

Preoperative Prediction of Pneumonia after CABG surgery: a retrospective cohort study

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Introduction

Background

Cardiovascular disease (CVD) is a worldwide problem that is responsible for millions of deaths a year. In the year 2007 CVD accounted for every six deaths in the United States (1) and in the European Union (EU) over 2.0 million deaths every year since 2005 (2). In the Netherlands, 18,581 men and 21,154 women die because of CVD (3). CVD causes 30 per cent of the total mortality in Dutch men and 28 per cent in Dutch women (3).

There are several treatments for CVD such as medication, Percutaneous Coronary Intervention (PCI) and the more invasive Coronary Artery Bypass Graft (CABG) surgery. CABG surgery is among the most common operation performed in the world (4). In 2009 there were over 11,682 CABG surgeries performed in the Netherlands (3).

Martin et al. (5) stated that the care of patients who undergo CABG surgery is intense, complex and needs proper preparation. Several studies have found that after coronary surgery, pulmonary functions decrease significantly (6, 7). Patients who undergo abdominal surgery or cardiothoracic surgery like CABG, carry the highest risk for post-operative pulmonary complications (PPC) (7, 8). Pulmonary dysfunction and associated complications are the major cause of increased morbidity, mortality and hospital length of stay in the period following cardiac CABG surgery (9, 10).

Therefore pulmonary care is an important part of the postoperative care after CABG surgery (5). In order to ensure positive outcomes for patients it is essential for nurses to prevent possible complications (5). Nurses individualize preoperative instructions to meet specific needs of the patients (5). Preoperative risk-assessment allows for careful preoperative and postoperative treatment in order to reduce postoperative morbidity and mortality (11). Additionally, preoperative risk-assessment helps to direct interventions more aggressively and might reduce the incidence of PPC's (8).

Problem Statement

Several studies have developed risk models in order to identify patients who have a risk developing PPC after surgery (8, 12-18). Most of these studies were not specific for cardiac surgery and one of the studies had a more specific outcome with pneumonia instead of PPC. The models have some similarities in variables, however there are differences. Several models have used specific spirometric results or other clinical results (e.g. age, productive cough). However, most of the risk model studies using intra- and postoperative factors (12, 13, 15, 16, 18). In their situation, PPC or pneumonia could only be predicted after surgery. This indicates that no preoperative interventions can be conducted.

Hulzebos et al. (8) developed a preoperative risk model to identify patients who are at risk developing PPC. This model is sensitive enough discriminate patients adequate. However the specificity of this model is 56 per cent, which lead to a great number of false positive identifications. Developing a risk model more specific with pneumonia as outcome, but retaining sensitivity is what this study wants to accomplish.

Aim of this study

The aim of this study is to develop a prognostic model that can be used in the preoperative period in order to predict the likelihood of developing pneumonia after CABG Surgery.

Research questions

1. Which preoperative factors can predict the occurrence of pneumonia in patients who undergo coronary artery bypass surgery?
2. Which set of prognostic factors will be adopted in the risk-model, in order to predict the likelihood of developing pneumonia after coronary artery bypass surgery?

Materials and methods

Design

A retrospective cohort study was conducted at a University Medical Center (UMC) on patients who underwent CABG surgery. Since data was already available in two different corresponding datasets, these datasets were merged together to increase the sample size. The first dataset has been assembled for a Randomized Controlled Trail (RCT) in the period July 2002 till August 2005. This dataset (n=563) exists from patients who were scheduled for CABG surgery and understood informed consent. Exclusion criteria were surgery performed within 2 weeks of initial contact, a history of cerebrovascular accident, use of immunosuppressive medication for 30 days before surgery, and presence or a neuromuscular disorder, cardiovascular instability, or an aneurysm. The second dataset (n=730) has been assembled in the period August 2008 till July 2009. All patients who underwent cardiac surgery in combination with a sternotomy, were included. For this current study we have excluded patients <18 years old.

