

VBHOM, a data economic model for predicting the outcome after open abdominal aortic aneurysm surgery

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Background: Vascular Biochemistry and Haematology Outcome Models (VBHOM) adopted the approach of using a minimum data set to model outcome. This study aimed to test such a model on a cohort of patients undergoing open elective and non-elective abdominal aortic aneurysm (AAA) repair.

Methods: A binary logistic regression model of risk of in-hospital mortality was built from the 2002–2004 submission to the UK National Vascular Database (NVD) (2718 patients). The subset of NVD data items used comprised serum levels of urea, sodium and potassium, haemoglobin, white cell count, sex, age and mode of admission. The model was applied prospectively using Hosmer–Lemeshow methodology to a test data set from the Cambridge Vascular Unit.

Results: The validation set contained 327 patients, of whom 208 had elective AAA repair and 119 had emergency repair of a ruptured AAA. Outcome following elective and non-elective AAA repair could be described accurately using the same model. The overall mean predicted risk of death was 14.13 per cent, and 48 deaths were predicted. The actual number of deaths was 53 ($\chi^2 = 8.40$, 10 d.f., $P = 0.590$; no evidence of lack of fit). The model also demonstrated good discrimination (c-index = 0.852).

Conclusion: The VBHOM approach has the advantage of using simple, objective clinical data that are easy to collect routinely. The VBHOM data items potentially allow prediction of risk in an individual patient before aneurysm surgery.

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Introduction

Clinical governance and professional revalidation has made the entire healthcare profession, especially surgeons, increasingly accountable to their patients, professional organizations and employing hospital trusts. Vascular surgeons operate on difficult and complex cases. The UK National Vascular Database (NVD)¹ was set up not only to meet these challenges but also to compare vascular surgical performance in a fair and robust manner.

Data items collected for the NVD are predominantly based on the Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) data set², and include additional vascular procedure-specific items. A major drawback of the NVD has been the large number of data items required. The

logistics associated with collecting such a large data set have undoubtedly been one of the factors inhibiting its universal adoption by vascular surgeons. The POSSUM approach requires collection of up to 12 preoperative physiological and six operative variables per patient². Furthermore, some of the data required are subjective and are not necessarily required as part of routine clinical care. Copeland and colleagues² have argued that all hospitals within the UK have the ability to collect the POSSUM data set without difficulty, but in practice it requires considerable effort, commitment and understanding, and effective information technology support. Difficulties in the application of POSSUM have been reported³. Another problem encountered with the POSSUM models is that they require operative variables, and are not suitable for

patients who do not undergo operation. In addition, as it is primarily an audit tool, POSSUM cannot be used to score risk before surgery as an adjunct to help decide whether to operate on high-risk patients.

Vascular Biochemistry and Haematology Outcome Models (VBHOM) adopted the approach of using a minimum data set to model outcome and has been shown previously to be feasible with index arterial operations⁴. VBHOM uses only data items that can be obtained before operation. They can be obtained from hospital pathology and patient administration computer systems⁴, and are collected routinely within the normal pathways of clinical care. Therefore, their application can be universal and data collection is not an additional burden to the staff providing care.

The aim of this study was to apply a newly developed VBHOM model, generated from recent NVD data, to all elective and ruptured open abdominal aortic aneurysm (AAA) operations over a 7-year interval at the Cambridge Vascular Unit.

Methods

The new VBHOM model was built from NVD data submitted between 1 January 2002 and 31 January 2004. This interval was chosen to ensure that application was entirely prospective and to minimize the effects of changes in practice. Records included patients who underwent open elective and non-elective AAA repair and infrainguinal bypass operations. The following data items were extracted from the database: discharge status of patient (alive or dead), admission date and discharge date, age at admission, mode of admission, sex, haemoglobin level, white cell count, and serum concentrations of urea, sodium and potassium. Using these data as the training set, binary logistic regression (SPSS[®] version 11; SPSS, Chicago, Illinois, USA) was used to form a model of adverse clinical outcome (mortality at discharge).

