A Quantification Method to Compare the Value of Surgery and Palliative Care in Patients With Complex Cardiac Disease: A Concept

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ABSTRACT

- Complex cardiac patients are often referred for surgery or palliative care based on the risk of perioperative mortality. This decision ignores factors such as quality of life or duration of life in either surgery or the palliative path. Here, we propose a model to numerically assess and compare the value of surgery vs palliation. This model includes quality and duration of life, as well as risk of perioperative mortality, and involves a patient's preferences in the decision-making process.
- For each pathway, surgery or palliative care, a value is calculated and compared to a normal life value (no disease symptoms and normal life expectancy). The formula is adjusted for the risk of operative mortality. The model produces a ratio of the value of surgery to the value of palliative care that signifies the superiority of one or another. This model calculation presents an objective estimated numerical value to compare the value of surgery and palliative care. It can be applied to every decision-making process before surgery. In general, if a procedure has the potential to significantly extend life in a patient who otherwise has a very short life expectancy with palliation only, performing high-risk surgery would be a reasonable option. A model that provides a numerical value for surgery vs palliative care and includes quality and duration of life in each pathway could be a useful tool for cardiac surgeons in decision making regarding high-risk surgery.

Keywords: high-risk surgery, palliative care, quality of life, life expectancy.

atients with complex cardiovascular disease are occasionally considered inoperable due to the high risk of surgical mortality. When the risk of perioperative mortality (POM) is predicted to be too high, surgical intervention is denied, and patients are often referred to palliative care. The risk of POM in cardiac surgery is often calculated using large-scale databases, such as the Society of Thoracic Surgeons (STS) records. The STS risk models, which are regularly updated, are based on large data sets and incorporate precise statistical methods for risk adjustment.¹ In general, these calculators provide a percentage value that defines the magnitude of the risk of death, and then an arbitrary range is selected to categorize the procedure as low, medium, or high risk or inoperable status. The STS database does not set a cutoff point or range to define "operability." Assigning inoperable status to a certain risk rate is problematic, with many ethical, legal, and moral implications, and for this reason, it has mostly remained undefined. In contrast, the low- and medium-risk ranges are easier to define. Another limitation encountered in the STS database is the lack of risk data for less common but very high-risk procedures, such as a triple valve replacement.

A common example where risk classification has been defined is in patients who are candidates for surgical vs transcatheter aortic valve replacement. Some groups have described a risk of <4% as low risk,

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4% to 8% as intermediate risk, >8% as high risk, and >15% as inoperable²; for some other groups, a risk of POM >50% is considered extreme risk or inoperable.3,4 This procedure-specific classification is a useful decision-making tool and helps the surgeon perform an initial risk assessment to allocate a specific patient to a group-operable or nonoperable-only by calculating the risk of surgical death. However, this allocation method does not provide any information on how and when death occurs in either group. These 2 parameters of how and when death occurs define the quality of life (QOL) and the duration of life (DOL), respectively, and together could be considered as the value of life in each pathway. A survivor of a high-risk surgery may benefit from good quality and extended life (a high value), or, on the other end of the spectrum, a high-risk patient who does not undergo surgery is spared the mortality risk of the surgery but dies sooner (low value) with symptoms due to the natural course of the untreated disease.

The central question is, if a surgery is high risk but has the potential of providing a good value (for those who survive it), what QOL and DOL values are acceptable to risk or to justify accepting and proceeding with a risky surgery? Or how high a POM risk is justified to proceed with surgery rather than the alternative palliative care with a certain quality and duration? It is obvious that a decision-making process that is based on POM cannot compare the value of surgery (*Vs*) and the value of palliation (*Vp*). Furthermore, it ignores patient preferences and their input, as these are excluded from this decision-making process.

To be able to include QOL and DOL in any decision making, one must precisely describe these parameters. Both QOL and DOL are used for estimation of disease burden by health care administrators, public health experts, insurance agencies, and others. Multiple models have been proposed and used to estimate the overall burden of the disease. Most of the models for this purpose are created for large-scale economic purposes and not for decision making in individual cases.

An important measure is the quality-adjusted life year (QALY). This is an important parameter since it includes both measures of quality and quantity of life.^{5,6} QALY

is a simplified measure to assess the value of health outcomes, and it has been used in economic calculations to assess mainly the cost-effectiveness of various interventions. We sought to evaluate the utility of a similar method in adding further insight into the surgical decision-making process. In this article, we propose a simple model to compare the value of surgery vs palliative care, similar to QALY. This model includes and adjusts for the quality and the quantity of life, in addition to the risk of POM, in the decision-making process for high-risk patients.

