

Risk Assessment and Decision Analysis Within Surgical Applications

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2.1 Introduction

Risk is an inherent consideration within any surgical operation. Even minor operations with high rates of success performed on otherwise healthy patients can sometimes induce severe intra- and postoperative complications. Conversely, major operations with low rates of success performed on chronically ill patients can sometimes lead to immediate recoveries with no complications. It is not uncommon when two identical procedures performed on two similar patients yield much different results.

These outcomes of surgical procedures can be explained in terms of risk, an innate property of the field of surgery that doctors and patients alike are challenged to understand when making decisions. Potential complications could ultimately change the outcome of the operation and have different degrees of risk. Thus, it is important for surgeons to understand and be able to evaluate surgical risk in order to identify the course of action that minimizes the likelihoods and consequences of potential complications.

Systematic techniques for measuring risk exist and are employed by decision-makers in various fields. In this chapter, we will discuss one such technique, which integrates risk assessment with multi-criteria decision analysis (MCDA), and examine its potential application in the field of surgery.

2.2 What Is Risk Assessment and Decision Analysis?

Present in virtually every aspect of human life, risk can be defined as any potential negative outcome of a given activity or action. The risk associated with a potential negative outcome is comprised of both its probability of occurring along with an associated consequence or range of possible consequences. As any given activity may give rise to dozens or even hundreds of negative events, fully comprehending the activity's associated risks in an ad hoc manner becomes a near impossibility. Under such concerns, greater structure is required to assess risks and gain improved insight into the potential hazards and consequences of a particular course of action.

A well-designed and thorough assessment of risks covers a spectrum of potential negative outcomes, ranging from the near certain yet marginal (i.e., patient fatigue after surgery) to the rare yet

Likelihood	High	Light Blue	Light Blue
	Low	Medium Blue	Light Blue
		Low	High
		Strength of impact	

■ Fig. 2.1 Standard risk matrix: frequency of event by strength of impact

catastrophic (death). In essence, risk is the product of the likelihood of a particular event occurring and the consequences of that event should it arise.

Formal risk assessments often utilize quantitative and visual tools, such as risk matrices, that provide structure when evaluating an activity's outcomes. When sufficient data is available, these tools allow their users to better understand the likelihoods of the various consequences associated with courses of action, along with the associated risks. Ultimately, risk assessment is a useful approach to identifying and measuring the various risks of a given course of action (■ Fig. 2.1).

However, simple risk assessment may not be optimal for comparing the risks of alternative courses of action in situations of uncertainty, when objective data is lacking. For example, hazard may not be easily assessed and there may not be a good model for exposure and effect assessment. In an uncertain context, evaluating alternative courses of action to identify the best option requires consideration of subjective information in addition to whatever data is available. In these situations, decision analysis can be used to integrate the preferences and opinions of physicians and patients with objective data and statistics. Decision analysis imparts structure within the decision-making process and offers methods for determining and interpreting how decision criteria may change due to the uncertainty of the situation. When used to supplement risk assessment, decision analysis can produce indications of relative risk levels for alternative courses of action, even in situations of uncertainty. Ultimately, decision analysis can be used to identify the most promising course of action given available data and stakeholder information.

Various approaches to decision analysis exist for different situations. One such approach is multi-criteria decision analysis (MCDA), which

includes a set of methods and tools for integrating quantitative measurements and models with more qualitative attributes generally expressed as the formalized judgment of an expert or stakeholder. MCDA refers to a class of structured analytical frameworks used to evaluate alternatives that must be compared against several criteria. Most MCDA methods include the construction of a decision model, which lists each alternative and criterion in a grid-based or tree-based format, yet different methods of MCDA may utilize different weighting and evaluation algorithms [1]. Numerical scores are assigned to each alternative with respect to its performance on individual and weighted criteria, and scores are aggregated for each alternative [2]. Regardless of the type of MCDA, all methods allow decision-makers to structure decision problems in a logical and more formal manner.