The equation was then applied prospectively to a test (validation) set of patients whose data had not been submitted to the NVD. These were patients who had elective or ruptured open AAA surgery at the Cambridge Vascular Unit, a regional academic teaching centre, between January 1998 and January 2005. All VBHOM physiological variables were collected prospectively on a structured clerking pro forma. Case notes were analysed retrospectively for death in hospital or within 30 days of operation. A vascular surgeon performed the majority of the procedures. A non-vascular consultant or higher surgical trainee was the principal surgeon in 57 operations (17.4 per cent). Surgical technique has been described elsewhere⁵.

Statistical analysis

The goodness-of-fit of the model against its training set was assessed using Hosmer–Lemeshow methodology^{6–9}. The model was then applied to the Cambridge data and the predicted risk of hospital mortality was calculated for each of the records in the validation set. The overall performance of the model was assessed using techniques designed to test both calibration and discrimination.

Hosmer–Lemeshow methodology was followed to assess the calibration of the model. This involved use of the χ^2 test to compare frequency tables obtained from prospective application of the equations. This is a null hypothesis test and $P < 0.050$ indicates a significant lack of fit. Although it is possible to say that a model is wrong, and did not predict outcome, it is not possible to state that a particular model is correct, only that it performed adequately.

The discriminative ability of the model was assessed using the c-index (equivalent to the area under the receiver–operator characteristic curve). Discrimination is the ability of a model to rank patients appropriately in terms of risk, that is its ability to ascribe high risks to high-risk patients and vice versa. Values of 0.5 represent no better than chance. It is generally accepted that reasonable models produce values in the range 0.7–0.8 and good models give values of 0.8–0.9.

Risk ranges were chosen to give at least five predicted deaths or complications in at least 80 per cent of the risk strata (Cochrane's rule) and to give, where possible, approximately equal predicted numbers in each risk range.

Results

The data from the 2002–2004 submission to the NVD contained 2718 complete records from patients who underwent elective or non-elective open AAA repair or infrainguinal bypass. Binary logistic regression analysis of the laboratory and administrative data of this training set (Table 1) produced the following outcome model for AAA repair:

$$\ln_e\{R/(1 - R)\} = -2.257 + (0.1511 \times \text{sex}) + (0.9940 \times \text{mode of admission}) + (0.05923 \times \text{age on admission \{years\}}) + (0.001401 \times \text{urea \{mmol/l\}}) + (-0.01303 \times \text{sodium \{mmol/l\}}) + (-0.03585 \times \text{potassium \{mmol/l\}}) + (-0.2278 \times \text{haemoglobin \{g/dl\}}) + (0.02059 \times \text{white cell count \{ \times 10^9 /l \}})$$

where R is the risk of death. Sex takes the value 1 for male and 0 for female, and mode of admission takes the value 0 for elective and 1 for non-elective admissions.

Table 1 National Vascular Database training set

Risk (%)	Discharges	Mean risk (%)	Predicted deaths	Reported deaths	χ^2
≥ 0 to ≤ 4.5	1153	2.18	25	24	0.05
> 4.5 to ≤ 6.9	445	5.71	25	27	0.11
> 6.9 to ≤ 9.4	313	8.09	25	25	0.00
> 9.4 to ≤ 12.7	228	10.79	25	28	0.53
> 12.7 to ≤ 16.6	173	14.51	25	20	1.21
> 16.6 to ≤ 23	137	19.56	27	22	1.07
> 23 to ≤ 30	89	26.18	23	29	1.89
> 30 to ≤ 37	77	33.40	26	30	1.07
> 37 to ≤ 49	58	42.72	25	22	0.54
> 49 to ≤ 100	45	57.71	26	25	0.09
≥ 0 to ≤ 100	2718	9.27	252	252	6.56

$\chi^2 = 6.56$, 8 d.f., $P = 0.585$; no evidence of lack of fit. C-index = 0.799.

