It has been debated whether intensive BG control is better than conventional BG control. In a landmark paper, Van den Berghe et al. conducted the first prospective randomized trial comparing tight BG control (target 80-110mg/dl) with intensive insulin therapy to conventional BG control in critically ill surgical patients [16]. They demonstrated that tight BG control resulted in a significant reduction in mortality (10.6% with intensive treatment vs 20.2% with conventional treatment, p=0.005), exclusively in those patients who required ≥ 5 days of ICU care with multiorgan failure and sepsis. Also, cardiac surgical mortality was reduced in those patients requiring ≥ 3 days of ICU care. D'Alessandro et al. reported a propensity analysis that showed that strict BG control significantly reduced the EuroSCORE expected mortality in DM patients undergoing CABG, especially in moderate to high-risk patients [17]. Their BG target in the operating room and ICU were 150-200mg/dl and ≤ 140mg/dl, respectively. In terms of long-term outcomes, Lazar et al. showed that tight perioperative glucose control with glucose-insulin-potassium solution improved not only perioperative outcomes, but also long-term survival and freedom from recurrent angina [18]. These studies clearly demonstrate the superiority of tight BG control over conventional control, especially in critically ill patients. On the other hand, Gandhi et al. showed in a prospective randomized study on 400 patients undergoing CABG, including non-DM patients, that intraoperative intensive insulin therapy with a target range of 80-100mg/dl did not reduce perioperative mortality and morbidity, but rather increased stroke rate and mortality [19]. Furthermore, a meta-analysis of 29 randomized studies focusing on the benefits and risks of tight glucose control in critically ill adult patients concluded that tight glucose control was not associated with significantly reduced hospital mortality but was associated with an increased risk of hypoglycemia [20]. To support these results, a recent prospective randomized multicenter trial (the NICE-SUGAR study) demonstrated that intensive BG control with a target of 81-108mg/dl increased mortality among adults in the ICU compared with conventional BG control with a target of 180mg/dl or less [21]. In this study, however, the mortalities in the intensive control group and conventional control group were 27.5% and 24.9% at 90 days after randomization, respectively. In both groups, potentially life-sustaining treatments were withheld or withdrawn in more than 90% of the patients who died. Also, it seems that severe hypoglycemia commonly occurred in the intensive BG control group of the study, which may raise the question of the safety and feasibility of the tight glucose control protocol itself. Because these patients in the study were so sick at the time of enrollment, it is difficult to compare the results of these studies with studies on regular cardiac surgery patients, given the current acceptable mortality after CABG of around 2%. It may be necessary to conduct a prospective randomized study to compare tight glucose control and conventional glucose control using more sophisticated protocols with a minimum risk of hypoglycemia in exclusively cardiac surgery patients to reach a definitive conclusion.

Perhaps, one of the other interesting features of this multi-center study is the fact that about 70% of all isolated CABG procedures were performed using the off-pump technique in both the DM and non-DM groups. This trend is far above the typical rates in the North America, given the fact that the adoption of off-pump CABG was only 21.8% in 2009 according to the STS database [22]. A systematic review and meta-analysis of propensity score analyses in more than 123,000 patients comparing off-pump and on-pump CABG demonstrated that off-pump provides favorable outcomes in mortality, stroke, renal failure, wound infection, blood transfusion, intraaortic balloon pump support and prolonged ventilation [23]. It will be interesting to see the impact of off-pump techniques in DM patients in terms of not only intraoperative and postoperative glucose control, but also in terms of postoperative complications and mortality. We are planning to perform a post-hoc subgroup analysis focusing on this in the near future.

There are several limitations to this study. This was a retrospective, observational study, and hence unknown patient selection processes may cause a bias. Our sample size was relatively large, however, it was not large enough to stratify the level of perioperative BG control as an indicator of risk events. Importantly, there was no standard BG control protocol across the participating hospitals.

Conclusions

DM patients had poor perioperative BG control and higher incidence of infection with a higher mortality rate than non-DM patients. Excess mortality and morbidity in DM patients may have been due to hyperglycemia during the perioperative period. These results highlight the need to initiate prospective studies to standardize perioperative BG control protocols to obtain strict BG control, which may yield better surgical outcomes in Japanese DM patients undergoing cardiac surgery.

