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European Journal of Cardio-thoracic Surgery 15 (1999) 401–407

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

The meaning of early mortality after CABG[1]

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Received 21 September 1998; received in revised form 7 January 1999; accepted 12 January 1999

Abstract

Objective: Investigations of early mortality after coronary artery bypass grafting (CABG) are predominantly based on 30-day mortality or hospital mortality. The advantages, disadvantages, and usefulness of hospital mortality and 30-day mortality analyses to investigate the early risk after CABG are evaluated. **Methods**: A total of 4985 patients underwent isolated CABG from June 1988 to June 1997. A follow-up was performed 180 days after CABG (response rate: 98.6%). **Results**: The mean hospital stay was 13.5 ± 9.6 days, the range was 0 to 142 days (25% quartile, 9 days; median, 12 days; 75% quartile, 15 days). The hospital mortality was 5.3%. The 30-day mortality was 5.6%. The non-parametric Kaplan–Meier curve of the time interval 0–180 days postoperatively proves the persistence of the still decreasing behaviour of the survival curve beyond the 30th day until about the 60th postoperative day. Stratified by era of operation, the 'early phase' after CABG seems to be prolonged beyond 30 days at least for the more recent operation era since 1991. Risk stratification proves that the higher the risk group, the more the early phase tends towards a prolongation. **Conclusions**: The hospital mortality reflects institutional habits concerning postoperative patient care. Therefore, a systematic underestimation of early mortality is likely. In contrast to hospital stay, the evaluation of 30-day mortality requires a follow-up procedure but allows interinstitutional comparisons. Nevertheless, 30-day mortality systematically underestimates the early risk, at least in the more recent CABG period. So, a standardized evaluation of a longer time period (p.e. 180 days) is recommended.

Keywords: Early mortality; Coronary artery bypass grafting; Risk analysis

1. Introduction

Investigations of early mortality are predominantly based on 30-day mortality or hospital mortality. However, hospital mortality depends on institutional discharge politics and therefore, can be seen as an 'ill-defined' time variable. Nevertheless, even the investigation of a well-defined interval, such as 30-days, bears the risk of interinstitutional differences in terms of incomplete follow-up (censored data). Furthermore, the 30-day interval needs to be determined whether the time interval itself represents a sufficiently reliable basis for the estimation of 'early mortality'. Therefore, we performed the present investigation to evaluate, whether a new definition of 'early mortality' is needed.

2. Patients and methods

A total of 4985 patients underwent isolated coronary artery bypass grafting (CABG) during June 1988 to June 1997 at the University of Heidelberg, including emergent operations and reoperations.

A regular follow-up was performed 180 days after CABG; the response rate was 98.6%. Tools of the HVMD (Heidelberger Verein für multizentrische Datenanalyse e.V.) were used for both follow-up procedures and the complete patient documentation. Statistical analysis was performed by using the tools of SAS® V. 6.12 (SAS

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[1] Presented at the 12th Annual Meeting of the European Association for Cardio-thoracic Surgery, Brussels, Belgium, September 20–23, 1998.

1010-7940/99/$ - see front matter
PII: S1010-7940(99)00029-9

Institute, Cary, USA). The non-parametric survival analysis was performed using Kaplan–Meier non-parametric estimation methodology [1]. For estimation of parametric survival and hazard, tools of the University of Alabama at Birmingham were used. The parametric multivariable analysis was performed using the time-adjusted parametric Hazard function [2].

3. Results

3.1. Hospital mortality

To evaluate hospital mortality, the time of operation to discharge was calculated. The mean hospital stay was 13.5 ± 9.6 days (minimum, 0 days; maximum, 142 days; 25% quartile, 9 days; median, 12 days; 75% quartile, 15 days). Hospital mortality was 5.3% (n = 264).

