encompasses different entities in a spectrum comprised between Intramural aortic hematoma (lack of intimal tear) and "bona fide" acute dissection with the possibility of transformation of one type into another.

Acute aortic dissections type I and II in the Debakey Classification or type A in the Stanford Classification are associated to many severe complications (cardiac, neurological, visceral, renal and muscular) which lead to death or severe disability without prompt surgical intervention.

The objective of surgery in this complex disease is mainly to protect the patient against cardiac tamponade, coronary ischemia, acute aortic insufficiency and systemic malperfusion. For this purpose the standard operation consists in replacement of the ascending aorta and fixation of the aortic valve under cardiopulmonary bypass. The procedure itself and the management of extra corporeal circulation are however, subjected to great variability between surgeons and institutions. The literature is also quite controversial although a consensus exists on open distal anastomosis, antegrade reperfusion and sparing or repair of the aortic valve whenever feasible.

The Database of the BACTS whose purpose is to "create therapeutic or epidemiological studies involving the cardio-thoracic therapy with the intention to improve the quality of care" (MOI available at [http:// www.bacts.org/doc/10747](http://www.bacts.org/doc/10747)) proposes a nation wide prospective study on acute type A aortic dissection with the aim to answer the following questions:

- Incidence of type A AaoD (arriving alive in OR)
- Modalities of diagnosis
- Surgical management
- Postoperative complications
- Outcome at 1 year (actuarial survival).

More than a hundred cases are expected with a high rate of complications and a one month mortality between 10 to 20 %. The participation to this national study implies the transfer of specific data the data manager of the Database. The data will be pooled and treated anonymously with strict confidentiality.

On behalf of the database committee,

Prof MA Radermecker

Dr E de Worm

Dr C Stefanidis



BACTS Questionnaire Acute Type A Aortic Dissection

DEMOGRAPHICS

Patient ID		
Gender	M	F
Date of birth (day, month, year)/...../.....	
Heightcm	
WeightKg	

DEFINITION OF THE PATHOLOGY:

Intramural hematoma*	Y	N
Acute (less than 1 week)	Y	N
Type I (DeBakey)	Y	N
Type II (DeBakey)	Y	N
Retrograde type B	Y	N

ETIOLOGY:

Medial degeneration Hypertension	Y	N	
Medial degeneration Bicuspidy	Y	N	
Medial degeneration Unknown	Y	N	
Marfan syndrom	Y	N	
Connective tissue disorder (other Than Marfan)	Y	N	
Pregnancy –Post partum	Y	N	
Previously aneurysmal aorta	Y	N	
Traumatic	Y	N	
Drug abuse	Y	N	
Iatrogenic	Y	N	
Related to Cardiac Surgery	Early (same hospitalization)	Y	N
	late	Y	N
Other If yes, please explain ...		Y	N

PREOP DIAGNOSIS:

Contrast enhanced CT	Y	N
MRI	Y	N
TEE	Y	N
Angiography	Y	N
Other If yes, please explain ...	Y	N

PATIENT S PREOP STATUS :

Stable *	Y	N	
If unstable :	Intubated	Y	N
	Inotrope	Y	N
	Vasopressor	Y	N
	Agitation	Y	N
	Ressucitation	Y	N
	Other Please, explain ...	Y	N

Preoperative Complications :				
	Pericardial effusion*	Y	N	
	Tamponade	Y	N	
	Coronary ischemia*	Y	N	
	Aortic insufficiency:	None	Y	N
		Mild	Y	N
		Moderate	Y	N
		Severe	Y	N
	Neurological deficit*	Y	N	
	Spinal cord ischemia	Y	N	
	Visceral malperfusion	Y	N	
	Limb ischemia	Y	N	
	Others Please, explain ...	Y	N	

SEVERITY SCORES :

Euroscore (additive)*	
Euroscore (logistic)*	

DELAY BETWEEN SYMPTOMS, DIAGNOSIS AND SURGERY :

First symptoms/...../2008	Hour :
Diagnosis/...../2008	Hour :
Induction of anaesthesia/...../2008	Hour :