The Model

The 2 decision pathways, surgery and palliative care, are compared for their value. We define the value as the product of QOL and DOL in each pathway and use the severity of the symptoms as a surrogate for QOL. If duration and quality were depicted on the *x* and *y* axes of a graph (**Figure 1**), then the area under the curve would represent the collective value in each situation. **Figure 2** shows the timeline and the different pathways with each decision. The value in each situation is calculated in relation to the full value, which is represented as the value of normal life (*Vn*), that is, life without disease and with normal life expectancy. The values of each decision pathway, the value of surgery (*Vs*) and the value of palliation (*Vp*), are then compared to define the benefit for each decision as follows:

If Vs/Vp > 1, the benefit is toward surgery; If Vs/Vp < 1, the benefit is for palliative care.

Definitions

Both quality and duration of life are presented on a 1-10 scale, 1 being the lowest and 10 the highest value, to yield a product with a value of 100 in normal, disease-free life. Any lower value is presented as a percentage to represent the comparison to the full value. QOL is determined by degradation of full quality with the average level of symptoms. DOL is calculated as a lost time (period of time from death after a specific intervention [surgery or palliation] until death at normal life expectancy) in fraction of full life (death at life expectancy). The *V*s is adjusted to exclude the nonsurvivors using the chance of survival (100–POM risk).



Figure 1. Quality of life and duration of life in normal life (disease-free) and in different disease pathways taken from a single sample. The area under the curve depicts the value of life, which is full in normal life (blue line). Quality and duration of life become lower and shorter, respectively, when the disease is treated with surgical care (SC) or with palliative care (PC). POM, perioperative mortality.



Figure 2. A timeline showing different situations from birth to death, including different outcomes after certain decisions. The red arrows show the duration of life in 3 scenarios: surgery with a successful outcome, surgery with perioperative mortality, and palliative care.

Value of a decision = Quality of Life × Duration of Life

$$V = QOL \times DOL$$

Vn = Value of normal life: without disease symptoms and living a full life to normal life expectancy

Vp = Value of palliative care

Vs = Value of surgery

 $Vn = (10-0) \times (Duration of Full Life = 0)/Duration of Full Life = 10 \times 1 = 10$

In normal life, symptoms=0, lost time=0.

Q=QOL=10-Grade of Severity of Symptoms (scale 1-10) Qn=Quality of normal life = 10 Qp=QOL with palliative care = 10-Grade of Severity of Average Symptoms During Palliative Care Qs=QOL with surgery=10-Grade of Severity of Symptoms After Surgery (scale 1-10) DOL = duration of life

For the DOL under any condition, a 10-year survival rate could be used as a surrogate in this formula. Compared to life expectancy value, using the 10-year survival rate simplifies the calculation since cardiac diseases are more prevalent in older age, close to or beyond the average life expectancy value.

Using the time intervals from the timeline in Figure 2: dh = time interval from diagnosis to death at life expectancy dg = time interval from diagnosis to death after successful surgery df = time interval from diagnosis to death after palliative care

Duration for palliative care:

$$Dp = \frac{dh - dg}{dh} \times 10$$

Duration for surgery:

$$Ds = \frac{dh - df}{dh} \times 10$$

Adjustment: This value is calculated for those who survive the surgery. To adjust for the POM, it is multiplied by the 100-POM risk.

$$V = (10 - \text{Average Symptoms Grade}) \times \frac{\text{DOL With Condition}}{\text{Normal Life Expectancy}} \times 10$$

Since value is the base for comparison in this model, and it is the product of 2 equally important factors in the formula (severity and duration of symptoms), a factor of 10 was chosen to yield a value of 100, which represents 100% health or absence of symptoms for any duration.

 $Vs/Vp = \frac{\frac{(10 - \text{Average Surgical Symptoms}) \times \frac{\text{DOL After Surgery}}{\text{Normal Life Expectancy}} \times 10 \times (100 - \text{Surgical Mortality Risk})}{(10 - \text{Average Palliation Symptoms}) \times \frac{\text{DOL With Palliation}}{\text{Normal Life Expectancy}} \times 10$

After elimination of normal life expectancy, form the numerator and denominator:

$$Vs/Vp = \frac{(10 - \text{Average Surgical Symptoms}) \times \text{DOL After Surgery} \times (100 - \text{Surgical Mortality Risk})}{(10 - \text{Average Palliation Symptoms}) \times \text{DOL With Palliation}}$$

