



Regular Article

Validity of standard gamble estimated quality of life in acute venous thrombosis ^{☆,☆☆}



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ABSTRACT

Introduction: The standard gamble is considered the ‘gold standard’ technique for measuring quality of life. We recently used the standard gamble to estimate quality of life in acute venous thrombosis, and found unexpected variability in the responses. The current study aimed to explore the reasons for variability by comparing the standard gamble technique in patients with acute venous thrombosis to other quality of life measurement tools.

Materials and Methods: Thrombosis clinic patients treated for venous thrombosis were eligible to participate. Patients evaluated their current health state by performing a standard gamble interview, reporting on a visual analogue scale, completing the SF-36 and disease specific questionnaires (PEmb-QoL and VEINES-QOL/Sym). Validity was assessed by correlating the standard gamble utilities with the other methods. Test-retest reliability, responsiveness and acceptability were also assessed.

Results: Forty-four patients were interviewed, with 16 attending for a repeat interview. The median standard gamble utility was 0.97 (0.84–1.0), SF-6D 0.64 (0.59–0.80) and visual analogue score 70 (60–80). Participants with pulmonary embolism had lower standard gamble estimates than those with deep vein thrombosis. There was good discriminant validity in that the standard gamble estimates were not associated with risk taking behavior, negative outlook, sex or education. Test-retest reliability with the standard gamble was moderate and there was evidence of a ceiling effect.

Conclusions: Standard gamble utilities are higher than other methods of measuring quality of life in venous thrombosis. The choice of utility values adopted in studies will impact on future economic studies.

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Introduction

There have been many changes in thrombosis medicine over the past decade. Although warfarin was the traditional anticoagulant for venous thromboembolism, low molecular weight heparins are currently used as the drug of choice in cancer associated venous thromboembolism and the new oral anticoagulants rivaroxaban, dabigatran, apixaban and edoxaban are increasingly used as first line therapy. There are many new oral anticoagulant economic evaluations of prophylaxis for venous thrombosis [1,2] and stroke prophylaxis [3]. We anticipate more economic analyses in the treatment of venous thrombosis. Provincial or national health funding bodies are likely to make future decisions

regarding which oral anticoagulant to fund, based on cost effectiveness. Government advisory boards such as the Ontario Committee to Evaluate Drugs and the National Institute of Clinical Excellence in the United Kingdom base their recommendations for funding of new medications on the cost per quality adjusted life year (QALY) gained.

The QALY is the common currency by which different treatments, prevention strategies and public health policies can be compared. The QALY is also a central parameter for economic analyses. The QALY is a score for quality of life which ranges from 1 (one year of life in perfect health) to 0 (death). QALYs for specific diseases (or health states) are derived from quality of life measurements. In general, there are three ways to determine quality of life.

Firstly, the utility is a point estimate of quality of life which is derived by a method incorporating uncertainty in the future. The standard gamble interview has historically been considered the ‘gold standard’ utility measure because it measures the strength of preference for a particular health state when the individual’s future is determined by probability. This simulates everyday life as we make many decisions based on risk and probability (driving over the speed limit, the decision to arrive at

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work five minutes late or crossing the road at a red light). The standard gamble does not ask questions specific to daily functioning, rather it asks the person to assess the value they place globally on their own life. This should correlate with the QALY which is also a global estimate.

Secondly, multi-attribute questionnaires are standardized and simple methods to measure quality of life. The short form 36 (SF-36) is a questionnaire based method for measuring quality of life which was originally calibrated and validated using standard gamble responses. The SF-36 can be used to measure all health states. Lastly, there are other newer disease specific questionnaires which were modelled on the SF-36 format, and focus on questions specific to individual diseases.

We recently interviewed 215 patients who had previously experienced venous thromboembolism, to determine utility estimates for pulmonary embolism, deep vein thrombosis, and three bleeding states [4]. Interviews were performed using the standard gamble technique. Our results showed wide variability in individual utility estimations, which prompted us to explore whether this represented true heterogeneity in human values and outlook, or whether the measurement tool had introduced artifact to the results.

All three methods for measuring quality of life are used in economic analyses. It is critical that venous thrombosis economic analyses use robust QALY estimates for acute pulmonary embolism, deep vein thrombosis, and common bleeding complications of treatment, to ensure valid conclusions regarding the cost of improved quality of life. An ideal measurement tool would have criterion validity (it should actually measure quality of life), construct validity (have a logical progression across a spectrum of health impairment) and discriminant validity (be free from external influences such as age, sex, race, education). The method should be reliable, reproducible and be an acceptable experience for the participant. An ideal measurement scale (such as the QALY) should be free from floor and ceiling effects meaning that the full spectrum (0 through 1) is represented, and that it demonstrates the differences between individual patient estimates.

