

### 3. 本研究の目的及び方法

本研究は、冠状動脈バイパス手術を必要とする患者さんを、手術前に、全く無作為に、人工心肺を使用しない心拍動下冠状動脈バイパス手術と人工心肺を使用した冠状動脈バイパス手術に振り分けて手術を行い、手術成績(合併症発生率・バイパス開存率等)、長期成績(生命予後・胸痛の再発等)を比較検討する研究です。

しかし、人工心肺を使用しない心拍動下冠状動脈バイパス手術を予定していても、術中の医学的理由により人工心肺を使用して手術を行うこともあります。

### 4. この研究に協力することの任意性と撤回の自由

今回あなたが冠状動脈バイパス手術を受けられるにあたって、この研究に協力していただけるかどうかは全くあなたの自由です。協力していただける場合には、通常の検査に加えて、血液検査のために、**10ml**程度の採血が必要となります。

いったん協力することを同意された後でも、いつでも同意を撤回することができます。その場合でも、担当医師はその後の治療に最善を尽くします。

### 5. この研究への協力に同意しない場合でも不利益を受けないこと

この研究に協力されなくても、当病院で行う治療・検査等に一切不利益は生じません。担当医師はあなたの治療に最善を尽くします。

### 6. 費用負担について

一般保険診療に要する費用のうち、自己負担分以外に、あなたに費用負担を求めることはありません。この研究に要する費用は、治療研究費から支出いたします。

### 7. プライバシーの保護

この研究に際して、あなたの診療情報や病院名等が必要となりますが、プライバシーの保護には充分配慮し、あなたの名前や個人を特定できるような情報が漏洩されることはありません。

何か質問、疑問、不安があればお答えしますので、いつでも遠慮なく申し出てください。

年 月 日

説明医師

所属 \_\_\_\_\_

氏名 \_\_\_\_\_ (印)

(自署または記名・押印)

## 同意書

国立循環器病センター

説明医師名 \_\_\_\_\_ 殿

私は、「前向き無作為試験による人工心肺を使用しない心拍動下冠状動脈バイパス手術の有用性に関する研究」について説明文書により下記の説明を受け、その目的、方法等について十分理解しましたので、この研究に参加することに同意します。

1. 本研究の目的及び方法
2. 有効性及び危険性
3. 本研究への自由意志による参加
4. 本研究への参加をいつでも撤回できること
5. プライバシーの保護

平成 年 月 日

本人 氏名 \_\_\_\_\_ (印)  
(自署又は記名・押印)

家族・代理人 住所 \_\_\_\_\_

(続柄) ( ) 氏名 \_\_\_\_\_ (印)  
(自署又は記名・押印)

# JOCRI

## Japanese Off-Pump Coronary Revascularization Investigation

### Database

A. Administrative	}	Form 1
B. Demographics		
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List

Click Form number,  
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March 15, 2002

<b>A. Administrative</b>		Participant ID: .....
<b>B. Demographics</b>		
Patient Medical Record Number: .....	Date of Birth: .....	(yyyy/mm/dd)
Name: .....	Gender: <input type="radio"/> Male <input type="radio"/> Female	
Postal Code: .....	Tel number: .....	
Address: .....		
<b>C. Hospitalization</b>		
Hospital Name: .....		
Day of Admission: .....	(yyyy/mm/dd)	Surgery: ..... Discharge: .....
<b>D. Pre-Operative Risk Factors</b>		
Weight: .....	kg	Height: ..... cm
CTR: ..... % Cognitive Function (Score): .....		
Smoker: <input type="radio"/> No <input type="radio"/> Yes	→	Current Smoker: <input type="radio"/> No <input type="radio"/> Yes
Family History of CAD: <input type="radio"/> No <input type="radio"/> Yes		
Diabetes: <input type="radio"/> No <input type="radio"/> Yes	→	Diabetes Control: <input type="radio"/> None <input type="radio"/> Diet <input type="radio"/> Oral <input type="radio"/> Insulin
Hypercholesterolemia: <input type="radio"/> No <input type="radio"/> Yes		
Hypertension: <input type="radio"/> No <input type="radio"/> Yes		
Preoperative: Hb: .....	WBC: .....	Platelets: .....
Respiratory Function: %VC: .....	FEV1.0%: .....	
Chronic Lung Disease: <input type="radio"/> No <input type="radio"/> Yes	→	Degree: <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
Liver Function: AST: .....	ALT: .....	T-Bil: .....
Liver Dysfunction: <input type="radio"/> No <input type="radio"/> Yes		
Renal Function: BUN: .....	Cr: .....	
Renal Failure: <input type="radio"/> No <input type="radio"/> Yes	→	Dialysis: <input type="radio"/> No <input type="radio"/> Yes
Aortic Aneurysm: <input type="radio"/> No <input type="radio"/> Yes		
Peripheral Vascular Disease: <input type="radio"/> No <input type="radio"/> Yes		
Cerebrovascular Accident: <input type="radio"/> No <input type="radio"/> Yes	→	When: <input type="radio"/> Recent (<= 2 weeks) <input type="radio"/> Remote (> 2 weeks)
Cerebrovascular Disease: <input type="radio"/> No <input type="radio"/> Yes	→	CVD Type: <input type="radio"/> Coma <input type="radio"/> CVA <input type="radio"/> RIND <input type="radio"/> TIA <input type="radio"/> Non Invasive >75%
<b>E. Previous Interventions</b>		
Previous CV Interventions: <input type="radio"/> No <input type="radio"/> Yes		
Prior Coronary Intervention: <input type="radio"/> No <input type="radio"/> Yes		
Thrombolysis: <input type="radio"/> No <input type="radio"/> Yes	→	Interval: <input type="radio"/> <= 6 hours <input type="radio"/> >6 hours
Previous Balloon Valvuloplasty: <input type="radio"/> No <input type="radio"/> Yes		
Previous Cardiac Surgery: <input type="radio"/> CABG <input type="radio"/> Valve <input type="radio"/> Aortic <input type="radio"/> Others		
Cerebrovascular Surgery: <input type="radio"/> No <input type="radio"/> Yes		
Peripheral Vascular Surgery: <input type="radio"/> No <input type="radio"/> Yes		