It applies to both datasets that demographics and preoperative risk factors were collected during routine care by standardized interviews and preoperative consultation. Preoperative age, sex, diabetes mellitus II, productive cough, Chronic Obstructive Pulmonary Disease (COPD), previous cardiac surgery, recent myocardial infarction, pulmonary hypertension, emergency surgery, Body Mass Index, history of smoking were recorded. Long volumes FEV_{1%predicted} (Forced expiratory volume in one second), FVC_{%predicted} (forced vital

capacity) and FEV_1/FVC were measured during preoperative consultation. Long volumes $FEV_{1\%predicted}$ and $FVC_{\%predicted}$ were predicted values calculated from regression equations according to age, height, and sex (19). MIP (maximal inspiratory pressure) and MEP (maximal expiratory pressure) were measured to evaluate the maximal respiratory strength. As well during preoperative consultation, MIP was also measured on the day of admission. A blinded independent assessor scored the incidence of pneumonia from the medical files during the postoperative period. The data were handled discreetly at all times and patients were anonymous. The total sample size of the dataset was $n=1293$ and with an incidence of 4.9 per cent the proportion is acceptable to include a minimal amount of candidate variables (20-22).

This study was not subject to the Medical Research Involving Human Subjects Act (WMO), since patients are not subjected to procedures and are not required to follow rules of behavior. The medical ethics review commission has reviewed the first dataset for previous studies and current ongoing studies. The second dataset has been collected during routine care and patients received an admission folder with a passage of the no objection rule. Therefore no medical ethics review was necessary for this study.

Study outcome

Chosen is to use pneumonia as primary outcome because PPC is a wide-ranging definition (23) and pneumonia is more framed and clinically relevant. The definition and criteria of pneumonia in this study is in accordance with the European Centers for Disease Control and Prevention (ECDC). Pneumonia is proved when radiological- or clinical findings have been found in combination with purulent or changing sputum, positive haemoculture, virus or viral-Ag in respiratory secretion, 1xIgM or 4xIgG titre for pathogen micro organism (PMO), histopathology positive, or PMO from a bronchoscopy with lavage (BAL). When besides radiological- or clinical findings, none of these second signs have found, or just PMO from coughed sputum, this will be defined as 'pneumonia is suspected' (24).

Statistical analysis

Missing data are a common problem in clinical research and in most cases inevitable (25, 26). This problem has occurred in this study since both two datasets contain unique variables, thus when both datasets are merged a great proportion of non-complete data will appear. Since this part of non-complete data has not been collected, and therefore the missing value depends on unknown or unobserved information, we conclude this data is missing not at random (MNAR) (25-27). Other variables also contain proportions of non-complete data. We assume these missing values are Missing At Random (MAR) and not Missing Completely At Random (MCAR) since there is no reasons to assume these missing

values are a random subset of the complete dataset (25-27). In order to confirm the assumption the data is MAR, a Little's MCAR test will be conducted (28).

The best method for dealing missing values is Multiple Imputation (MI) (25, 27, 29). MI has been shown to generate less biased estimations with more statistical efficiency (30). MI is a statistical technique that uses all observed data to fill in the missing values with generally 5-10 plausible values (29, 30) which means that 5-10 new datasets are created with their own configuration. Simulation studies have shown that the required number of repeated imputations can be as low as three for data with 20 per cent of missing entries (31). Since we have several variables with >50 per cent missing values, we consider $m = 10$ as a conservative choice.

The number of candidate variables that can be selected is limited. The total number of candidate variables will be in compliance with the 10 events per case rule (21, 22). Univariate results were not used in selecting candidate variables since selecting predictors using univariate statistics leads to biased results (32) and with that in unstable prediction models. Selecting candidate variables was based on literature reporting risk models (8, 12, 14-18, 33) and subject matter knowledge, since there is an agreement that subject matter knowledge or content knowledge should be used as a guide in model building (20, 34). Candidate variables that are selected will be multivariate analyzed using a binary logistic regression. A backward elimination approach will be conducted and variables that meet the Akaike's information criterion with a P -value of 0.157 will be adopted in the final model (32).

The models' performance was evaluated in discrimination techniques and the goodness of fit. The models' discrimination performance was assessed with an area under the receiver operating characteristics (ROC) curve. The ROC-curve or the equivalent of the c (concordance) index, estimates the probability of concordance between predicted and observed responses (34) i.e. discrimination between patients with a likelihood of developing pneumonia after CABG surgery and patients who have not. A c index with a value of 0.5 indicates no predictive discrimination and a value of 1.0 indicates perfect discrimination (34). In prognostic models the c index is usually between about 0.6 and 0.85 (35). The goodness of fit was assessed with the use of the Hosmer-Lemeshow test, which plots the observed proportions of events against the predicted risks (35).