3.2. Thirty-day mortality and investigation of larger time intervals

Thirty-day mortality was 5.6% (n = 267). The non-parametric Kaplan–Meier curve of the total patient group (n = 4985) during 180 days after intervention is shown in Fig. 1 represented by the black line ±70% confidence limits. As to be seen in most of the surgical or interventional survivorship functions, there is a relatively high initial decreasing survivorship curve which turns with increasing time towards a more linear behaviour. By focusing on the 30-day interval, the major part of the early decrease is clearly depicted by the time interval. However, there is a further decrease even after the 30th postoperative day until about the 60th postoperative day (Fig. 1) indicating that a substantial number of events occur between the 30 and 60th postoperative day. For subsequent analyses, using the time-adjusted parametric hazard function [2] a parametric model has been adjusted; the model and its 70% confidence limits are represented by grey lines in Fig. 1. Specifications of the parametric model are given in Appendix A.

The stratification by era of operation from 1988 to 1991 and from 1992 to 1997 indicates a prolongation of the early intervention-related mortality in the more recent era. Fig. 2a,b show the era-dependent differences of the instantaneous hazards of the stratified era of operation. The total patient group has been divided into a former group which has been operated between June 1988 and December 1991 (n = 1549, 75 events), and a recent group (January 1992 to June 1997) (n = 3436, 263 events). The actual hazard is superimposed by the parametric hazard of two separate parametric models (see Appendix B) to illustrate the substantially later occurrence of the vertex of the parametric hazard recent patient group. The very early reduction of the hazard in the former stratification era (Fig. 2a) indicate, that 30-days sufficiently reflect the total ‘early mortality’ after CABG. However, in the more recent era (Fig. 2b) a 30-day ‘cut-off’ ignores the persistence of ‘hazard peaks’ beyond the 30th day.

To investigate the reason of this phenomenon, the above-described parametric model of the total patient group (see Appendix A) has been taken for the multivariable analysis of preoperative concomitant information. Out of the identified ‘risk factors’ (see Appendix C), five ‘risk groups’ have been separated (up to 2, 2.1–3, 3.1–5, 5.1–9 and over 9%

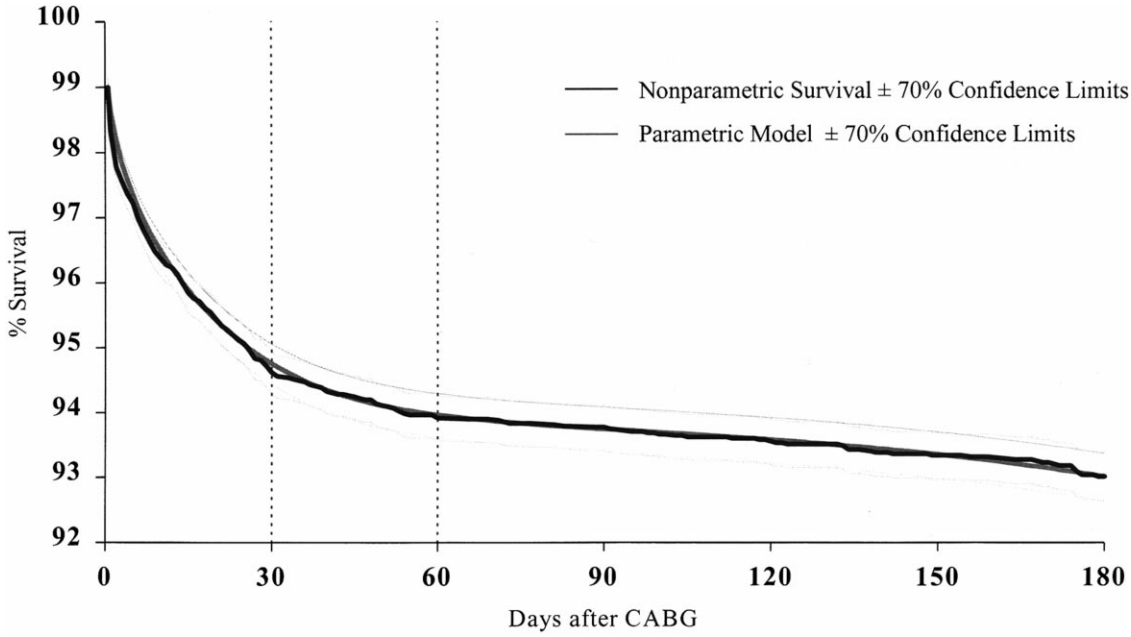

Fig. 1. Survival estimates and 70% confidence limits of 4985 patients illustrate the typical behaviour of survival after any intervention. The very early postinterventional course is characterized by a rapidly decreasing survival which becomes more constant by time. However, the ‘end’ of the rapid decreasing survival is more likely to be at about the 60th day, but at the mostly investigated 30th day.