Participant ID: \_\_\_\_\_ Name: \_\_\_\_\_ Gender:  Male  Female  
 Patient Number: \_\_\_\_\_ Hospital: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
 Date of Surgery: \_\_\_\_\_

**F. Pre Operative Cardiac Status**

Myocardial Infarction:  No  Yes  
 When:  ≤6 hours  1-7 days  >21 days  
 >6 hours but <24 hours  8-21 days  
 Rythm:  non-Q  Q → Q rythm:  I, aVL  II, III, aVF  V1-V3  
 Congestive Heart Failure:  No  Yes  
 Angina:  No  Yes → Type:  Stable  Unstable → Unstable Type:  
 Rest Angina  Variant Angina  
 New Class 3  Non-Q MI  
 Recent Accel  Post-Infarct Angina  
 Arrhythmia:  No  Yes → Type:  VF  af  
 VT  PAT  
 Classification CCS:  0  I  II  III  IV NYHA:  I  II  III  IV

**G. Pre Operative Medications**

Digitalis:  No  Yes Beta Blockers:  No  Yes Nitrates - I.V.:  No  Yes Anticoagulants:  No  Yes  
 Diuretics:  No  Yes Inotropic Agents:  No  Yes Steroids:  No  Yes Aspirin:  No  Yes

**H. Pre Operative Hemodynamics and Catheterization**

Number of Diseased Coronary Vessels:  None  One  Two  Three  
 Left Main Disease > 50%:  No  Yes (Note: LM Disease (>50%) counts for two: LAD+CFX)

Hemodynamic Data : →Method:  None  LV gram  Radionucleotide  Estimate  ECHO

Pulmonary Artery mean Pressure: \_\_\_\_\_

Angio : LVEDVI: \_\_\_\_\_ LVESVI: \_\_\_\_\_ LVEF: \_\_\_\_\_ %

UCG : LVDd: \_\_\_\_\_ LVDs: \_\_\_\_\_ FS: \_\_\_\_\_ %

RI : LVEDVI: \_\_\_\_\_ LVESVI: \_\_\_\_\_ LVEF: \_\_\_\_\_ %

CAG - Stenosis rate: segment 1  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 2  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 3  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 4AV  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 4PD  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment LMT  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment LAD  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment DB ( 9)  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment DB (10)  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 11  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 12  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 13  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 14  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 15  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total

Aortic Stenosis:  No  Yes Insufficiency:  0=None  1=Trivial  2=Mild  3=Moderate  4=Severe  
 Mitral Stenosis:  No  Yes Insufficiency:  0=None  1=Trivial  2=Mild  3=Moderate  4=Severe  
 Tricuspid Stenosis:  No  Yes Insufficiency:  0=None  1=Trivial  2=Mild  3=Moderate  4=Severe  
 Pulmonic Stenosis:  No  Yes Insufficiency:  0=None  1=Trivial  2=Mild  3=Moderate  4=Severe

Participant ID: \_\_\_\_\_ Name: \_\_\_\_\_ Gender:  Male  Female  
 Patient Number: \_\_\_\_\_ Hospital: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
 Date of Surgery: \_\_\_\_\_

**I. Operative**

Day of Surgery: \_\_\_\_\_ (yyyy/mm/dd)

Surgeon's Name: \_\_\_\_\_

Operation time: \_\_\_\_\_ min

Status of the procedure:  Elective  Urgent  Emergent  Salvage

**Bypass Grafting:**

	Inflow	Graft	Site	Size	Suture			
					Fashion	Technique	Size	Material
1: _____								
2: _____								
3: _____								
4: _____								
5: _____								
6: _____								
7: _____								

	In situ Graft	Free Graft		
		Graft	Inflow	Design
1: _____	1: _____			
2: _____	2: _____			
3: _____	3: _____			
4: _____	4: _____			

Number of Distal Anastomoses total: \_\_\_\_\_  
 with Arterial Conduits: \_\_\_\_\_  
 with Vein Grafts: \_\_\_\_\_

IMA { IMA Used as Grafts:  Left  Right  Both  None  Abandon  
 Type of IMA Harvest:  Pedicle  Semi-skeletonized  Skeletonized  
 Device for IMA Harvest:  Ultrasonic  Cautery  
 Number of IMA Distal Anastomoses: \_\_\_\_\_