To adjust for surgical outcomes in special circumstances where less than optimal or standard surgical results are expected (eg, in very rare surgeries, limited resource institutions, or suboptimal postoperative surgical care), an optional coefficient *R* can be added to the numerator (surgical value). This optional coefficient, with values such as 0.8, 0.9 (to degrade the value of surgery) or 1 (standard surgical outcome), adjusts for variability in interinstitutional surgical results or surgeon variability. No coefficient is added to the denominator since palliative care provides minimal differences between clinicians and hospitals. Thus, the final adjusted formula would be as follows:

 $V_{S/Vp} = \frac{(10 - \text{Average Surgical Symptoms}) \times \text{DOL After Surgery} \times (100 - \text{Surgical Mortality Risk}) R}{(10 - \text{Average Palliation Symptoms}) \times \text{DOL With Palliation}}$

Example

A 60-year-old patient with a 10% POM risk needs to be allocated to surgical or palliative care. With palliative care, if this patient lived 6 years with average symptoms grade 4, the *Vp* would be 20; that is, 20% of the normal life value (if he lived 18 years instead without the disease).

Using the formula for calculation of value in each pathway:

$$Vp = (10 - 4) \times \frac{6}{18} \times 10$$

 $Vp = 6 \times 6/18 \times 10 = 20\%$

a surgery with a
$$10\%$$
 risk of POM with an average

If the same patient undergoes a surgery with a 10% risk of POM, with an average grade 2 related to surgical recovery symptoms for 1 year and then is symptom-free and lives 12 years (instead of 18 years [life expectancy]), his *Vs* would be 53, or 53% out of the normal life value that is saved if the surgery is 100% successful; adjusted *Vs* with (chance of survival of 90%) would be $53 \times 90\% = 48\%$.

$$V = (10 - \text{Average Symptoms Grade}) \times \frac{\text{DOL With Condition}}{\text{Normal Life Expectancy}} \times 10$$

$$V_{s} = (10 - 2) \times \frac{12}{18} \times 10$$

$$V_{\rm S} = 8 \times 12/18 \times 10 = 53\%$$

With adjustment of 90% survival chance in surgery, $53 \times 90\% = 48\%$. In this example, Vs/Vp = 48/20 = 2.4, showing a significant benefit for surgical care. Notably, the unknown value of normal life expectancy is not needed for the calculation of Vs/Vp, since it is the same in both pathways and it is eliminated by calculation in fraction.

Based on this formula, since the duration of surgical symptoms is short, no matter how severe these are, if the potential duration of life after surgery is high (represented by smaller area under the curve in Figure 1), the numerator becomes larger and the value of the surgery grows. For example, if a patient with a 15% risk of POM, which is generally considered inoperable, lives 5 years, as opposed to 2 years with palliative care with mild symptoms (eg 3/10), *Vs/Vp* would be 2.7, still showing a significant benefit for surgical care.

Discussion

Any surgical intervention is offered with 2 goals in mind, improving QOL and extending DOL. In a high-risk patient, surgery might be declined due to a high risk of POM, and the patient is offered palliative care, which other than providing symptom relief does not change the course of disease and eventually the patient will die due to the untreated disease. In this decision-making method, mostly completed by a care team only, a potential risk of death due to surgery which possibly could cure the patient is traded for immediate survival; however, the symptomatic course ensues until death. This mostly unilateral decision-making process by a care team, which incorporates minimal input from the patient or ignores patient preferences altogether, is based only on POM risk, and roughly includes a single parameter: years of potential life lost (YPLL). YPLL is a measure of premature mortality, and in the setting of surgical intervention, YPLL is the number of years a patient would lose unless a successful surgery were undertaken. Obviously, patients would live longer if a surgery that was intended to save them failed.

In this article, we proposed a simple method to quantify each decision to decide whether to operate or choose surgical care vs palliative care. Since quality and duration of life are both end factors clinicians and patients aspire to in each decision, they can be considered together as the value of each decision. We believe a numerical framework would provide an objective way to assist both the patient at high risk and the care team in the decision-making process.

The 2 parameters we consider are DOL and QOL. DOL, or survival, can be extracted from large-scale data using statistical methods that have been developed to predict survival under various conditions, such as Kaplan-Meier curves. These methods present the chance of survival in percentages in a defined time frame, such as a 5- or 10-year period.