Acknowledgments: We are indebted to the participating centers, investigators and clinical research coordinators for their great contributions to data collection. The centers and investigators are listed in Appendix III. Also, we deeply thank the Independent Clinical Events Evaluation Committee and the External Advisory Board of this study as listed in Appendix III. Lastly, we are grateful to the organizing committee of JACVSD. There are no conflicts of interest.

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Table 1. Patients' baseline characteristics

Variables	DM Group (n=849)	Non-DM Group (n=572)	P value
Mean age (SD)	68.6 (8.4)	68.0 (10.1)	0.282
Age $\geq$ 75	208 (24.5%)	162 (28.3%)	0.107
Male gender	649 (76.4%)	451 (78.9%)	0.288
Mean body mass index (SD)	23.7 (3.3)	23.4 (3.1)	0.094
Steroid use	18 (2.1%)	8 (1.4%)	0.320
Congestive heart failure	131 (15.5%)	98 (17.1%)	0.397
Renal insufficiency	117 (13.8%)	45 (7.9%)	0.001
Chronic obstructive pulmonary disease	57 (6.7%)	64 (11.2%)	0.003
Peripheral artery disease	193 (22.7%)	101 (17.7%)	0.021
Left ventricular ejection fraction < 50%	212 (26.6%)	115 (20.5%)	0.010
Operative status			
Elective	732 (86.2%)	484 (84.6%)	0.154
Urgent	76 (9.0%)	67 (11.7%)	
Emergency	41 (4.8%)	21 (3.7%)	
Bilateral internal thoracic artery use	400 (47.1%)	285 (49.8%)	0.316
Intraoperative steroid use	246 (29.0%)	200 (35.0%)	0.017
On-pump or off-pump			
On-pump	214 (25.2%)	154 (26.9%)	0.754
On-pump beating	43 (5.1%)	27 (4.7%)	
Off-pump	592 (69.7%)	391 (68.4%)	

DM: diabetes mellitus

Table 2. Adverse events and outcomes

	DM Group (n=849)	Non-DM Group (n=572)	Risk ratio (95%CI)	P value
Primary composite endpoint	105 (12.4%)	60 (10.5%)	1.18 (0.87-1.59)	0.279
Additional composite endpoint	92 (10.8%)	42 (7.3%)	1.48 (1.04-2.09)	0.027
All-cause deaths	18 (2.1%)	6 (1.1%)	2.02 (0.81-5.06)	0.124
Acute myocardial infarction	11 (1.3%)	12 (2.1%)		
Related death	2 (0.2%)	0		
Cerebrovascular accident	12 (1.4%)	6 (1.1%)		
Related death	1 (0.1%)	0		
Other cardiovascular event	11 (1.3%)	15 (2.6%)		
Related death	3 (0.4%)	1 (0.2%)		
All infections	78 (9.2%)	35 (6.1%)	1.50 (1.02-2.21)	0.036
Related death	10 (1.2%)	1 (0.2%)		
Infection site				
Deep sternal wound	17 (2.0%)	6 (1.1%)	1.91 (0.76-4.81)	0.163
Superficial sternal wound	22 (2.6%)	15 (2.6%)		
Graft harvest site	22 (2.6%)	9 (1.6%)		
Blood stream	5 (0.6%)	2 (0.4%)		
Urinary tract	5 (0.6%)	1 (0.2%)		
Pneumonia	9 (1.1%)	8 (1.1%)		
Acute renal failure	12 (1.4%)	5 (0.9%)	1.62 (0.57-4.57)	0.359
Related death	1 (0.1%)	0		
Other deaths	1 (0.1%)	4 (0.7%)		

CI: confidence interval, DM: diabetes mellitus

Table 3. Results of the logistic regression for the additional composite endpoint

Variables	Odds ratio	95% CI	P value
Diabetes mellitus	1.28	0.85-1.92	0.235
Age (in 10-year increments)	1.01	0.81-1.26	0.935
Male gender	0.58	0.38-0.89	0.012
Body mass index	1.07	1.02-1.14	0.012
Congestive heart failure	0.94	0.51-1.67	0.843
Renal insufficiency	3.23	2.00-5.14	0.000
Chronic obstructive pulmonary disease	1.91	1.02-3.41	0.034
Peripheral artery disease	0.94	0.57-1.49	0.787
Left ventricular ejection fraction < 50%	1.39	0.89-2.13	0.139
Urgent	1.60	0.82-2.95	0.149
Emergency	1.13	0.34-3.13	0.823
Bilateral internal thoracic artery use	1.31	0.89-1.94	0.177
Intraoperative steroid use	0.66	0.42-1.01	0.060