RA { Radial Artery(ies) Used as Grafts:  Left  Right  Both  None  Abandon  
 Type of RA Harvest:  Pedicle  Semi-skeletonized  Skeletonized  
 Device for RA Harvest:  Ultrasonic  Cautery  
 Number of RA Distal Anastomoses: \_\_\_\_\_

GEA { Gastro-Epiploic Artery Used as Grafts:  Yes  No  Abandon  
 Type of GEA Harvest:  Pedicle  Semi-skeletonized  Skeletonized  
 Device for GEA Harvest:  Ultrasonic  Cautery  
 Number of GEA Distal Anastomoses: \_\_\_\_\_

Acute Flow Patency Assess of Grafts:  Intraop Doppler  Intraop Angio  Others  None

IABP:  No  Yes → When Inserted:  Preop  Intraop  Postop  
 Indication:  Hemodynamic Instab  Unst. Angina  Prophylatic  
 PTCA Support  CPB Wean

PCPS:  No  Yes → When Inserted:  Preop  Intraop  Postop  
 Indication:  Hemodynamic Instab  Unst. Angina  Prophylatic  
 PTCA Support  CPB Wean

Participant ID: \_\_\_\_\_ Name: \_\_\_\_\_ Gender:  Male  Female  
 Patient Number: \_\_\_\_\_ Hospital: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
 Date of Surgery: \_\_\_\_\_

**J. Cardiopulmonary Bypass**

Cardiopulmonary Bypass:  Yes →Go to K  
 No →Go to L

**K. On-Pump**

Cardiopulmonary Bypass:  Elective  Conversion from Off-pump  
 ↳ Reason:  Hypotension  Rhythm  Bleeding  Anatomical  Others  
 Perfusion time: \_\_\_\_\_ min Low Core Temp. during CPB: \_\_\_\_\_ °C  
 Cross Clamp time: \_\_\_\_\_ min Cardioplegia:  No  Yes ↳ Temperature:  Blood  Crystalloid  
 ↳ Temperature:  Warm  Tepid  Cold

	Graft	Inflow	Design	Technique
Free Graft 1:	_____	_____	_____	_____
2:	_____	_____	_____	_____
3:	_____	_____	_____	_____
4:	_____	_____	_____	_____

**L. Off-Pump**

	Graft	Site	Preconditioning	Vessel Stabilization	CO <sub>2</sub> Blower	Coronary Perfusion	Anast. time
Bypass Grafting 1:	_____	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	_____
2:	_____	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	_____
3:	_____	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	_____
4:	_____	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	_____
5:	_____	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	_____
6:	_____	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	_____
7:	_____	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	<input type="radio"/> No <input type="radio"/> Yes	_____	_____

	Graft	Inflow	Design	Technique
Free Graft 1:	_____	_____	_____	_____
2:	_____	_____	_____	_____
3:	_____	_____	_____	_____
4:	_____	_____	_____	_____

# JOCRI Database

Japanese Off-Pump Coronary Revascularization Investigation

5/10

Participant ID: \_\_\_\_\_ Name: \_\_\_\_\_ Gender:  Male  Female  
 Patient Number: \_\_\_\_\_ Hospital: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
 Date of Surgery: \_\_\_\_\_

## M. Post Operative

Blood Products Used during Operation:  No  Yes → MAP: \_\_\_\_\_ units  
 FFP: \_\_\_\_\_ units  
 PC: \_\_\_\_\_ units

Blood Products Used after Operation:  No  Yes → MAP: \_\_\_\_\_ units  
 FFP: \_\_\_\_\_ units  
 PC: \_\_\_\_\_ units

Autologous Blood Transfusion:  No  Yes

Postop. Chest Tube Drainage (~12hrs): \_\_\_\_\_ ml

Postop. Ventilated Hours: \_\_\_\_\_ hours

ICU stay: \_\_\_\_\_ hours

CKMB Max: \_\_\_\_\_

S-100 Protein: \_\_\_\_\_

NSE: \_\_\_\_\_

WBC: POD0: \_\_\_\_\_ POD1: \_\_\_\_\_ POD7: \_\_\_\_\_

Platelets: POD0: \_\_\_\_\_ POD1: \_\_\_\_\_ POD7: \_\_\_\_\_

CRP: \_\_\_\_\_ POD1: \_\_\_\_\_ POD7: \_\_\_\_\_

Cognitive Function: POD14: \_\_\_\_\_ Postop 6 mo: \_\_\_\_\_ (Date: \_\_\_\_\_)

Hospital stay Total: \_\_\_\_\_ days (Auto) Postop.: \_\_\_\_\_ days (Auto)

Medical charge: \_\_\_\_\_ yen

## N. Post Operative Evaluation

Angiographic Evaluation:  Elective  Emergent

Date: \_\_\_\_\_ (yyyy/mm/dd)