All analyses performed in this study were carried out with the use of IBM SPSS Statistics 19.0.

Results

After merging the datasets there were 940 men and 353 women, with a mean age (SD) of 65 (± 11.33) years. The incidence of pneumonia was 4.9 per cent. Demographic and other preoperative characteristics are listed in Table 1.

<<<<< Insert Table 1 here >>>>>

The dataset contains 22 variables and 17 variables had missing values with proportions that varied over 0.4-89.2 per cent. Variables covering the highest number of missing values were the spirometric outcomes MIP and MEP with 79.7-89.2 per cent, respectively. The variables BMI, history of smoking, previous cardiac surgery, pulmonary hypertension and emergency surgery containing 43.5-60 per cent missing values. Variables with 12.4-19.7 per cent missing values were spirometric outcomes FEV₁, FVC, FEV₁%, MIP_{force}, MIP_{endurance} and the variable productive cough. Variables with the lowest percentage of missing values were recent myocardial infarction, left ventricle function and extra cardiac arteriopathy with 1.3-0.4 per cent, respectively. In order to test if the data was MAR, a Little's MCAR test was conducted (28). This test turned out to be statistical significant with a *P*-value of 0.010, which indicates the missing data is MAR.

During the MI procedure missing values were filled in with ten simulated values i.e. ten new data sets were created beside the original data set. Every data set was filled in with 12,184 original data values and 9,798 values were imputed.

In total five variables were selected as candidate variables, respectively *productive cough*, *FEV₁ (%predicted)*, *MIP_{force}*, *current smoking*, and *recent myocardial infarction* (Table 1). These five candidate variables were entered into the binary logistic regression analysis and additional backward selection was conducted. Three variables were significant associated with pneumonia (productive cough, FEV₁ and recent myocardial infarction) (See Table 2). Hence, these three variables were adopted into the final model. This linear prediction model is as follow:

$$LP = -0.461 + 0.893 \cdot \text{productive cough}^x - 0.035 \cdot \text{FEV}_1^x + 0.823 \cdot \text{recent myocardial infarction}^x$$

<<<<< Insert Table 2 here >>>>>

To test the models performance, *c* statistics were applied and are presented in Figure 1. Since the database consist ten imputed datasets the results of these *c* statistics are pooled. The *c*-statistic of the model was 0.75 (95 CI 0.662 – 0.849). The Hosmer-Lemeshow

test showed no significant differences (P : 0.146) between the observed proportions and the models' predicted risk.

<<<<< Insert Figure 1 >>>>>

Discussion

We have developed a prognostic model that predicts the likelihood of developing pneumonia after CABG surgery. This model contains three easily obtainable variables that can be registered during preoperative consultation. This makes the model practical in use, which is essential using it in general practice. We distinguish ourselves from other models with the use of preoperative variables, since most of them using intra- and postoperative variables (8, 12, 14-18, 33). Predicting the likelihood of pneumonia in de preoperative period, results in that interventions to prevent pneumonia can be taken adequately.

The selection of variables was the most fundamental methodological difference with other studies that have built prognostic models for PPC or pneumonia. Most of the other studies that have built prognostic models for PPC or pneumonia used univariate results during the selection procedure (8, 12, 14-18, 33). Our choice was to select candidate variables not on the bases of significant results after univariate analysis, which is consistent with literature of building prognostic models (20, 32), however we have chosen to select the variables based on subject matter knowledge (20, 34). We would like to have seen in the other studies that the consideration choosing for univariate selection would have been described, since it is known that selecting predictors using univariate analysis leads to biased results (32).

We consider our models' performance as decent (AUC : 0.75), since in prognostic models the c-index is usually between 0.6 and 0.85 (35). However, our intention was to make the model more specific than other models such as the prediction model of Hulzebos et al. (8), unfortunately this was not entirely successful. Our model is a regression model with a continuous variable, which means that before using it in general practice it is preferred to make it more practical, for example in the form of a scorecard. Nevertheless we believe this model can deliverer a contribution in patient care related to CABG surgery. This model can predict pneumonia adequate and we believe this outcome is more framed and clinical relevant than PPC. However, further study is needed to transform this regression model into a more practical tool before it can be used in general practice.