CI: confidence interval

Table 4. Results of the logistic regression for all infections

Variables	Odds ratio	95% CI	P value
Diabetes mellitus	1.29	0.84-2.01	0.253
Age (in 10-year increments)	0.96	0.76-1.22	0.751
Male gender	0.52	0.33-0.83	0.005
Body mass index	1.08	1.02-1.14	0.014
Congestive heart failure	0.96	0.49-1.79	0.904
Renal insufficiency	3.13	1.86-5.16	0.000
Chronic obstructive pulmonary disease	1.85	0.93-3.46	0.064
Peripheral artery disease	0.85	0.49-1.40	0.533
Left ventricular ejection fraction < 50%	1.42	0.88-2.26	0.142
Urgent	1.37	0.65-2.69	0.386
Emergency	0.72	0.16-2.36	0.619
Bilateral internal thoracic artery use	1.37	0.90-2.09	0.144
Intraoperative steroid use	0.68	0.42-1.06	0.099

CI: confidence interval

Table 5. Results of the logistic regression for all cause death

Variables	Odds ratio	95% CI	P value
Diabetes mellitus	1.89	0.72-5.61	0.219
Age (in 10-year increments)	1.10	0.67-1.88	0.715
Male gender	0.66	0.25-1.97	0.429
Body mass index	0.90	0.78-1.04	0.169
Congestive heart failure	2.27	0.69-7.03	0.165
Renal insufficiency	3.04	1.12-7.80	0.023
Chronic obstructive pulmonary disease	4.22	1.24-12.60	0.013
Peripheral artery disease	1.56	0.55-4.07	0.374
Left ventricular ejection fraction < 50%	2.33	0.92-5.87	0.071
Urgent	3.15	0.89-10.32	0.065
Emergency	5.30	1.05-26.7	0.043
Bilateral internal thoracic artery use	1.85	0.71-4.81	0.204
Intraoperative steroid use	0.35	0.10-1.00	0.073

CI: confidence interval

Appendix I

Preoperative variables include age, gender, height, and weight. Preoperative co-morbidities included systemic hypertension, dyslipidemia, insulin-controlled DM, oral medication-controlled DM, diet-controlled-DM, congestive heart failure, renal insufficiency, chronic obstructive pulmonary disease, peripheral artery disease, cigarette smoking, cerebrovascular accidents, and advanced New York Heart Association functional class. Cardiovascular variables included left main coronary disease, number of diseased coronary arteries, left ventricular ejection fraction, unstable angina, acute MI, previous MI, history of atrial fibrillation and ventricular tachycardia or fibrillation, cardiogenic shock, PCI, and intra-aortic balloon pump insertion. Preoperative blood laboratory variables included random and fasting serum glucose, HbA1c, albumin, serum creatinine, blood urea nitrogen, total cholesterol, high density and low density lipoproteins, triglycerides, and C-reactive protein. Preoperative medications included digitalis, beta-blockers, nitrates, inotropic agents, oral hypoglycemics, insulin, diuretics, steroids and immunosuppressants. Intraoperative variables were operative status (elective, urgent or emergency), reoperative procedure, single or bilateral internal thoracic artery or other arterial conduit usage, saphenous vein grafts and their targets, use of cardiopulmonary bypass, application of aortic cross-clamping, aortic cross-clamp time, cardiopulmonary bypass time, administration of intravenous insulin and steroids, and blood transfusion.

Appendix II

Definitions of clinical events

Acute myocardial infarction: the presence of at least two of the following symptoms or findings:

(1) CK-MB $\geq$ 5% of total CK and total CK $\geq$ 3x normal control, or CK-MB $\geq$ 100 mg/dl.

(2) typical symptoms.

(3) typical ECG change (new onset of ST-T change in more than 2 consecutive leads on 12-lead ECG or abnormal Q wave).

(4) New onset abnormal wall motion abnormality lasting $\geq$ 24 hours on echocardiography.