Angio : LVEDVI: \_\_\_\_\_ LVESVI: \_\_\_\_\_ LVEF: \_\_\_\_\_ %

UCG : (Date: \_\_\_\_\_) LVDd: \_\_\_\_\_ LVDs: \_\_\_\_\_ FS: \_\_\_\_\_ %

RI : (Date: \_\_\_\_\_) LVEDVI: \_\_\_\_\_ LVESVI: \_\_\_\_\_ LVEF: \_\_\_\_\_ %

Distal Anastomoses problem:  No  Yes

	Inflow	Graft	Site	Patency
1:	_____	_____	_____	_____
2:	_____	_____	_____	_____
3:	_____	_____	_____	_____
4:	_____	_____	_____	_____
5:	_____	_____	_____	_____
6:	_____	_____	_____	_____
7:	_____	_____	_____	_____

Course:  Observation / Medication  
 Catheter Intervention  
 Reoperation

Momo: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

In situ Graft problem:  No  Yes ↴

	In situ Graft	Patency
1:	_____	_____
2:	_____	_____
3:	_____	_____

Free Graft problem:  No  Yes ↴

	Free Graft	Patency
1:	_____	_____
2:	_____	_____
3:	_____	_____
4:	_____	_____

Participant ID: \_\_\_\_\_ Name: \_\_\_\_\_ Gender:  Male  Female  
 Patient Number: \_\_\_\_\_ Hospital: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
 Date of Surgery: \_\_\_\_\_

**O. Complications in Hospital**

**Intraoperative**

Complications:  No  Yes

- No  Bleeding  
 Yes →  Arrhythmia → Type:  VF  VT  af  PAT  
 Other

memo : \_\_\_\_\_

**Operative**

- No  
 Yes →  Perioperative Myocardial Infarction  
 Need Reoperation  
 ↓  
 Reason :  Bleeding  
 Valvular Dysfunction  
 Graft Occlusion  
 Other Cardiac Problem  
 Non Cardiac Problem

**Neurologic**

memo : \_\_\_\_\_

- No  
 Yes →  Stroke  
 Transient  
 Continuous Coma >=24Hrs

**Renal Failure**

- No  
 Yes → BUN : \_\_\_\_\_  
 Cr : \_\_\_\_\_  
 ↓  
 Dialysis :  No  
 Yes →  Transient  
 Permanent

**Vascular**

- No  
 Yes →  Aortic Dissection  
 Illiac/Femoral Dissection  
 Acute Limb Ischemia

**Infection**

- No  
 Yes →  Sternum-Deep  
 Wound-Chest  
 Wound-Arm  
 Wound-Leg  
 Septicemia

**Pulmonary**

- No  
 Yes →  Prolonged Ventilation  
 Pneumonia  
 Pulmonary Embolism

**Others**

- No  
 Yes →  Heart Block  
 Cardiac Arrest  
 Atrial Fibrillation  
 Anticoagulant Complication  
 Tamponade  
 Gastro-Intestinal Complication  
 Multi-system Failure  
 DIC  
 Liver Dysfunction  
 ↓  
 AST : \_\_\_\_\_  
 ALT : \_\_\_\_\_  
 T-Bil : \_\_\_\_\_

**P. Mortality**

Discharge: \_\_\_\_\_ (yyyy/mm/dd)  
 Status at discharge:  Alive  Dead  
 Patient Activities:  Not affected  Moderately compromised  Severely compromised  
 Status at 30 days after Sugery:  Alive  Dead  
 Mortarity Date: \_\_\_\_\_ (yyyy/mm/dd)  
 Location of Death:  OR  Hospital  Home  Other Facility  
 Primary Cause of Death:  Cardiac  Renal  Infection  Valvular  
 Neurological  Vascular  Pulmonary  Other  
 Mortality - Operative Death:  No  Yes

Participant ID: \_\_\_\_\_ Name: \_\_\_\_\_ Gender:  Male  Female  
 Patient Number: \_\_\_\_\_ Hospital: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
 Date of Surgery: \_\_\_\_\_

**Q. Late Examination**

Angiographic Evaluation: Date: \_\_\_\_\_ (yyyy/mm/dd)

Angio : LVEDVI: \_\_\_\_\_ LVESVI: \_\_\_\_\_ LVEF: \_\_\_\_\_ %  
 UCG : (Date: \_\_\_\_\_) LVDd: \_\_\_\_\_ LVDs: \_\_\_\_\_ FS: \_\_\_\_\_ %  
 RI : (Date: \_\_\_\_\_) LVEDVI: \_\_\_\_\_ LVESVI: \_\_\_\_\_ LVEF: \_\_\_\_\_ %

- CAG - Stenosis rate: segment 1  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 2  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 3  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 4AV  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 4PD  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment LMT  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment LAD  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment DB ( 9)  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment DB (10)  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 11  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 12  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 13  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 14  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 15  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total

Distal Anastomoses problem:  No  Yes

	Inflow	Graft	Site	Last Patency	Patency
1:	_____	_____	_____	_____	_____
2:	_____	_____	_____	_____	_____
3:	_____	_____	_____	_____	_____
4:	_____	_____	_____	_____	_____
5:	_____	_____	_____	_____	_____
6:	_____	_____	_____	_____	_____
7:	_____	_____	_____	_____	_____

In situ Graft problem:  No  Yes

Free Graft problem:  No  Yes

In situ Graft	Last Patency	Patency	Free Graft	Last Patency	Patency
1:	_____	_____	1:	_____	_____
2:	_____	_____	2:	_____	_____
3:	_____	_____	3:	_____	_____
			4:	_____	_____