There were some limitations in this study. Since the sample size was relatively small ($n=1293$), we were restricted to adopt five variables into the multivariate analysis. In developing prognostic models adopting five candidate variables is considered as minimum

(20). Reducing the variables to five candidate variables was based on literature and subject matter knowledge. In observance of time this was the most proper choice, however other methods such as the LASSO (least absolute shrinkage and selection operator) method were considered, because shrinkage factors may help to improve prediction and reduce selection bias (20). Since the possibility that a greater sample size provides the opportunity to select more candidate variables and the use of the LASSO method is a proper method to select candidate variables, further study can be considered as a relevant and worthy sequel. Another limitation in this study was that we had to deal with a substantial amount of missing values (45 per cent), since two datasets were merged together and subsequently missing values occurred. The most proper way dealing with this problem was MI (25, 27, 29, 30). It is however conceivable that with the amount of missing values in our dataset, and the fact that a main part of our missing values were MNAR, MI might lead to some uncertainty in the results.

Through a validation study, bias- or over fitting estimates can be corrected with the use of calibration plot or the shrinking coefficient (34). We recommend a validation study to validated the models' performance in new individuals before it can be implemented in general practice. According to literature, this is what always should be tested in developing (prognostic) models (36, 37).

Conclusion

A prognostic model predicting the likelihood of developing pneumonia after CABG surgery has been developed. Three easily obtainable variables were adopted into this model, respectively *productive cough*, *FEV₁*, and *recent myocardial infarction*. The benefit of this model is that it can be used in the preoperative period, and therefore interventions can be taken adequately to prevent pneumonia after CABG surgery. However, this study has some limitations and shows possibilities for altered approaches in the selection of candidate variables and the practical usage of the model. Therefore, further study is recommended.

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Table 1 Characteristics and candidate variables of 1294 patients. Values are N (%) or stated otherwise.

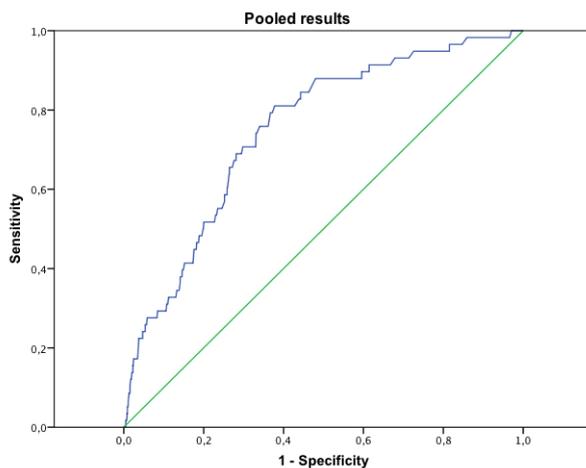
Variable	Pneumonia		RR (95 CI)	OR (95 CI)
	Yes	No		
Age, years	65.61 ¹	64.82 ¹		
Sex				
- Male	50 (3.89)	890 (68.83)	1.303 (0.712-2.386)	1.318 (0.702-2.475)
- Female	14 (1.08)	339 (26.22)		
Productive cough	27 (2.08)	211 (16.32)	2.996 (1.791-5.010)	3.223 (1.845-5.632)
FEV ₁ (predicted)	76.81 ¹	91.07 ¹		
MIP _{Force}	75.07 ¹	73.84 ¹		
Current smoking	16 (1.12)	219 (16.94)	2.255 (1.202-4.231)	1.795 (0.978-3.293)
Recent myocardial infarction	20 (1.55)	204 (15.78)	1.739 (0.984-3.073)	2.381 (1.200-4.723)

¹ Mean of the outcome when pneumonia (not) accurse.

Table 2 Final model after multivariate analysis.