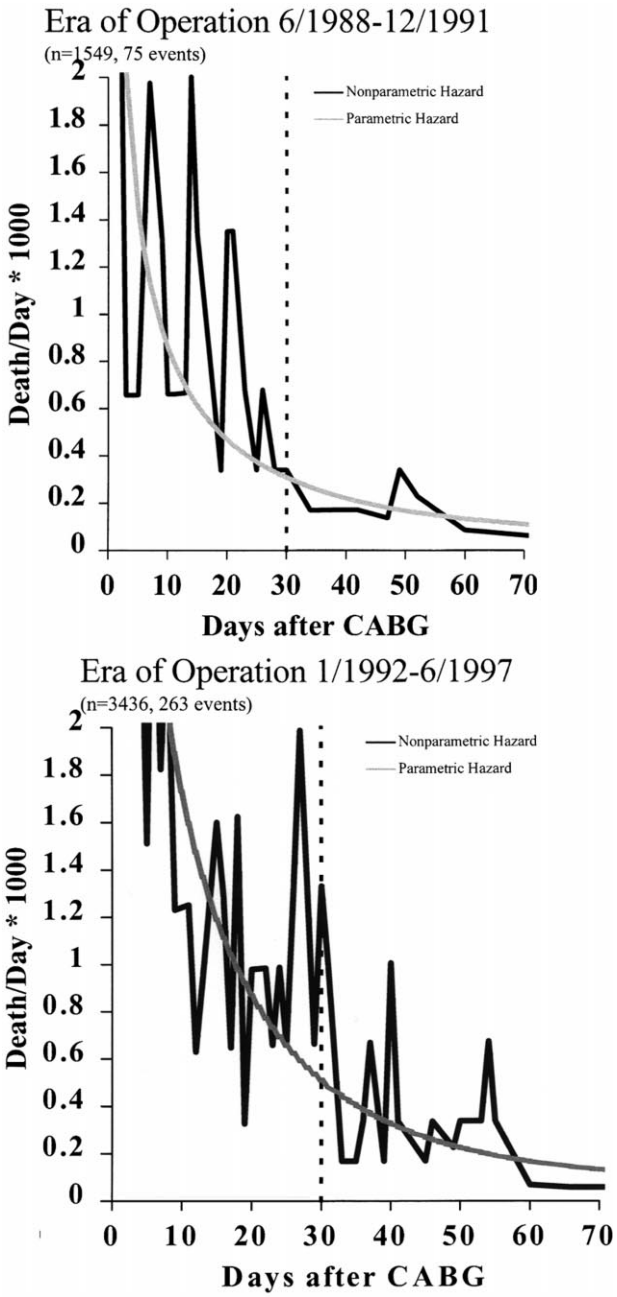

Fig. 2. (a) The instantaneous hazard between day 0 and 70 for the former investigation period from June 1988 to December 1991 indicates the appropriateness of the 30-day analyses to investigate the total early mortality. The vertex of the superimposed parametric hazard is located within the 30-day interval. (b) The instantaneous hazard between day 0 and 70 for the more recent investigation period from January 1992 to June 1997 indicates the underestimation of early mortality by 30 day analyses. Furthermore, the vertex of the parametric hazard is located beyond 30 days after CABG.

predicted mortality at the 180th postoperative day). Table 1 shows the mean occurrence and the mean age, respectively, of each variable stratified by predicted risk. Fig. 3 demonstrates, that in the lowest risk group, the early phase lasts a short period of time. The higher the risk group, the longer the early period lasts. So, the increasing early period after operation is at least partially to be explained by an increase of high risk patients in the recent operation era.

4. Discussion

Thirty-day mortality and hospital mortality, are both predominantly used to evaluate the early risk of surgical procedures. In our investigation, both death rates did not differ greatly. Nevertheless, each of those time intervals implies advantages and disadvantages.