Course:  Observation / Medication  
 Catheter Intervention  
 Reoperation

Momo: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Participant ID: \_\_\_\_\_ Name: \_\_\_\_\_ Gender:  Male  Female  
 Patient Number: \_\_\_\_\_ Hospital: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
 Date of Surgery: \_\_\_\_\_

**R. Event (I)**

Date: \_\_\_\_\_ (yyyy/mm/dd) Event <=30 days from Date of Procedure:  No  Yes  
 Anticoagulant Compl  MI/Recurrent Angina  Cerebrovascular Accident  
 Arrhythmias  Pericardial Effusion/Tamponade  Vascular Accident  
 CHF  Pneumonia Respiratory Complication  Sudden death  
 Incisional Complication  Valve Dysfunction  Other

Readmission:  No  Yes

Day of Admission: \_\_\_\_\_ Discharge: \_\_\_\_\_ Hospital stay: \_\_\_\_\_ days  
 Ischemia:  No  Yes (yyyy/mm/dd)

Stress ECG Date: \_\_\_\_\_  Treadmill  Ergometer  Master → Ischemia:  Negative  Positive

RI Date: \_\_\_\_\_  Rest  Stress (Exercise)  Stress (Drug) → Ischemia:  Negative  Positive

CAG Date: \_\_\_\_\_

Angio: LVEDVI: \_\_\_\_\_ LVESVI: \_\_\_\_\_ LVEF: \_\_\_\_\_ %  
 UCG : (Date: \_\_\_\_\_) LVDd: \_\_\_\_\_ LVDs: \_\_\_\_\_ FS: \_\_\_\_\_ %  
 RI: LVEDVI: \_\_\_\_\_ LVESVI: \_\_\_\_\_ LVEF: \_\_\_\_\_ %

CAG - Stenosis rate: segment 1  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 2  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 3  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 4AV  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 4PD  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment LMT  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment LAD  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment DB ( 9)  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment DB (10)  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 11  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 12  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 13  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 14  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total  
 segment 15  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total

Distal Anastomoses problem:  No  Yes  

	Inflow	Graft	Site	Last Patency	Patency
1:	_____	_____	_____	_____	_____
2:	_____	_____	_____	_____	_____
3:	_____	_____	_____	_____	_____
4:	_____	_____	_____	_____	_____
5:	_____	_____	_____	_____	_____
6:	_____	_____	_____	_____	_____
7:	_____	_____	_____	_____	_____

In situ Graft problem:  No  Yes ↴

Free Graft problem:  No  Yes ↴

	In situ Graft	Last Patency	Patency	Free Graft	Last Patency	Patency
1:	_____	_____	_____	_____	_____	_____
2:	_____	_____	_____	_____	_____	_____
3:	_____	_____	_____	_____	_____	_____
4:	_____	_____	_____	_____	_____	_____

# JOCRI Database

Japanese Off-Pump Coronary Revascularization Investigation

8/10

Medical charge: ..... yen

Status at discharge:  Alive  Dead

Patient Activities:  Not affected  Moderately compromised  Severely compromised

Mortality Date: ..... (yyyy/mm/dd)

Primary Cause of Death:  Cardiac  Renal  Infection  Valvular  
 Neurological  Vascular  Pulmonary  Other

Course:  Observation / Medication  
 Catheter Intervention  
 Reoperation

Memo: .....  
.....  
.....

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Participant ID: \_\_\_\_\_ Name: \_\_\_\_\_ Gender:  Male  Female  
 Patient Number: \_\_\_\_\_ Hospital: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
 Date of Surgery: \_\_\_\_\_

**R. Event ( II )**

Date: \_\_\_\_\_ (yyyy/mm/dd) Event <=30 days from Date of Procedure:  No  Yes

- |  |   |   |
|--|---|---|
| <input type="checkbox"/> Anticoagulant Compl     | <input type="checkbox"/> MI/Recurrent Angina                | <input type="checkbox"/> Cerebrovascular Accident |
| <input type="checkbox"/> Arrhythmias             | <input type="checkbox"/> Pericardial Effusion/Tamponade     | <input type="checkbox"/> Vascular Accident        |
| <input type="checkbox"/> CHF                     | <input type="checkbox"/> Pneumonia Respiratory Complication | <input type="checkbox"/> Sudden death             |
| <input type="checkbox"/> Incisional Complication | <input type="checkbox"/> Valve Dysfunction                  | <input type="checkbox"/> Other                    |

Readmission :  No  Yes

Day Admission: \_\_\_\_\_ Discharge: \_\_\_\_\_ Hospital stay: \_\_\_\_\_ days

Ischemia :  No  Yes (yyyy/mm/dd)

Stress ECG Date : \_\_\_\_\_  Treadmill  Ergometer  Master → Ischemia :  Negative  Positive

RI Date : \_\_\_\_\_  Rest  Stress (Exercise)  Stress (Drug) → Ischemia :  Negative  Positive