Predictor	Beta ¹ (P value)	S.E.	Odds Ratio (95 CI)
Productive cough	0.893 (0.002)	0.291	3.223 (1.845-5.632)
FEV ₁ (predicted)	-0.035 (0.000)	0.007	
Recent myocardial infarction	0.823 (0.006)	0.298	1.795 (0.978-3.293)

¹ Regression coefficient

**Figure 1** ROC-curve of the prognostic model

Dutch Summary

Titel. Preoperatief voorspellen van een pneumonie na een CABG operatie; een retrospectief cohort studie.

Inleiding. Pulmonale zorg is een belangrijk onderdeel in postoperatieve zorg na een Coronaire Artery Bypass Graft (CABG) operatie, gezien pulmonale functies significant afnemen. Afname van pulmonale functie en geassocieerde complicaties zijn de grootste oorzaak van een verhoogde morbiditeit, mortaliteit en lengte van ziekenhuisopname in de periode na een CABG operatie.

Doel. Het doel van de studie is om een prognostisch model te ontwikkelen op de aanwezigheid van een pneumonie na een CABG operatie.

Onderzoeksvragen.

1. Welke preoperatieve factoren kunnen de aanwezigheid van een pneumonie bij patiënten die een Coronary Artery Bypass Graft operatie voorspellen?
2. Welke set van prognostische factoren worden in het risico-model opgenomen om de aanwezigheid van een pneumonie na een Coronary Artery Bypass operatie te voorspellen?

Methode. Wij hebben een retrospectief cohort studie uitgevoerd op patiënten die een CABG operatie hebben ondergaan. Twee datasets zijn gebruikt die beide in verschillende tijdsperiodes zijn ontwikkeld. Omdat beide datasets unieke variabelen bevatte, ontstond er na het samenvoegen van beide sets missende waardes. Multiple imputatie (MI) was toegepast als oplossing voor dit probleem. Prognostische factoren zijn bepaald met het gebruik van backward eliminatie.

Resultaten. Een multivariaat analyse was uitgevoerd en drie variabelen geïdentificeerd en opgenomen in het prognostisch model, respectievelijk *producerende hoest*, *FEV₁ (forced expiratory volume)* en *recente myocardinfarct*.

Conclusie. Een prognostisch model is ontwikkeld om de aanwezigheid van een pneumonie na CABG operatie te voorspellen. Het voordeel van dit model is dat het in de preoperatieve fase gebruikt kan worden. Daarom kunnen interventies adequaat ondernomen worden om een pneumonie na een CABG operatie te voorkomen.

Aanbevelingen. Een validatie studie om de performance van het model te valideren op nieuwe individuen.

Trefwoorden. Hart en vaatziekten; Prognostisch model; Voorspellen; Pneumonie; Coronary artery bypass graft.

English Abstract

Title. Preoperative Prediction of Pneumonia after CABG surgery; a retrospective cohort study.

Introduction. Pulmonary care is an important part of the postoperative care after Coronary Artery Bypass Graft (CABG) surgery since pulmonary functions decrease significantly. Pulmonary dysfunction and associated complications are the major cause of increased morbidity, mortality and hospital length of stay in the period following cardiac CABG surgery.

Aim. The aim of this study is to develop a prognostic model that predicts the likelihood of developing pneumonia after CABG Surgery.

Research questions.

1. Which preoperative factors can predict the occurrence of pneumonia in patients who undergo coronary artery bypass surgery?
2. Which set of prognostic factors will be adopted in the risk-model, in order to predict the likelihood of developing pneumonia after coronary artery bypass surgery?

Method. We conducted a retrospective cohort study on patients who underwent CABG surgery. Two datasets were used developed in different time periods. Because the datasets contained unique variables, after merging the datasets missing values occurred. Multiple imputation (MI) was applied as a solution for this problem. Prognostic factors were determined by the use of backward elimination.

Results. A multivariate analysis was performed and three variables were identified and adopted into the prognostic model, respectively *productive cough*, *FEV₁* (*forced expiratory volume*) and *recent myocardial infarction*.

Conclusion. A prognostic model predicting the likelihood of developing pneumonia after CABG surgery has been developed. The benefit of this model is that it can be used in the preoperative period. Therefore interventions can be taken adequately to prevent pneumonia after CABG surgery.

Recommendations. A validation study to validate the models' performance in new individuals.

Keywords. Cardiovascular disease; Prognostic model; Predicting; Pneumonia; Coronary artery bypass graft.