4.1. Hospital mortality

Hospital mortality summarizes the time between admission and discharge. However, the hospitalization time is usually calculated by one single institution for only one period of hospitalization. Therefore, the time after discharge will be excluded from any analysis even if the patient was hospitalized again at another or even the same institution. In addition, even the patient at home is a patient ‘at risk’ to experience an ‘early event’. So, an overall underestimation of ‘early mortality’ is very likely. Furthermore, hospital mortality summarizes even ‘late’ events which occur in our study up to 142 days after operation. The influence of surgical technique and strategy on the length of hospital stay at the 142nd postoperative day is likely to be low compared with the risk deriving from preoperative morbidity and comorbidity in an unselected patient group. Hospital mortality is affected by either potential known or unknown manipulation and its representativity in view of the evaluation of early mortality or even interinstitutional risk-adjustment might be doubtful. To reduce the distortion of results by varying time intervals, in various studies the 30-day hospital mortality is used [3–5]. However, the varying length of hospitalization remains as a problem for the comparability with studies which are using complete 30-day information.

4.2. Thirty-day mortality

Fixed time intervals such as 30-days imply the possibility of ‘well-defined’, reliable interinstitutional comparisons. However, some studies who express 30-day mortality as a synonym of ‘early mortality’ may not necessarily evaluate the ‘true’ 30-day mortality by any follow-up procedure [6]. So, one of the disadvantages of 30-day mortality analyses is the necessity to perform an appropriate follow-up. The ‘appropriateness’ of follow-up is another point of discussion since, various studies prove the potential bias of analyses which are based on data with incomplete follow-up [7,8]. The evaluation of early mortality in even discharged patients implies a further major benefit for either patients and surgeons, since the outpatient-contact remains one of the most important feedback mechanism to evaluate and improve personal and institutional quality.

Table 1

Variables and mean values of the five risk groups. In general, the mean occurrence of the variable per group has been included. The only exception is age (mean age [years; mean ± SD])

Variables	Predicted survival				
	≥ 98% (n = 714)	≥ 97% (n = 697)	≥ 95% (n = 1150)	≥ 91% (n = 1218)	< 91% (n = 1206)
Age [years; mean ± SD]	51 ± 6.7	58 ± 5.8	62 ± 6.2	67 ± 6.3	71 ± 6.2
Male [%]	96	92	85	74	57
Dyspnea at excercise [%]	31	47	58	70	82
LV dilation [%]	1.3	2.0	3.2	7.5	21
LV akinesia [%]	14	19	25	27	33
LV aneurysm [%]	0.4	1.7	2.0	4.0	8.0
Sinus rhythm [%]	96.9	95.7	96.0	92.5	87.7
Preop. β-blocker [%]	81	77	74	65	60
Preop. diuretics [%]	7	15	27	37	62
Peripheral vascular disease [%]	13	19	22	27	36
Diabetes [%]	6	12	20	30	47
Renal disease [%]	1	4	7	17	38
Dialysis dependency [%]	0.0	0.0	0.1	0.3	2.5
≥ 3 vessels ≥ 50% stenosis [%]	53	62	69	74	80
LAD occlusion [%]	3.1	4.6	6.4	7.5	11
Emergent indication [%]	1.8	2.9	2.1	1.8	3.0

The dependency of risk evaluation on the era of operation becomes obvious even if a well-known and established scoring system for patients who are operated for an acquired adult heart disease like the Parsonnet-Score [9] had to be re-evaluated 7 years after its introduction. The reweighing of variables in accordance with current practice and the reduction of optional fields was necessary, because progressive overestimation of mortality rates and an abuse of optional fields had occurred [10]. The primary score system was suggested to calculate the 'operative mortality', defined as any death occurring within 30 days of surgery, by simple addition of the weighed components. Unfortunately, the completeness of follow-up is not given in both of the studies. Besides the progress in surgical and anaesthesiological techniques, monitoring, and management, the increase of high risk patients in the recent era has already been part of a former study [11]. The prolongation of the early risk after CABG by an increasing number of high risk patients, where the 'prolongation of hazard' is an interpretation of the observed pattern of risk, based on a continuing trajectory of the hazard functions. So, investigations of early results after CABG need to take into account the apparently decreasing 30-day mortality, and the increasing number of patients with severe comorbidity and/or a worse preoperative status. Although the beneficial results of the general progress in medical systems over the last years