CAG Date : \_\_\_\_\_

UCG : ( Date: \_\_\_\_\_ )  
 Angio : LVEDVI: \_\_\_\_\_ LVESVI: \_\_\_\_\_ LVEF: \_\_\_\_\_ %  
 LVDD: \_\_\_\_\_ LVDs: \_\_\_\_\_ FS: \_\_\_\_\_ %  
 RI : LVEDVI: \_\_\_\_\_ LVESVI: \_\_\_\_\_ LVEF: \_\_\_\_\_ %

- CAG - Stenosis rate:
- |                  |                                    |                                |                                |                                |                           |                             |
|------------------|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------|-----------------------------|
| segment 1        | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment 2        | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment 3        | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment 4AV      | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment 4PD      | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment LMT      | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment LAD      | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment DB ( 9 ) | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment DB (10)  | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment 11       | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment 12       | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment 13       | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment 14       | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |
| segment 15       | <input type="radio"/> normal - 49% | <input type="radio"/> 50 - 74% | <input type="radio"/> 75 - 89% | <input type="radio"/> 90 - 98% | <input type="radio"/> 99% | <input type="radio"/> total |

Distal Anastomoses problem:  No  Yes

	Inflow	Graft	Site	Last Patency	Patency
1:	_____	_____	_____	_____	_____
2:	_____	_____	_____	_____	_____
3:	_____	_____	_____	_____	_____
4:	_____	_____	_____	_____	_____
5:	_____	_____	_____	_____	_____
6:	_____	_____	_____	_____	_____
7:	_____	_____	_____	_____	_____

In situ Graft problem:  No  Yes ↴

Free Graft problem:  No  Yes ↴

In situ Graft	Last Patency	Patency	Free Graft	Last Patency	Patency
1:	_____	_____	1:	_____	_____
2:	_____	_____	2:	_____	_____
3:	_____	_____	3:	_____	_____
			4:	_____	_____

# JOCRI Database

Japanese Off-Pump Coronary Revascularization Investigation

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Medical charge: \_\_\_\_\_ yen

Status at discharge:  Alive  Dead

Patient Activities:  Not affected  Moderately compromised  Severely compromised

Mortality Date: \_\_\_\_\_ (yyyy/mm/dd)

Primary Cause of Death:  Cardiac  Renal  Infection  Valvular  
 Neurological  Vascular  Pulmonary  Other

Course:  Observation / Medication  
 Catheter Intervention  
 Reoperation

Memo: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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Participant ID: \_\_\_\_\_ Name: \_\_\_\_\_ Gender:  Male  Female
Patient Number: \_\_\_\_\_ Hospital: \_\_\_\_\_ Date of Birth: \_\_\_\_\_
Date of Surgery: \_\_\_\_\_

R. Event ( III )

Date: \_\_\_\_\_ (yyyy/mm/dd) Event <=30 days from Date of Procedure:  No  Yes
[ ] Anticoagulant Compl [ ] MI/Recurrent Angina [ ] Cerebrovascular Accident
[ ] Arrhythmias [ ] Pericardial Effusion/Tamponade [ ] Vascular Accident
[ ] CHF [ ] Pneumonia Respiratory Complication [ ] Sudden death
[ ] Incisional Complication [ ] Valve Dysfunction [ ] Other

Readmission :  No  Yes

Day Admission: \_\_\_\_\_ Discharge: \_\_\_\_\_ Hospital stay: \_\_\_\_\_ days

Ischemia :  No  Yes (yyyy/mm/dd)

Stress ECG Date : \_\_\_\_\_  Treadmill  Ergometer  Master -> Ischemia :  Negative  Positive

RI Date : \_\_\_\_\_  Rest  Stress (Exercise)  Stress (Drug) -> Ischemia :  Negative  Positive

CAG Date : \_\_\_\_\_

Angio : LVEDVI: \_\_\_\_\_ LVESVI: \_\_\_\_\_ LVEF: \_\_\_\_\_ %

UCG : ( Date: \_\_\_\_\_ ) LVDd: \_\_\_\_\_ LVDs: \_\_\_\_\_ FS: \_\_\_\_\_ %

RI : LVEDVI: \_\_\_\_\_ LVESVI: \_\_\_\_\_ LVEF: \_\_\_\_\_ %

- CAG - Stenosis rate: segment 1  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment 2  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment 3  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment 4AV  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment 4PD  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment LMT  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment LAD  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment DB ( 9 )  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment DB (10)  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment 11  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment 12  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment 13  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment 14  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total
segment 15  normal - 49%  50 - 74%  75 - 89%  90 - 98%  99%  total

Distal Anastomoses problem: Inflow Graft Site Last Patency Patency
 No 1: \_\_\_\_\_
 Yes 2: \_\_\_\_\_
3: \_\_\_\_\_
4: \_\_\_\_\_
5: \_\_\_\_\_
6: \_\_\_\_\_
7: \_\_\_\_\_

In situ Graft problem:  No  Yes Free Graft problem:  No  Yes

In situ Graft Last Patency Patency Free Graft Last Patency Patency
1: \_\_\_\_\_ 1: \_\_\_\_\_
2: \_\_\_\_\_ 2: \_\_\_\_\_
3: \_\_\_\_\_ 3: \_\_\_\_\_
4: \_\_\_\_\_

# JOCRI Database

Japanese Off-Pump Coronary Revascularization Investigation

10/10

Medical charge: ..... yen

Status at discharge:  Alive  Dead

Patient Activities:  Not affected  Moderately compromised  Severely compromised

Mortality Date: ..... (yyyy/mm/dd)

Primary Cause of Death:  Cardiac  Renal  Infection  Valvular  
 Neurological  Vascular  Pulmonary  Other

Course:  Observation / Medication  
 Catheter Intervention  
 Reoperation

Memo: .....  
.....  
.....