Of note, a pathological diagnosis of acute myocardial infarction on autopsy does not require any of the above findings.

Cerebral infarction: including all the following symptoms and findings:

(1) Apparent focal neurological deficits and symptoms or signs compatible with no other identified causes.

(2) Neurological symptoms and signs lasting $\geq$ 24 hours (excluded if patient died).

(3) Radiological diagnosis on computed tomography or magnetic resonance image.

Acute renal failure: increased creatinine of more than twice the preoperative baseline and equal to or more than 2.0mg/dl, or newly requiring hemodialysis.

Infection: infection occurs within 30 days after surgery

1. ***Deep sternal wound infection***: infection involving deep sternum and/or anterior mediastinum (fascia, sternum, mediastinum) and either:

   (1) Purulent drainage from the deep incision or the chest tube which is placed in the area communicating to the anterior mediastinum.

   (2) Organisms isolated from an aseptically obtained culture of fluid or tissue from the deep sternal wound or anterior mediastinum.

   (3) A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38°C), localized pain, or tenderness, unless site is culture-negative.

   (4) An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

   (5) Diagnosis of a deep incisional surgical site infection by a surgeon or attending physician.

2. ***Superficial sternal wound infection***: infection involving only the skin or subcutaneous tissue of the incision and either:

   (1) Purulent drainage, with or without laboratory confirmation, from the superficial incision.

   (2) Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.

   (3) At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless the incision is culture-negative.

   (4) Diagnosis of superficial incisional surgical site infection by the surgeon or attending physician.

3. ***Graft harvest site infection***: surgical site(s) infection including saphenous vein and radial artery harvesting:

   (1) At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat.

(2) Superficial incision is deliberately opened by the surgeon, or required resection of tissue or drainage, unless the incision is culture-negative.

(3) Diagnosis of superficial incisional surgical site infection by the surgeon or attending physician.

4. ***Blood stream infection***: the presence of a positive non-contaminated blood culture.

Contamination is diagnosed if one or more of the following organisms is identified in only one of a series of blood cultures: coagulase-negative staphylococci; *Propionibacterium acnes*; *Micrococcus* species; "viridans"-group streptococci; *Corynebacterium* species; or *Bacillus* species.

5. ***Urinary tract infection***: defined as the presence of symptoms or signs compatible with no other identified source of infection along with either:

(1) $>10^5/\text{mm}^3$ colony forming units/ml of at least one bacterial species in a single urine specimen.

(2) purulent urine (> 10 white blood cells/field in a microscopic urinalysis).

6. ***Pneumonia***: The clinical suspicion of pneumonia is based on clinical criteria; new or progressive radiological pulmonary infiltrate plus more than two of the following characteristics: temperature (38°C < or < 35.5°C), leukocyte count (>12,000 cells/mm^3 or <4,000 cells/mm^3) or purulent respiratory secretions. Ventilator-associated pneumonia is diagnosed in patients with microbiologic evaluation including the collection of at least one lower respiratory airway sample by sputum, tracheobronchial aspirate, bronchoscopy or by blind bronchoalveolar lavage. Blood cultures and cultures of pleural fluid specimens, if puncture was indicated, were also undertaken. Microbiologic confirmation of pneumonia was defined by the presence of ≥ 1 potentially pathogenic microorganism in the respiratory samples above the predefine thresholds (for bronchoalveolar lavage specimens, $>10^4$ colony forming units/ml; for sputum or tracheobronchial aspirate specimens, $>10^5$ colony forming units/ml); in pleural fluid specimens; or in blood cultures, if an alternative cause of bacteremia was ruled out.

Appendix III

Participating centers and other investigators: Yoshino Mitsunaga (Iwate Medical University), Shigefumi Matsuyama (Sakakibara Heart Institute), Shin-ichi Mizutani (Nagoya University Graduate School of Medicine), Hiroyuki Muranaka, Akira Fujimoto, Mariko Nakamoto, Masami Fukutomi, Koji Oba (Kyoto University Graduate School of Medicine), Kiyoshi Doi (Kyoto Prefectural University of Medicine), Yuki Okamoto (Tominaga Hospital), Kentaro Honda

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Gen Thorac Cardiovasc Surg (2010) 58:356–383
DOI 10.1007/s11748-010-0604-0

ANNUAL REPORT

Thoracic and cardiovascular surgery in Japan during 2008

Annual report by The Japanese Association for Thoracic Surgery

Committee for Scientific Affairs

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The Japanese Association for Thoracic Surgery has conducted annual surveys of thoracic surgery throughout Japan since 1986 to determine the statistics regarding the number of procedures according to the operative category. Here we have summarized the results from our annual survey of thoracic surgery performed during 2008.