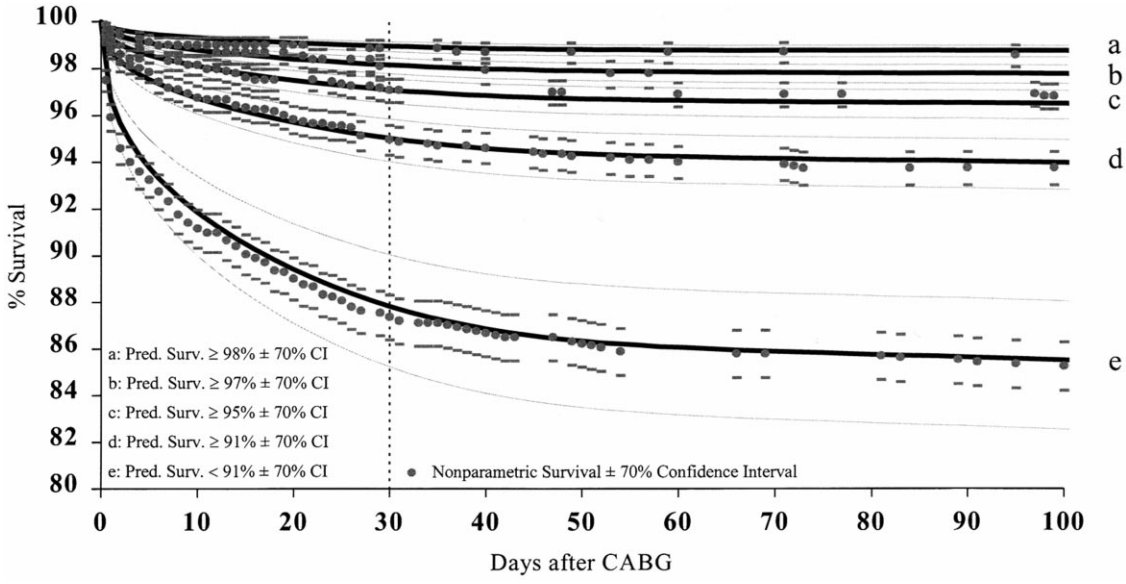

Fig. 3. Stratification of the patients by predicted survival (black line ± 70% confidence limit).

remains obvious, we might have to focus on mid- or even long-term results.

It is to be stressed, that the fact that the crude 30-day mortality presented as an absolute or relative value is of limited value. The distribution of events per time allows a much closer entry to problem-orientated analyses. Even the rough distribution pattern of events may help to identify 'weak points' which may require special considerations. This fact has been prescribed by Ascher [12] in his discussion of the Lawless article about 'Statistical methods in reliability'; three different systems were called 'happy', 'non-committal', and 'sad' according to the frequency of failures (less frequently, about as frequently, more frequently) with increasing operating time. Applied on our situation, the more 'happy' the survivorship function appears, most of the events will be located at the beginning of the time period. So, the more 'noncommittal' or 'sad' the survivorship function becomes, the more likely happiness will reappear, if a larger time interval is investigated; however, this statement is only true for the 'early period' after any intervention.

Nowadays, advanced computational methods, registries, and computerized administrations facilitate the performance of follow-up procedures. Although, even in larger patient groups, follow-up procedures are still time-consuming and rely on the aggressiveness of the follow-up process, the advantages of long-term surveys become obvious when guidelines from studies which enrole about 9600 [13] or even 24 959 [14] participants are presented. However, even less time- and money-consuming efforts to evaluate postinterventional results are recommended to evaluate at least the personal and institutional standards. Many documentation systems and clinical information systems include patient-related variables and can be used for multivariable analyses. As extensively considered by Vahl et al. [15], the follow-up method is one of the most crucial factors to obtain reliable data for reliable calculations. Instead of cross-sectional designs, the anniversary follow-up implies many advantages, such as being a part of 'routine process' instead of 'additional work'. Furthermore, the number of patients lost to follow-up might be reduced to a minimum if the chosen time interval remains in a considerable range.