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# Japanese Off-Pump Coronary Revascularization Investigation Database Definition Form

## A. Administrative

Participant ID: 各施設共通の通し番号

## B. Demographics

Patient Medical Record No. : 病院における患者番号

Initial: 名前をイニシャルで記載。姓、名の順（外国人もこの順）に記載。

Date of Birth: 誕生日を西暦にて記載

Gender: 性別の選択

## C. Hospitalization

Hospital name: 病院名

Date of Admission: 入院日を西暦にて記載、転科もしくは転棟日ではなく必ず当該病院入院日を記載すること。

Surgery, Discharge は I 自動入力

## D. Pre-Operative Risk Factors

Weight: 体重、術前直近の体重が望ましい

Height: 身長

CTR: 手術前心胸郭比(%)

Cognitive Function: 術前の高次機能検査 (Score)

Chronic Obesity: Body Mass Index ( $W/H^2$ ) > 26 であるもの

Smoker : 過去に喫煙歴があるものすべて（紙巻き、葉巻、パイプ、刻みタバコ等の種類を問わない）

Current smoker: 術前 1 ヶ月以内に喫煙歴のあるもの

Family history of CAD: 直系親族のいずれかが 55 歳未満で（●狭心症●心筋梗塞●原因不明の突然心臓死）の履歴のあるもの

Diabetes: 病悩期間に関わらず糖尿病の既往のあるもの

Diabetes Control: None 無治療 / Diet 食事療法のみ / Oral 経口糖尿病薬内服 / Insulin インスリン注射使用者

Hypercholesterolemia: 高脂血症（●TC > 200 ●LDL  $\geq$  130 ●HDL < 30 ●入院時 TC > 200 mg/dl）の既往のあるもの

Hypertension: 高血圧症（●高血圧症の診断のもとに降圧剤の投与、減量、運動療法を行った既往 ●収縮期 140mmHg 以上もしくは拡張期 90mmHg 以上が最低 2 回以上記録された ●現在降圧剤を内服中）の既往のあるもの

Preoperative: Hb, WBC, Platelets

Respiratory Function: 術前呼吸機能

%VC:

FEV1.0%:

Chronic Lung Disease:

No 肺機能正常

Mild 1 秒率 60-75% and / or 気管支拡張薬の吸入もしくは内服

Moderate 1 秒率 50-59% and/or 呼吸器疾患に対するステロイド使用

Severe 1 秒率 50%以下 and/or Room Air にて  $PO_2 < 60$  もしくは  $PCO_2 > 50$

Liver Function: 術前肝機能

AST:

ALT:

T-Bil:

Liver Dysfunction: Hepatitis, Liver Cirrhosis の既往

Renal Function: 術前直近の腎機能

BUN:

Creatinine:

Renal Failure: 腎機能障害、腎不全の既往のあるもの

Dialysis: 人工透析、腹膜透析施行中のもの

Aortic Aneurysm: 胸部または腹部大動脈の動脈瘤の有無

Peripheral Vascular Disease:

●間歇性跛行 ●血行不全による下肢切断 ●腹部大動脈、腸骨動脈再建 ●末梢血管バイパス ●血管形成もしくは STENT 挿入 ●非侵襲性検査陽性所見、解離性大動脈瘤などの一過性の血流不全は含めない。

Cerebrovascular Accident: 24 時間以上持続した中枢神経症状の既往

When: 発生時期が 2 週間以内か以上か

Cerebrovascular Disease: 下記のいずれかの既往のあるもの

CVD Type:

Coma: 24 時間以上持続した昏睡

CVA: 中枢神経障害が 72 時間以上持続したもの

RIND: 72 時間以内に消失した中枢神経障害の既往

TIA: 24 時間以内に消失した中枢神経障害の既往

Non Invasive >75% : Ultrasound, MRA による頸動脈や脳血管の有意狭窄病変(>75%)の有無

## E. Previous Interventions

Previous CV Interventions : 血栓溶解や手術、非手術を含めた術前の心臓血管 intervention 履歴の有無、今回入院時を含める。

Prior Coronary Intervention: 今回入院時も含めた冠動脈 Intervention の既往の有無

Thrombolysis: 今回入院時を含めて術前に血栓溶解療法を行ったもの

Thrombolysis Interval: 血栓溶解が術前 6 時間より前か後か  $\leq 6H / > 6H$

Previous Balloon Valvuloplasty: 過去に Balloon による弁形成の履歴のあるもの

Previous Cardiac Surgery: 過去の手術の既往について記載する。

CABG: 冠動脈バイパス術 (off pump、on pump を問わない)

Valve: 弁膜症手術

Aortic: 大動脈手術 (胸部大動脈、胸腹部大動脈、腹部大動脈のいずれも含む)