The incidence of hospital mortality was added to the survey to determine the nationwide status, which can be useful not only for surgeons, who can better compare their work with that of others, but also for the Association, which can gain a better understanding of present problems as well as future prospects. Thirty-day mortality (sometimes termed "operative mortality") is death within 30 days of an operation regardless of the patient's geographic location and even though the patient had been discharged from the hospital within those 30 days.

Hospital mortality is death within any time interval after an operation if the patient had not been discharged from the hospital. Hospital-to-hospital transfer is not considered discharge; transfer to a nursing home or a rehabilitation unit is considered hospital discharge unless the patient subsequently dies of complications of the operation. (The definitions of terms are based on the published guidelines of the Ad Hoc Liaison Committee for Standardizing Definitions of Prosthetic Heart Valve Morbidity of the Society of Thoracic Surgeons and the American Association for Thoracic Surgery (Edmunds et al. *Ann Thorac Surg* 1996;62:932–5; *J Thorac Cardiovasc Surg* 1996;112:708–11).

Thoracic surgery was classified into three categories—cardiovascular, general thoracic, and esophageal surgery—and the pertinent data were examined and analyzed for each group. Access to the computerized data is offered to all members of this Association. We honor and value your continued kind support and contributions.

This is the annual report by The Japanese Association for Thoracic Surgery from the Committee for Scientific Affairs.

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Abstract of the survey

We sent out survey questionnaire forms to the departments of each category in all 1,989 institutions nationwide in early April 2009. The response rates in each category by the end of December 2009 were 99.0%, 95.3%, and 95.7% for cardiovascular, general thoracic, and esophageal surgery, respectively.

Questionaires sent out and received back by the end of December 2009

	Sent out	Returned	Response rate
(A) Cardiovascular surgery	599	593	99.0%
(B) General thoracic surgery	785	748	95.3%
(C) Esophageal surgery	605	579	95.7%

Categories subclassified according to the number of operations performed

No. of operations performed	Category	
	Cardiovascular surgery	General thoracic surgery
0	62	33
1–24	53	136
25–49	101	143
50–99	162	202
100–149	96	118
150–199	42	55
≥200	77	61
Total	593	748

No. of operations performed	Esophageal surgery
0	78
1–4	184
5–9	121
10–19	92
20–29	36
30–39	25
40–49	11
≥50	32
Total	579

2008 Final report

(A) Cardiovascular surgery

First, we are very pleased with the high response rate to our survey of cardiovascular surgery (99%), which definitely enhances the quality of this annual report. We very much appreciate the enormous effort put into completing the survey at each participating institution.

Figure 1 shows the development of cardiovascular surgery in Japan over the last 23 years. Aneurysm surgery includes only operations for thoracic or thoracoabdominal aortic aneurysms. The number of pacemaker and assist device implantation operations is not included in the total number of surgical operations. A total of 57,941 cardiovascular operations were performed at 593 institutions during 2008 alone and included 11 cardiac transplantation operations, which were started from 1999. The number of operations for thoracic aortic aneurysm consistently increased, by 9.1%, and that for valvular heart disease also increased, by 10%, compared with 2007. Surgery for congenital heart disease slightly increased, by 2.7%. Of great interest, the number of operations for ischemic heart disease increased by 2.8% in 2008 compared with 2007, after a consecutive decline for the last 5 years. We hope that this trend steadily continues.

Data for individual categories are summarized in Tables 1–7. In 7,328 open-heart operations performed for congenital heart disease, the overall hospital mortality was 2.6%, which has varied little since 2005. Mitral valve repair constituted 28.2% of all valvular heart disease operations (16,747), which is similar to that of the last 3 years. Aortic valve replacement with a bioprosthesis was performed in 5,417 cases, with the number consistently increasing. The hospital mortality rates associated with primary single valve replacement were

2.8% and 4.5% for aortic and mitral valve replacement, respectively, while that for primary mitral valve repair was 1.3%. However, hospital mortality rates for redo valve replacement were 7.4% and 6.4% for aortic and mitral procedures, respectively.