Since the introduction of the parametric time-adjusted hazard function by Blackstone et al. [2], the analysis of patient-related data gained a further dimension; by using the parametric mathematical model, not only the differentiation between risk factors of the early, intermediate and late time period after any intervention is possible, but even the most reliable individual predictions are to be obtained. This methodology succeeded, to re-use risk adjustment as a tool for clinical application and to generate new knowledge rather than being absorbed by administrative or political purposes [16,17]. These perspectives however, rely on an accurate data acquisition, a unique definition of the investigated variables, and an appropriate follow-up. Since even the evaluation of early mortality is 'only' predominantly used for risk-adjusted analyses, even those 'limited' analyses depend on the quality of the primary data, on the use of adequate statistical methods, and a high degree on the goodness of follow-up. Besides the choice of the follow-up logistics, 'goodness' focus on the appropriateness of the investigation interval.

5. Conclusions

Hospital mortality highly reflects institutional habits concerning postoperative patient care. Consequently, mortality is likely to be low if patients are dismissed early. Due to the relatively wide range of length of hospital stay, an underestimation of mortality is very likely. In contrast to hospital stay, the evaluation of 30-day mortality requires a follow-up procedure. The goodness of follow-up may influence the reliability of the investigation. A clear advantage of 30-day mortality is the standardized time point which allows interinstitutional comparisons and multicentric analyses, independent of local conditions of the participating institutions. However, the 'risk profile' of the patients has to be taken into account since 30-day mortality, systematically, underestimates the early risk at least in patients who underwent CABG in the recent era. The advantage of data comparability by using a fixed time span overweighs the simplicity and inexpensive acquisition of the length of hospital stay. Summarizing the results, for the evaluation of early mortality, a standardized evaluation of a longer time period (p.e. 180 days) is recommended.

Appendix A. Parameters

Parameters of the time-adjusted hazard function for the total 4985 patients after CABG:

Early phase: Mue, 0.064479; Thalf, 7.812961; nu, 0.3257734; m, 7.477079.

Late phase: Tau, 1; Alpha, 1; Eta, 3.208733; Gamma, 1; Mul, 4.638948E-10.

Appendix B. Parameters

Parameters of the time-adjusted hazard function for 1549 patients after CABG (June 1988 to January 1991):

Early phase: Mue, 0.0392642; Thalf, 5.405364; nu, 0; m, –2.53156.

Constant phase: Muc, 6.154087E-05.

Parameters of the time-adjusted hazard function for 3436 patients after CABG (January 1992 to June 1997)

Early phase: Mue, 0.0676598; Thalf, 5.786915; nu, 0; m, –1.97382.

Constant phase: Muc, 8.185489E-05.

Appendix C. Variables

1. Variables at the beginning of the multivariable analysis of death

Demographic

Gender, age (years) at operation, weight, height, body mass index, obesity (men: height in cm, 90; women: height in cm, 100), blood group, rhesus factor.

Cardiac comorbidity

NYHA (1, mild; 2, mild symptoms; 3, symptoms with normal activities; 4a, severe with symptoms at rest; 4b, unstable angina), Holper (1, mild; 2, mild symptoms at higher degree of physical stress; 3, symptoms at mid degree of physical stress; 4, symptoms at low degree of physical stress; 5, stable out of unstable angina; 6, beginning unstable angina; 7, unstable angina; 8, cardiogenic shock), severe heart failure in history, subjective impression of heart failure, clinical sign of heart failure, dyspnea at excercise, dyspnea at rest, excercise-related angina, angina at rest, treatment for unstable angina (0, neither oral nor i.v.-medication; 1, oral medication; 2, intravenous medication), pathologic valvular findings without necessity for surgical treatment, urgency of operation (elective, urgent, emergent, emergent + CPR).

Left ventricular function

Normal left ventricular size, left ventricular hypertrophy, left ventricular dilation, left ventricular hypokinesia, left ventricular akinesia, left ventricular aneurysm, systolic aortic pressure, diastolic aortic pressure, mean aortic pressure, left ventricular systolic pressure, left ventricular enddiastolic pressure, left ventricular function qualifier (0, good; 1, fair; 2, bad). Ejection fraction was available for only 63% of all patients, acute myocardial infarction, chronic pulmonary edema, acute pulmonary edema, cardiogenic shock.

Preoperative drugs

Diuretics, ACE inhibitors, antibiotics, aspirin, digitalis, b-blocker, calcium antagonists, anticoagulation, antiarrhythmic agents, any preoperative drug.