Others: 上記以外の心臓手術

Cerebrovascular Surgery: 頸動脈血栓内膜剥離術、脳血行再建術の既往

Peripheral Vascular Surgery: 四肢末梢血管、頸動脈等血管系の末梢血管手術の既往

## F. Pre Operative Cardiac Status

Myocardial Infarction: 過去に心筋梗塞の診断を受けたもの、以下の下記の条件のうち 2 つ以上に該当するものを心筋梗塞とする。

- 安静もしくは亜硝酸剤の投与にても消失しない 20 分以上持続する胸痛
- CK-MB が Total CK の 5% を越える、CK が正常上限の 2 倍を越える、LDH isozyme subtype 1  $>$  subtype 2、トロポニン  $>$  0.2 microgram/ml、のいずれかの血中酵素上昇を認める。
- 新たに出現した壁運動異常
- 連続する 2 つ以上の誘導で ST-T 変化を認める、または/もしくは連続する 2 つ以上の誘導で Q 波 (幅 0.03 秒以上 and/or QRS complex の 1/3 以上の深さを有する) を認める。

When: 発生時期を選択  $\leq 6H / > 6H$  but  $< 24H / 1-7$  days /  $8-21$  days /  $> 21$  days

Congestive Heart Failure: 術前 2 週間以内に下記の症状により心不全と診断されたもの

- 発作性夜間呼吸困難
- 心不全による労作時呼吸困難
- 胸部レントゲン写真による肺鬱血所見  
(利尿剤、もしくはジゴシンの投与を伴わない下肢浮腫、呼吸困難の存在は心不全とみなさない)

Angina: 狭心症が認められるもの

Type: 現在の狭心症のタイプを選択する

Stable: 経口、経皮薬で安定してコントロールされている狭心症

Unstable: ICU 入室、亜硝酸剤の点滴静注を要するもの、または下記の Unstable type のいずれかに該当するもの

Unstable Type: 下記の Unstable type より 1 つだけ選択する。

Rest Angina: 20 分以上持続する安静時胸痛

New Class 3: 最近 2 ケ月以内に CCS class III 狭心症 (日常生活が著しく制限される狭心症、数十 m の歩行、階段で 1 階登ると狭心症状の出現する) が発生したもの

Recent Accel: 最近 2 ケ月以内に狭心症症状が CCS class III に悪化したもの

Variant: 異型狭心症による症状出現

Non-Q: non Q MI の発生

Post-Infarct Angina: 急性心筋梗塞発症後 24 時間以上続く梗塞後狭心症

Cardiogenic Shock: 手術施行時に下記のいずれかの状況で臨床的に循環不全と判断されるもの

Refractory Shock: 最大限の治療にても収縮期血圧<80mmHg and/or 心係数<1.8 l/min/m<sup>2</sup>

Hemodynamic Instability: 収縮期血圧>80mmHg、心係数>1.8 l/min/m<sup>2</sup>を保つために強心剤や亜硝酸製剤等の点滴 and/or IABP が必要

Resuscitation: 手術開始 1 時間以内に心肺蘇生を要したもの

Arrhythmia: 術前 2 週間以内に下記のうちいずれかの不整脈を認めたもの

Type:

Sust VT or VF: cardioversion もしくは amiodarone の静注を必要とした sustained VT or Vf

CAVB (Complete Atrioventricular Block) : 完全房室ブロック

Af or AF: 治療を要した Atrial Fibrillation or Atrial Flutter

Classification:

CCS: (Canadian Cardiovascular Society Classification) 入院もしくは intervention に至った最大の分類を選択する

- 0 狭心症症状を認めないもの
- I 歩行、階段昇降などの通常の労作で狭心症の症状を生じないもの。激しい、長時間の労作にて狭心症症状が生じるもの。
- II 日常生活に軽度の制限があるもの。急いで歩いたり、階段を登ったり、坂を登ったり、食後や寒いとき、風の中、感情的なストレスを伴っての歩行、階段昇降、2 ブロック以上の平地歩行、通常の歩調で階段一続き以上登る、などで狭心症の症状の生じるもの。
- III 日常生活に著明な制限があるもの。平地 1、2 ブロックの歩行、通常の歩調で階段一続き登るなどで狭心症の症状の生じるもの。
- IV 症状を伴わずに日常生活が全く行えないもの。もしくは安静時に狭心症の症状を認めるもの。

NYHA: (New York Heart Association Class) 入院時もしくは手術直前に診断する

- I 心疾患はあるが、身体活動に制限がないもの。普通の運動では特別な疲労感、動悸、呼吸困難、あるいは狭心痛を認めないもの。
- II 軽度の運動制限があるもの。安静時は異常ないが、日常の体動で上記の症状を認めるもの。
- III 著明な運動制限があるもの。安静時は異常ないが、日常以下の体動で上記の症状を認めるもの。
- IV 安静時にも上記の症状を認めるもの。

## G. Pre Operative Medications

それぞれの種類の薬物投与を受けていたもの

Digitalis: No Yes      Beta Blockers: No Yes      Nitrates:      No Yes

Diuretics: No Yes      Inotropic Agents: No Yes      Aspirin:      No Yes

Antip latelets other than aspirin: No Yes      Anticoagulants: No Yes

Steroids: No Yes