SURGICAL SET UP AND SURGICAL PROCEDURE :

Urgent	Y	N	
Emergent	Y	N	
Ph (1st in OR)		
Blood lactate (1st in OR) mg/100 ml		
Arterial cannulation			
	Femoral	Y	N
	Subclavian-axillary	Y	N
	Carotid	Y	N
	Aortic	Y	N
	LV	Y	N
Open distal anastomosis			
If yes,			
	Duration of Circulatory arrest in minutes	
	T° during Circulatory arrest°	
	Specific surgical cerebral protection	Y	N
	If yes, retrograde perfusion	Y	N
	Selective antegrade brain perfusion	Y	N
	Via subclavian perfusion	Y	N
	Other Please, explain ...	Y	N
Antegrade Reperfusion			
Entry tear			
	Entry tear found	Y	N
	Entry tear in the aortic root	Y	N
	Entry tear in the ascending aorta	Y	N
	Entry tear in the arch	Y	N
	Entry tear in the descending aorta	Y	N



Associated procedures :			
	CABG	Y	N
	Valve other than aortic	Y	N
	Fenestration	Y	N
	Arterial bypass (i.e. femoro-femoral) If yes, explain ...	Y	N
	Repeat ECC*	Y	N

SURGICAL PROCEDURE

Use of glue		Y	N
Replacement of the aortic valve		Y	N
If yes,			
	Biological	Y	N
	Mechanical	Y	N
	Other Please, explain ...	Y	N
Conservation – repair of the aortic valve		Y	N
Reimplantation of the aortic valve (David)		Y	N
Replacement of the aortic root		Y	N
Replacement of the ascending aorta		Y	N
Hemi-arch		Y	N
Complete arch		Y	N
Elephant trunk		Y	N

POSTOPERATIVE PERIOD

Simple		Y	N
Complicated		Y	N
	LV Dysfunction	Y	N
	RV Dysfunction	Y	N
	Arrhythmias (VF-VT)	Y	N
	Myocardial infarction	Y	N
	CKmb (maximum value)		.. µg/l
	Aortic insufficiency :		
	None	Y	N
	Mild	Y	N
	Moderate	Y	N
	Severe	Y	N
	Stroke*	Y	N
	Diffuse brain injury (agitation-confusion)	Y	N
	Prolonged ventilation (≥ 48H)	Y	N
	Renal failure (dialysis-CVVH)	Y	N
	Total bilirubine ≥ 20 mg/l	Y	N
	INR ≥ 2.0	Y	N
	Lactate ≥ 40 mg/dl at anytime	Y	N
	Mesenteric ischemia- infarction	Y	N
	Limb ischemia	Y	N
	Transfusion of any blood products	Y	N
	Reexploration for bleeding	Y	N
	Abnormal bleeding-coagulopathy	Y	N
	Sepsis	Y	N
	Other Please, explain ...	Y	N
	Days in ICU	

OUTCOME at first hospital discharge

Date of discharge/...../20.....	
Status	Alive	Dead

Appendix

- Intramural hematoma = dissection without entry tear.
- "Stable" = without any criteria for "unstable".
- Pericardial effusion = blood effusion without cardiac tamponade.
- Coronary ischemia = clinical symptoms, ECG anomaly (other than st modifications seen in pericarditis), positive troponines.
- Neurological deficit = any neurological deficit, present or resolved.
- Euroscore : for calculation please visit www.euroscore.org.
- Repeat ECC: repeat run of extracorporeal circulation, caused by cardiac failure, during the same or later operative procedure (same hospitalisation).
- Stroke = any neurological deficit (reversible or not) with lesion demonstrated at contrast enhanced CT or MRI.