Non-cardiac comorbidity

Smoking, diabetes, hyperlipoproteinemia, hypertension, hyperuricemia, positive family history, any of the known 'risk' factors, syncopy, embolism, gastrointestinal disease, extracardiac vascular disease, calcified aortic wall, pulmonary obstructive disease, pulmonary restrictive disease, any pulmonary disease, renal disease, dialysis dependency, neurologic disease.

Coronary status

Number of affected vessels, diffuse arteriosclerotic affection of coronary arteries, left main disease, dominant vessel, number of coronary vessels disease ≥50, ≥70, ≥90, 100% stenosis, number of coronary systems disease ≥50, ≥70, ≥90, 100% stenosis, stenosis of LAD ≥50, ≥70, ≥90, 100%, stenosis of RCA ≥50, ≥70, ≥90, 100%, stenosis of the circumflex artery ≥50, ≥70, ≥90, 100%, diagonals.

Preoperative rhythm

Sinus rhythm, atrial fibrillation, ventricular tachycardia, pacemaker, ventricular ectopic beats.

Previous procedures

PTCA, coronary stent implantation, laser ablation, complication of PTCA, unsuccessful PTCA, bypass occlusion, bypass stent implantation, thrombolytic therapy (within the last 14 days), reoperation for CABG, number of previously performed CABG procedures.

2. Selected variables (coefficients, standard error, *P*-values)

Early phase: intercept: −7.185

Age = 0.0539 ± 0.0079, $P = 0.0001$. Male = −0.4588 ± 0.1269, $P = 0.0003$. Exercise-related dyspnea = 0.4700 ± 0.1396, $P = 0.0008$. Left ventricular dilation = 0.6548 ± 0.1553, $P = <0.0001$. Left ventricular aneurysm = 0.6177 ± 0.2309, $P = 0.008$. Diuretics = 0.3493 ± 0.1234, $P = 0.005$. Diabetes = 0.4183 ± 0.1224, $P = 0.0006$. Renal disease = 0.4757 ± 0.1387, $P = 0.0006$. Dialysis-dependency = 1.173964 ± 0.3732, $P = 0.01$, at least 50% stenosis of LAD = 0.4567 ± 0.1997, $P = 0.02$, at least three vessels with 50% stenosis or higher = 0.3510 ± 0.1392, $P = 0.01$. Emergent operation = 0.9522 ± 0.1903, $P = <0.0001$.

Late phase: intercept: −20.5843

Age = 0.0678 ± 0.0221, $P = 0.002$. Renal disease = 0.7784 ± 0.3510, $P = 0.03$. Left ventricular akinetic areas = 0.9530 ± 0.3354, $P = 0.005$. Periphereal vascular disease = 0.7929 ± 0.3384, $P = 0.02$, intake of b-blocker = −0.8508 ± 0.3325, $P = 0.01$. Sinusrhythm = −0.8338 ± 0.4128, $P = 0.04$. Previous cardiac surgery = 1.3703 ± 0.6282, $P = 0.03$.

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Appendix D. Conference discussion

Dr W.-P. Kloevekorn (*Bad Nauheim, Germany*): We all know the reasons for the early mortality in the first 30 postoperative days. Is there a difference in your late mortality between the 30th and 120th postoperative day?

Dr Osswald: There is some, at least. But we are using the parametric, time-adjusted hazard function, which differentiates between different phases, and which means early phase is also included into some later phases. This is a kind of relationship of each phase to the other. So everything is just calculated within the model. This is time-related and so we do have just a continuous alteration of variable-specific coefficients.

Dr Kloevekorn: I see. But there are also mainly cardiac-related problems, so it is the whole mixture?

Dr Osswald: Yes, it is.

Mr D. Wheatley (*Glasgow, UK*): This is quite a serious problem for us in the UK, now, where we're all being required to look at mortality. The actual time period you choose is terribly important. This must take a lot more work to look at 180 days?

Dr Osswald: Most of the score systems are based on 30-day mortality. Also, lots of studies are done, but it might be too short now, at least in the recent era. The work to look at 180 days is almost the same as looking at 30 days. You have to perform a follow-up for either time period.