As a field with myriad evaluation criteria and significant uncertainty, surgical risk assessment would greatly benefit from a formalized aid to review the risks associated with alternative surgical procedures for a given patient [3]. As we will examine later in this chapter, MCDA could allow surgeons to aggregate qualitative or subjective information, opinions, and preferences alongside more objectively driven data to measure surgical risk and support surgical decision-making.

2.3 A Brief History of Risk

Management of risk has existed for centuries. Many in ancient Egypt, Greece, and Rome turned their hand to a simplistic understanding of risk to estimate the flooding of the Nile River, one's chances of striking it rich in a gamble, or the possibilities of loss when shipping one's goods by sea [4, 5]. Especially due to a lack of computational power expressed by our electronics and devices today, early understandings of risk were measured based on qualitative assessments of one's ability to succeed. For decision-makers in antiquity, this early understanding of risk was characterized based upon experience and anecdotal information from similar circumstances of previous events rather than on quantitative projections due to current or futuristic data. Nevertheless, those with a greater understanding of risk were able to minimize opportunities for loss and maximize potential gains, leaving a fortunate few with more than they began with.

More recently, the need for increased precision and prediction of future events spurred the rise of quantitative assessment. A historical example of this shift includes an exchange of letters in 1654 between Blaise Pascal and Pierre de Fermat [6]. Known today as The Enigma of Méré's, Pascal and de Fermat were able to mathematically prove why Chevalier de Méré consistently lost a gamble of two dice through fundamental theorems of probability [5, 7]. In essence, Chevalier de Méré used a dice gambling rule that consistently lost matches, while Pascal and de Fermat demonstrated how de Méré should place bets on specific die based upon the probability that they should arise through quantitative assessment. Though simple compared to today's measures of probability estimation, the solution to the Enigma of Méré's demonstrated an ability of a capable analyst to use probability and available quantitative information to estimate the future. Quantitative probabilistic estimation stands as a central crux in modern risk and decision science, as risk is generally measured based upon the probabilities that a positive or negative outcome could occur.

Since then, the idea of using numbers to estimate outcomes under uncertainty has infiltrated virtually every discipline in the modern world. From understanding trends in the stock market to estimating the chance of technological failure in a nuclear power plant, mapping the probabilities of certain risks under uncertainty has offered the ability to improve the management of limited resources.

2.4 Risk Assessment in Medicine: Current Practices and Methods

Throughout their training and education, doctors are taught to base their decisions upon the aggregation of evidence, inference, and experience. As such, medical decision-making is undertaken via both an inductive analysis of a given patient's symptoms as well as through deductive and probabilistic decision making driven by medical experience and corresponding data on symptoms and outcomes. More recently, patient preferences have become a significant qualitative aspect of medical decision-making. In a sense, modern medicine has become individualized [8]. The risk communication involved when considering a range of treatment options is often altered to accommodate the concerns of the patient. Faced with constraints on time and information, however, doctors must

often make decisions based entirely on classifications of common symptoms, given the characteristics of a specific patient [9].

In the field of surgery, the same constraints on time and information exist. When computing the risk of a particular procedure, myriad variables begin to apply. Many of these variables are difficult to quantify. Qualities such as the specialty of a particular surgeon may affect the procedural choice in an informal manner. When these aspects factor into a decision, the output is often affected detrimentally because the process may not be transparent or quantitatively robust. Ad hoc decision-making also becomes problematic when considering subjective variables such as quality of life. This is due to the difficult task of placing values on not only the cost of a particular procedure but also when evaluating the type of lifestyle that is likely to follow a major surgical procedure.

Robust methods that manage the risks for patients confronted with surgical options for a certain problem are difficult to find. This type of analysis should be transparent in order for the patient and practitioner to understand how risk is calculated and how to factor it into the underlying decision. In the past, cardiovascular risk calculators of this type have been used to determine procedure estimates. These forms of calculators are now being applied to more specialized surgeries, but in a very limited scope. Once the background of risk computation has been formalized, more advanced models such as decision analysis could be successfully applied.