Isolated coronary artery bypass grafting (CABG) was performed in 17,764 cases which is an increase of 2.7% compared with 17,295 in 2007.

The operative and hospital mortality rates associated with primary elective CABG procedures in 14,943 cases were 0.7% and 1.2%, respectively. However, hospital mortality of primary emergency CABG in 2,487 cases was 7.4%, which was still high. Off-pump coronary bypass grafting (OPCAB) was performed in 11,222 cases, constituting 63.2% of the total isolated CABG procedures. The percentage of OPCAB cases among the total isolated CABG procedures has been at the same level since 2005.

A total of 1,466 patients underwent surgery for complications of myocardial infarction, including 505 operations for a left ventricular aneurysm or infarction and 386 operations for ischemic mitral regurgitation. Operations for thoracic aortic dissection were performed in 5,013 cases. For 3,283 type A acute aortic dissections, hospital mortality was 13.0%, which was similar to that in 2007 (12.7%). Operations for a nondissected thoracic aneurysm were carried out in 5,985 cases, with an overall hospital mortality of 7.6%, which was equivalent to that in 2007 (7.6%). The hospital mortality associated with unruptured aneurysms was 5.0%, and that for ruptured aneurysms was 28.1%, which remains markedly high compared with that in 2007 (24.7%).

The number of stent graft procedures remarkably increased. A total of 331 patients with aortic dissection underwent stent graft placement: transluminal stent grafting (TEVAR) in 247 cases, open stent grafting in 82 cases. The hospital mortality rates of TEVAR for type B aortic dissection were 6.5% in acute dissection and 4.2% in chronic dissection. A total of 1,075 patients with a nondissected aortic aneurysm underwent stent graft placement (TEVAR in 823 cases; open stent grafting in 246 cases). The hospital mortality rates for TEVAR were 2.7% and 18.3% for nonruptured and ruptured aneurysms, respectively.

In summary, the total cardiovascular operations increased during the year 2008 by 5.3%. They were performed with steadily improving results in almost all categories compared with those in 2007.

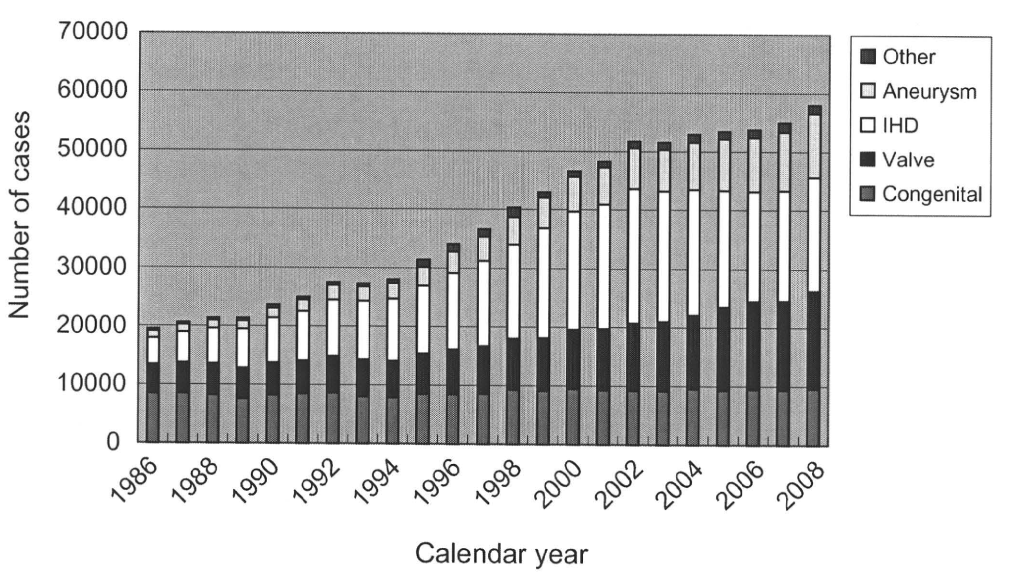

Fig. 1 General thoracic surgery. IHD, ischemic heart disease