Table 2 Patient demographics in the validation set of 327 open aortic aneurysm procedures in Cambridge, 1998–2005

	Elective AAA surgery (n = 208)	Ruptured AAA surgery (n = 119)
Age (years)*	73 (44–86)	75 (47–89)
Sex ratio (M:F)	186:22	105:14
Haemoglobin (g/dl)†	13.8(1.5)	11.3(2.4)
White cell count ($\times 10^9/l$)†	8.6(4.1)	12.3(5.4)
Serum sodium (mmol/l)†	140(3)	138(6)
Serum potassium (mmol/l)†	4.5(0.6)	4.4(0.9)
Serum urea (mmol/l)†	7.2(3.0)	8.6(3.3)
Known cardiac co-morbidity	114 (54.8)	70 (58.8)
Known respiratory co-morbidity	89 (42.8)	67 (56.3)
In-hospital death	13 (6.3)	40 (33.6)
In-hospital morbidity	111 (53.4)	83 (69.7)

Values in parentheses are percentages unless indicated otherwise; *values are median (range); †values are mean(s.d.). AAA, abdominal aortic aneurysm.

Rather than following the Vascular Society's stated intention of dividing AAAs into unruptured and ruptured according to the findings at laparotomy, it was necessary to categorize them by mode of admission to obtain sufficient numbers for modelling and testing.

The Cambridge Vascular Unit undertook 429 open AAA procedures (271 elective and 158 for ruptured AAAs) between January 1998 and January 2005; 208 elective (76.8 per cent) and 119 (75.3 per cent) ruptured AAA procedures were included in this study as the validation test set. Eighty-one (18.9 per cent) were excluded from the study as they had been submitted to the NVD during 2002–2004 (50 elective and 31 for ruptured AAA). The remaining 21 (13 (3.0 per cent) elective and eight (1.9 per cent) for ruptured AAA) had incomplete or missing details at the time of data collection. Over this time a

Table 3 Mortality: prospective application of the new VBHOM model to whole validation set

Predicted mortality (%)	No. of patients	Mean predicted risk (%)	Predicted deaths	Reported deaths	χ^2
> 0 to ≤ 6.5	121	3.95	5	2	1.68
> 6.5 to ≤ 9.5	58	7.81	5	4	0.07
> 9.5 to ≤ 13.6	40	11.38	5	5	0.05
> 13.6 to ≤ 18.6	29	16.64	5	5	0.01
> 18.6 to ≤ 27.3	21	22.08	5	6	0.51
> 27.3 to ≤ 32	17	29.67	5	8	2.46
> 32 to ≤ 37	16	34.32	5	8	1.75
> 37 to ≤ 44	12	39.28	5	7	1.83
> 44 to ≤ 59	9	53.46	5	5	0.02
> 59 to ≤ 76	4	40.96	3	3	0.03
> 0 to ≤ 100	327	14.13	48	53	8.40

VBHOM, Vascular Biochemistry and Haematology Outcome Models. $\chi^2 = 8.40$, 10 d.f., $P = 0.590$; no evidence of lack of fit. C-index = 0.852.

further 18 patients were turned down for elective AAA repair. Patient demographics are shown *Table 2*.

It was found that the single unified model could successfully describe both elective and ruptured AAA mortality combined in the validation test set (*Table 3*). The model could also be applied successfully (no evidence of lack of fit) to ruptured and elective AAA repair separately (data not shown). The c-index for elective AAA procedures was 0.796 and that for ruptured AAA was 0.756.

Discussion

AAAs constitute a significant part of the workload of vascular surgeons. Despite advances in perioperative care, there has been only a minimal improvement in outcome after ruptured AAA repair over the past 50 years, with an

operative mortality rate often in excess of 50 per cent¹⁰. After elective open AAA surgery the mortality rate remains around 6–8 per cent with associated high morbidity rates^{11,12}. Subjecting patients at high operative risk to a futile AAA repair has resource and ethical implications. Patient selection is usually dependent on the opinion and experience of the consultant vascular surgeon in conjunction with the anaesthetist. Therefore, a scoring system that could identify patients before surgery in whom operative intervention would be unsuccessful would be valuable, but a reliable tool has not yet been found. It is not justified to deny a patient a potentially life-saving operation based on an inaccurate predictive instrument. In this study, using the VBHOM approach, a model that successfully predicts risk of death after elective and non-elective AAA repair was developed.