While the DOL is a numerical parameter and quantifiable, the QOL is a more complex entity. This subjective parameter bears multiple definitions, aspects, and categories, and therefore multiple scales for quantification of QOL have been proposed. These scales have been used extensively for the purpose of health determination in health care policy and economic planning. Most scales acknowledge that QOL is multifactorial and includes interrelated aspects such as mental and socioeconomic factors. We have also noticed that QOL is better determined by the palliative care team than surgeons, so including these care providers in the decision-making process might reduce surgeon bias.

Since our purpose here is only to assist with the decision on medical intervention, we focus on physical QOL. Multiple scales are used to assess health-related QOL, such as the Assessment of Quality of Life (AQoL)-8D,⁷ EuroQol-5 Dimension (EQ-5D),⁸ 15D,⁹ and the 36-Item Short Form Survey (SF-36).¹⁰ These complex scales are built for systematic reviews, and they are not practical for a clinical user. To simplify and keep this practical, we define QOL by using the severity or grade of symptoms related to the disease the patient has on a scale of 0 to 10. The severity of symptoms can be easily determined using available scales. An applicable scale for this purpose is the Edmonton Symptom Assessment Scale (ESAS), which has been in use for years and has evolved as a useful tool in the medical field.¹¹

Once DOL and QOL are determined on a 1-10 scale, the multiplied value then provides a product that we consider a value. The highest value hoped for in each decision is the achievement of the best QOL and DOL, a value of 100. In Figure 1, a graphic presentation of value in each decision is best seen as the area under the curve. As shown, a successful surgery, even when accompanied by significant symptoms during initial recovery, has a chance (100-risk of POM%) to gain a larger area under curve (value) by achieving a longer life with no or fewer symptoms. However, in palliative care, progressing disease and even palliated symptoms with a shorter life expectancy impose a large burden on the patient and a much lower value. Note that in this calculation, life expectancy, which is an important but unpredictable factor, is initially included; however, by ratio comparison, it is eliminated, simplifying the calculation further.

Using this formula in different settings reveals that high-risk surgery has a greater potential to reduce YPLL in the general population. Based on this formula, compared to a surgery with potential to significantly extend DOL, a definite shorter and symptomatic life course with palliative care makes it a significantly less favorable option. In fact, in the cardiovascular field, palliative care has minimal or no effect on natural history, as the mechanism of illness is mechanical, such as occlusion of coronary arteries or valve dysfunction, leading eventually to heart failure and death. In a study by Xu et al, although palliative care reduced readmission rates and improved symptoms on a variety of scales, there was no effect on mortality and QOL in patients with heart failure.¹²

No model in this field has proven to be ideal, and this model bears multiple limitations as well. We have used severity of symptoms as a surrogate for QOL based on the fact that cardiac patients with different pathologies who are untreated will have a common final pathway with development of heart failure symptoms that dictate their QOL. Also, grading QOL is a difficult task at times. Even a model such as QALY, which is one of the most used, is not a perfect model and is not free of problems.6 The difference in surgical results and life expectancy between sexes and ethnic groups might be a source of bias in this formula. Also, multiple factors directly and indirectly affect QOL and DOL and create inaccuracies; therefore, making an exact science from an inexact one naturally relies on multiple assumptions. Although it has previously been shown that most POM occurs in a short period of time after cardiac surgery,¹³ long-term complications that potentially degrade QOL are not included in this model. By applying this model, one must assume indefinite economic resources. Moreover, applying a single mathematical model in a biologic system and in the general population has intrinsic shortcomings, and it must overlook many other factors (eg, ethical, legal). For example, it will be hard to justify a failed surgery with 15% risk of POM undertaken to eliminate the severe long-lasting symptoms of a disease, while the outcome of a successful surgery with a 20% risk of POM that adds life and quality would be ignored in the current health care system. Thus, regardless of the significant potential, most surgeons would waive a surgery based solely on the percentage rate of POM, perhaps using other terms such as "peri-nonoperative mortality."

Conclusion

We have proposed a simple and practical formula for decision making regarding surgical vs palliative care in high-risk patients. By assigning a value that is composed of QOL and DOL in each pathway and including the risk of POM, a ratio of values provides a numerical estimation that can be used to show preference over a specific decision. An advantage of this formula, in addition to presenting an arithmetic value that is easier to understand, is that it can be used in shared decision making with patients. We emphasize that this model is only a preliminary concept at this time and has not been tested or validated for clinical use. Validation of such a model will require extensive work and testing within a large-scale population. We hope that this article will serve as a starting point for the development of other models, and that this formula will become more sophisticated with fewer limitations through larger multidisciplinary efforts in the future.

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