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Development and Validation of a Predictive Model to Aid in the Management of Intact Abdominal Aortic Aneurysms

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WHAT THIS PAPER ADDS

Repair of an intact abdominal aortic aneurysm (AAA) is a prophylactic procedure against death from a rupture. Level 1 evidence has provided data on the expected outcomes for both open and endovascular aneurysm repair in a trial setting rather than for individual patients. In this study, a validated a model predictive of patient survival was developed and was shown to be accurate for those undergoing AAA repair or surveillance. The management strategy of AAA can therefore be tailored to individuals to achieve the greatest benefit.

Objective/Background: Predicting outcomes prior to elective abdominal aortic aneurysm repair (AAA) requires critical decision making, as the treatment offered is a prophylactic procedure to prevent death from a ruptured AAA. The aim of this work was to develop and validate a model that may predict outcomes for patients with an AAA and hence aid in clinical decision making.
Methods: A discrete event simulation model was built to simulate the natural history of a patient with an AAA and to predict the 30 day and 2—5 year survival of patients undergoing treatment and surveillance. The input parameters of AAA behavior and impact of comorbidities on survival were derived from the published literature and the New Zealand national life tables. The model was externally validated using a cohort of patients that underwent AAA repair ($n = 320$) and a cohort of patients undergoing small AAA surveillance ($n = 376$). All patients had completed at least 5 years of follow up.
Results: The model was run three times for each data set to test. This produced a SD $< 1\%$, indicating excellent reproducibility. The observed 30 day mortality for the patients undergoing AAA repair was 9/320 (2.8%) and the expected (model predicted) mortality was 3.8% (c-statistic 0.87 [95 confidence interval 0.75—1.0]). The c-statistic for the predicted 2—5 year survival ranged from 0.68 to 0.71 for the repaired AAA cohort and 0.69 to 0.73 for patients with a small AAA on surveillance.
Conclusion: The AAA clinical decision tool has the ability to accurately predict the 5 year survival of patients with an AAA. This tool can be used during clinical decision making to better inform clinicians and patients of long-term outcomes. Further validation studies in a wider AAA population are required to test the broader clinical utility of this AAA clinical decision tool.

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INTRODUCTION

In health care, there are many unknowns with regard to predicting clinical outcomes, and direct experimentation is not always possible. Clinical trials can be very costly and often require a long time to complete.[1] In response to growing knowledge of diseases, national or societal guidelines and protocols have been developed to assist in clinical decision making.[2] However, such documents are not always individualised to unique patients, and in such instances health models and simulations might be a more appropriate strategy to assist in the decision making process.

The use of decision making models has increasingly become an important component of clinical research and the number of decision analysis publications in the literature has risen exponentially in the last decade.[3] Models are particularly useful in situations of uncertainty and high

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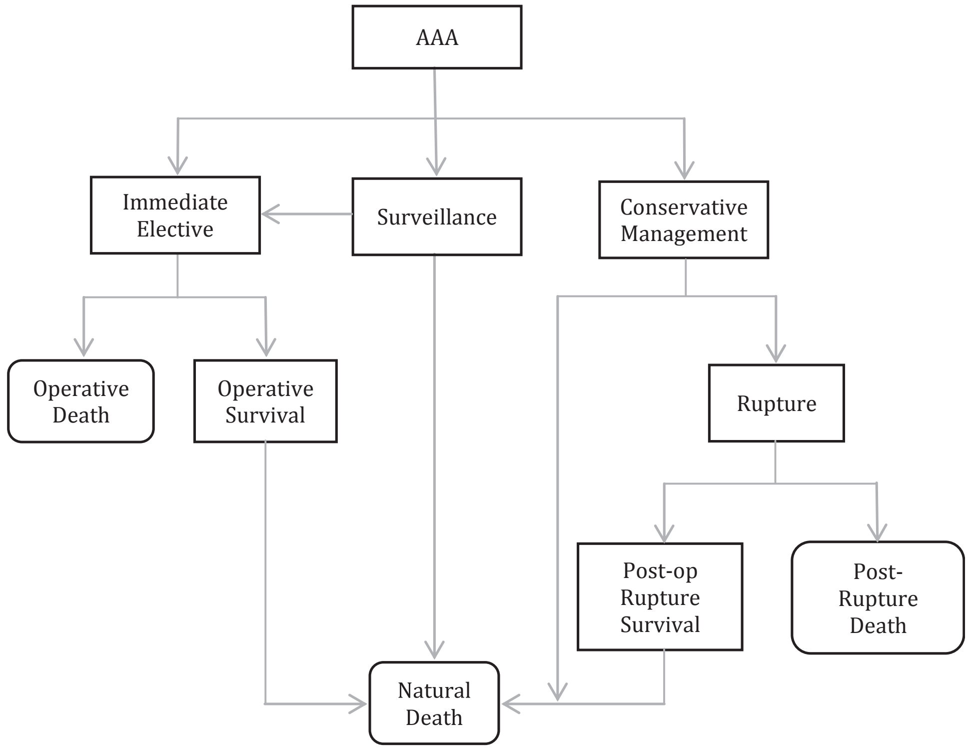

Figure 1. Model flow diagram to produce the simulation of abdominal aortic aneurysm (AAA) management.

complexity, especially when randomised controlled trial data are lacking and it is important to individualise care.

The ongoing risk of abdominal aortic aneurysm (AAA) related death, uncertainty of aneurysm expansion and rupture, and the background mortality risk from other causes make AAA management pathways ideal for predictive modelling. When open AAA repair (OAR) was the dominant treatment option, several AAA specific models were developed and validated to predict inpatient and 30 day mortality. Although some of these models predicted outcomes reasonably accurately,[4,5] they are not routinely used clinically.[6] With the now liberal use of endovascular aneurysm repair (EVAR) to treat AAA and the associated significantly lower 30 day mortality, a few models to predict mid- and long-term survival have been developed, but their use has been very limited,[6,7] unlike in cardiac surgery where the EuroSCORE model has been widely adopted.[8]

Therefore, the aim of this study was to develop an interactive model, specific to the New Zealand (NZ) population that can assist in clinical decision making of AAA management for individual patients, and externally validate the model against existing databases of patients with small AAA and those who have had an aneurysm repair.

METHODS

A discrete event simulation (DES) was developed to simulate the clinical natural history of patients with a detected AAA defined as ≥3 cm. This modelling approach focuses on the individual's defined characteristics, their associated events over time, and the consequences of those events at patient level. The micro-simulation and flexibility of DES allow the model to take into account the patients' clinical profiles and therefore take heterogeneity into consideration. The process randomly samples time to event distributions, making it ideal for time to event analysis.[9]

A DES was built to simulate the natural history of AAA where time to death from all causes competes with time to death from aneurysm rupture and post-operative mortality. Time to death from all causes was drawn from an all cause cumulative mortality distribution function. Time to rupture was modelled based on AAA growth and the annual probability of rupture, whereas time to post-operative mortality was drawn from the patient's specific profile cumulative mortality distribution function.

Model structure and development

An individual with an AAA diameter range of 3–10 cm was entered into the simulation model and three management options considered: immediate elective repair, surveillance, or conservative management. The first decision is made when setting an aneurysm threshold for AAA treatment (usually 5.5 cm for males and 5 cm for females), but the threshold for intervention can be altered by the user, depending on age, sex, and patient or surgeon preferences.

The surveillance survival is based on AAA expansion until the threshold is reached, then the patient undergoes elective aneurysm repair without the possibility of a rupture. The conservative management survival is based on the aneurysm rupture risk, depending on the baseline AAA diameter selected by the user, and no elective repair is