The VBHOM model, developed from the NVD, used mode of admission, rather than ruptured or unruptured AAA, to classify the procedures. The categorization of AAAs as ruptured or unruptured is based on the operative finding, whereas mode of admission is known before operation. In practice, rupture is effectively synonymous with emergency or non-elective admission and unruptured with elective admission. Nonetheless, it is an important drawback of this study that the validation data set was categorized as ruptured or unruptured as opposed to elective or non-elective.

This study focused on the development of a new VBHOM model and its validation. The model was built from data collected prospectively from around the UK. As demonstrated, it provided a single unified model that allows good prediction of surgical mortality after both open elective and non-elective AAA repair. This study validates previous work based on the VBHOM concept showing that the risk of in-hospital death can be modelled in patients undergoing index arterial operations such as AAA repair using a small number of commonly used laboratory and administrative items⁴.

The ability to predict clinical outcomes from laboratory measurements taken from a single venesection before surgery would provide significant advantages. It could facilitate the optimal use of limited resources such as intensive care by allowing focused postoperative surveillance of high-risk patients in clinical areas capable of close monitoring and early therapeutic intervention. It may also allow the vascular surgeon to predict risk in an individual patient before surgery, so that this risk can be discussed confidently with both patient and relatives while gaining informed consent. If the predicted risk assessment is too high for a patient, a less invasive procedure such as endovascular stenting or conservative management may be

chosen. Other advantages of this scoring system are that it is generally simple and applicable to all admissions, and it is usually possible to collect all the items required as part of routine clinical care. It therefore makes no demands on the staff providing the care and all that is necessary is access to the hospital information systems to view the results. The biochemical and haematological data items are precisely measurable, objective and are subject to the routine quality control processes implemented by hospital laboratories. Furthermore, the data required for predicting risk are likely to be available soon after admission, although in a prospective study only 80 per cent of patients admitted with a ruptured AAA had biochemical results available when the decision to operate was made¹³.

Risk-adjusted analysis is required to allow for differences in case mix between surgeons and surgical units. Up to now POSSUM methodology² has been recognized as the most appropriate available score for assessing risk in non-cardiac surgical patients¹⁴. Many studies have tried previously to use what is primarily an audit tool to predict mortality in a subset of patients different from that used to derive the original model, and naturally the fit and performance of the scoring system has varied. Furthermore, most studies have used retrospective data that are either incomplete or missing. POSSUM also requires data items that are not necessarily collected as part of routine clinical practice and was criticized because it overpredicted the mortality rate of patients at low risk¹⁵. The Portsmouth modification of POSSUM (P-POSSUM) and vascular POSSUM (V-POSSUM), although more accurate predictors of death than POSSUM in vascular patients, have not been shown to be robust in different geographical locations^{1,16}. Although the prospective application of the P-POSSUM and V-POSSUM models accurately predicted mortality for elective AAA surgery, they did not predict outcome for both elective and non-elective AAA surgery as a combined group, even when operative urgency was included in their predictor variables¹⁷. A similar attempt to model the outcome of both elective and non-elective AAA surgery again necessitated the formation of two separate models⁴. The new VBHOM model allowed the accurate prediction of both types of presentation.

The VBHOM approach was developed in response to the difficulty of collecting all data items required by the NVD. It is essentially a minimalist approach designed to overcome the problem of missing data, which bedevils all clinical data collection exercises. The VBHOM approach uses simple data that can be collected for all patients before operation. All risk models can only predict risk within the 'dimensions' of the data items used within the model. It is certain that there are numerous other

factors, many of which would be found only at operation, that influence the risk of adverse outcome for individual patients.

This new VBHOM model should not be taken as a definitive predictor equation. It will require refinement and is likely to evolve as knowledge increases and the NVD expands. This approach seems generally applicable but, before it can be used to influence patient care, it should be further validated in other geographical locations.

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