Frailty in patients undergoing major limb amputation for peripheral arterial disease: a retrospective cohort study project protocol

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# Introduction

Frailty is a multi-factorial concept encompassing the accumulated effects of comorbidity, mobility, social isolation, cognitive decline and poor nutritional status which build up with age1. It is an increasing problem in our aging population, and affects many outcomes following surgery2. In patients undergoing major limb amputation, it is also likely to affect the ability to mobilise with a prosthetic limb.

Little is known about which aspects of frailty are most important in patients undergoing major limb amputation. The aims of the project are:

* Collect data on frailty-related factors in patients who have undergone major limb amputation, and information on outcomes, including whether the patient went on to successfully walk with a prosthesis.
* Build statistical models to determine which factors are important in predicting outcomes.
* Compare the performance of these models, which include specific measures of frailty, with generic models of outcome following major lower limb amputation.

# Methods

All patients having a lower limb amputation above the ankle at any of three hospitals in South East Wales between January 2010 and January 2017 will be included in the study. Data will be collected on basic demographics, comorbidity (in the form of the Charlson Comorbidity Index),3 functional status (Katz score),4 residential status, Waterlow score,5 pre-operative blood tests and ECG, and pre-operative haemodynamics (highest heart rate and lowest blood pressure on the day of surgery). The Addenbrookes Vascular Frailty Score6 will be calculated, along with generic models for outcome following amputation.7 An amputation-specific frailty score will then be developed using stepwise logistic regression modelling, with mortality at 12 months as the primary outcome. Performance of the new tool will be compared to existing models.

Missing data is a common issue observational studies such as this one, so we will use multiple imputation methodology to account for missing data.8 During model generation, Information Criterion analysis will be used to select predictors. This will enable us to develop a parsimonious model which avoids over-fitting. Bootstrap methodology9 will then be used to assess performance of the model.

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