The aim of this study was to explore the validity, reproducibility and acceptability of the standard gamble measurement tool for estimating utility values in pulmonary embolism and deep vein thrombosis.

Materials and Methods

The study was approved by The Ottawa Hospital Research Ethics Board (protocol number #20120260-01H). Our prior study [4] recruited people with previous experience of venous thrombosis. We wished to ascertain the true quality of life in this condition, therefore in the current study we recruited only people with a recent diagnosis, rather than people in the general population. The reasoning behind this was two fold. Firstly, it is difficult to convey to a member of the public how it feels to be diagnosed with a life threatening condition. Secondly, the symptoms and severity of this condition vary, so a single description will not represent the spectrum of clinical scenarios.

Patients attending The Ottawa Hospital Thrombosis Clinic within 12 months of the date of diagnosis of pulmonary embolism or deep vein thrombosis were eligible to be consented. Pulmonary embolism was diagnosed with either CT pulmonary angiogram (segmental or more proximal filling defects) or a high probability ventilation-perfusion lung scan in a patient with high clinical probability of pulmonary embolism. Deep vein thrombosis was diagnosed with compression

ultrasound. All patients had been diagnosed and followed clinically by a Thrombosis physician. Exclusion criteria included the inability to speak either English or French. Patients treated for calf deep vein thrombosis or unusual site thrombosis (upper limb, splanchnic or cerebral venous thrombosis) were excluded in order to focus on proximal lower limb venous thrombosis and pulmonary embolism which are a continuum of the same disease.

One researcher attended all thrombosis clinics. The thrombosis physicians alerted the researcher whenever they had an eligible patient. Written informed consent was taken prior to the interview. Participants were given the option of being interviewed at that time or arranging a meeting at a preferred time. They could be interviewed in either English or French. The researcher collected data on each participant's thrombosis history (provoking events, type of anticoagulant, days since diagnosis, and number of prior thrombotic episodes), co-morbidities, number of family dependents, family history of thrombosis and independent mobility outside of the house. Following this the participant was asked a series of questions relating to outlook on life, depression and anxiety, and risk taking behavior (ingestions of drugs and alcohol, smoking, speaking out, standing up for themselves and choice of dress). We did not collect data for severity of illness, hospitalization, length of anticoagulation, bleeding with anticoagulation or difficulty with adequate anticoagulation.

Participants completed four methods for measuring their current quality of life: the standard gamble, the SF-36 (version 2 Health Survey, four week recall) [5], a disease specific questionnaire (either the PembQol [6] or VEINES-QOL/Sym [7], depending on their diagnosis), and visual analogue score from 0 to 100. All questionnaires were available in French and English. These three methods were chosen for comparison in order to include both direct and indirect measurements of quality of life.

The methods were applied in random order. The bilingual interviewer talked the participants through each questionnaire. For the standard gamble the participant was asked to imagine that they had only six months to live, following which they would die an immediate and painless death. They were then asked to rate an imaginary scenario (see Fig. 1), which describes a highly dependent health state following a severe stroke. We offered a curative treatment, which comes with a risk of immediate death. The risk was varied using the ping pong method [8] to find the point of indecision whether to accept or decline the treatment. This determined the utility of the stroke health state. Immediately following this, the participant was asked to rate their own current health state, however the side effect of death was switched for the stroke health state. A treatment that would return the participant to a state of perfect health was offered multiple times, with the risk of severe disability (the stroke health state) varied using the ping pong method. An Excel computer program was used as a visual aid (see Fig. 2) throughout the process. We opted to use this 'chained' standard gamble technique in order to rate the participants' current health state against a severe disability, so that decision making was more acceptable for those who value life above anything else. The derived utility was then calibrated for the utility of severe stroke, to give the final result.

The SF-36 is a standardized questionnaire with 11 groups of questions and eight dimensions. The scores are calibrated from 0-100 and results are displayed for each of the eight dimensions. The SF-36 can be converted using the Short Form-6D (SF-6D) [9] to give a single quality

You are permanently weak on the right side of your body. You can no longer walk. You need help to dress yourself in the morning, and you cannot move from your bed to your wheelchair on your own. You are incapable of pronouncing words clearly and therefore find it very difficult to be understood by your caregivers.

Fig. 1. Description of disabled health state.

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