Please send the document, after the first hospital discharge of the patient to: BACTS

The follow-up at one year will be asked through another document



MEMORY OF UNDERSTANDING (MOU)

1. The BACTS is the Belgian Association for Cardio-Thoracic Surgery, founded in November 1995.
2. The Database Committee, is a committee of the BACTS.
3. The Data-manager is a non-physician, responsible for data collection, data optimisation and data mapping in preparation of the data-analysis. The data-manager optimises the layout of the reports, as proposed by the Committee.
4. The Data-analyst is a non-physician expert in biomedical statistics, responsible for data analysis. The data-analyst interfaces with the data-manager concerning the data and with the Committee concerning the data-analysis.
5. The purpose of the Database Committee is mainly
 - a. To create, maintain and analyse a registry of the cardio-thoracic surgical activity in Belgium. (Could be extended to Luxemburg).
 - b. To create therapeutic or epidemiological studies involving the cardio-thoracic therapy, with the intention to improve the quality of care.
 - c. To participate directly (centre) or indirectly (database) in international projects.
 - d. The database will never serve to rank centres or surgeons, will never participate in malpractice investigation or conformity checking with legal requirements of centres and surgeons.
6. The Privacy Law (Dec 8th 1992) dictates that: (1) The database should be registered at the Commission for Protection of Privacy; (2) All centres have to be informed about the identity and the address of the holder of the database, the purpose of the database, the fact that one can get more information at the "Commission Protection of Privacy", the right to access and when necessary to correct their data; (3) The person responsible for analyzing the data, has to indicate the persons who have access to the data. The contents as well as the limits of this access have to be described in a registry. The registry of the Database Committee is registered at the Commission for Protection of Privacy, Ministry of Justice, Waterloolaan 115, 1000 Brussel. The holder's identification number is 003002666, the unique identification number is 005008830.
7. The access to the data has three levels. The first two levels concern the Database Committee members.
 - a. The first level is unrestricted. This access is given to the chairman of the database committee, the data-analyst and the data manager.
 - b. The second level is restricted to a "need to know level", defined by the committee and this access is given to all the members of the committee.
 - c. The third level is restricted to the centre's own data. This access is given to the Chairman of the center. This access is unrestricted in time but limited to the data of the center.

All members of the committee, including the data manager and the data analyst are under the medical secret. The database is protected by secret entry-codes. In addition the names of the centres and the RIZIV/INAMI numbers are recoded into secret codes. The password and codes are kept in a sealed envelope with the chairman of the database committee. No database committee chairman or member has access to the actual identification of the centre or the surgeon. The Law on the Medical Secret: data cannot and should not be transferred to any third party, e.g. council of BACTS, Health authorities, industry. There are two exceptions: (1) there is a database-specific law ordering the transfer of these data; (2) all parties or centres give their written permission for each specific output.

No centre- or surgeon-specific information can be given to any third part outside the database committee without the written permission of the chairman of the centre or the individual surgeon. No centre-, nor surgeon- identified information can be looked into by the members of the database committee.



The database committee guarantees that the data (conditional to the approval of each head of the department) that are transferred, after approval of the Board of Directors of the BACTS to a supra-national organisation (e.g. EACTS), will be transferred with secret coding of the identification of the department and additional secret coding of the surgeon.

8. There is a possible conflict of interest leading to the incompatibility of simultaneous membership of the Database Committee and membership of the Board of Directors of the BACTS or membership of the College. Any other position with possible conflict of interest needs to be presented to the database committee. The acting members of the database committee will not be member of any other national audit or malpractice committee during their membership of the Committee.

9. The chairman of the database committee is chosen by the Board of Directors of the BACTS. The Board of directors of the BACTS nominates and dismisses the members of the Committee. The number of members can be changed on the suggestion of the Chairman of the Committee. A chairman and the Committee members remain custodians of the database till the nomination of their successors, in the event that their term has ended or that they are dismissed by the Board of Directors. Violation of the confidentiality (identified by the Committee) leads to automatic dismissal of the member or chairman by the Board of Directors of the BACTS.

The chairman of the database committee reports to the Board of Directors of the BACTS on a regular basis, as requested by the Board or the Committee. In addition an annual report is given at the business meeting of the annual convention. He will answer to the questions of the members concerning all matters of the Committee. The website will be updated on a regular basis.

10. The Committee will propose an annual budget to the Board of Directors.

11. The BACTS will take charge of the legal protection of the Committee members and the Database.