Communication of the risks involved with a particular surgery is important for both the patient and doctors involved. Informed consent is required in order to conduct a surgical procedure involving risk. Landro depicts a typical communication of the risks involved with a certain procedure [10]. This case deals specifically with a female patient considering an abdominal surgery for colon and uterine cancer (■ Fig. 2.2).

Statistics like these are valuable because they are reasonably easy to understand and communicate to a patient. This type of risk communication,

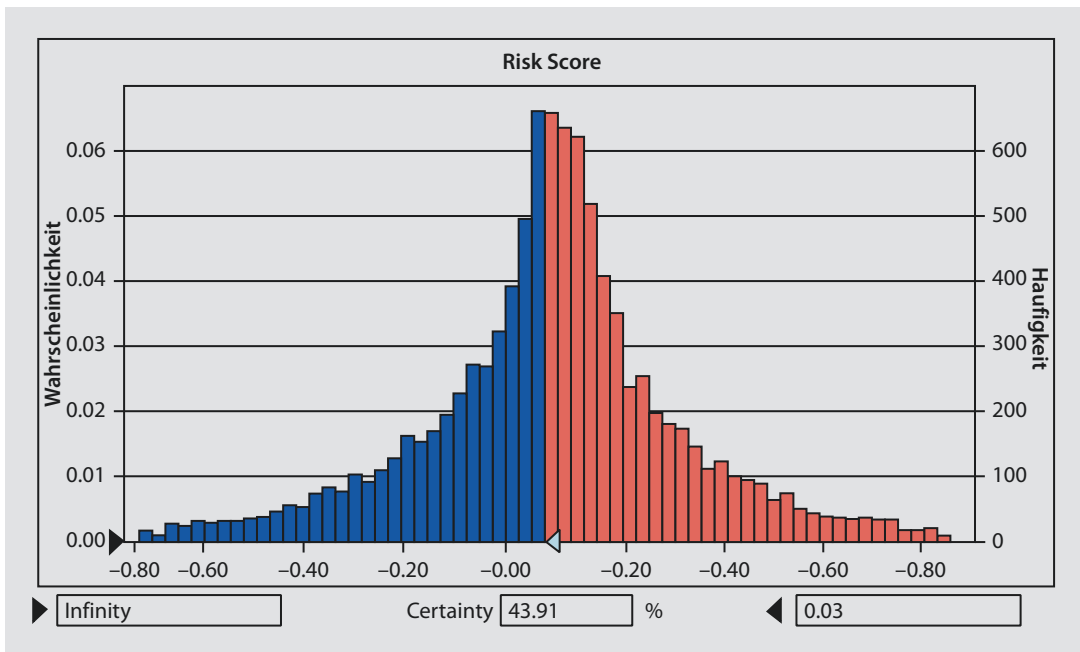
however, provides no transparency of methodology. Further, the complication statistic does not reflect the severity of a particular complication to the specific patient being discussed. Current methods of surgical decision-making often involve the analysis of physical and intellectual databases of millions of patient cases and surgical procedures. Strategies such as data mining often take years to conduct, requiring large sample sizes which may not be available. Bias affects clinical decision-makers attempting to synthesize and apply tremendous amounts of data on an individual patient basis. This very often leads to classification of patients into groups, either consciously or subconsciously, in an attempt to expedite the process of diagnosis. This type of stereotype results from the natural desire to simplify a decision when faced with enormous amounts of data. Limitations on the conventional ad hoc methods of medical decision-making have established an interest in a more formal, quantitative method of risk assessment.

In some specific cases, formalized models of decision analysis have already been applied. These models have been generally linear and focus on a formal evaluation of a medical decision. Numerous forms of quantitative approaches to medical risk management have been developed for years. Weiss et al. offers an early decision model that couples robust statistical data with the opinions of physicians to make more informed medical decisions. In this model, computer-aided decision-making attempts an explicit approach through artificial intelligence (AI) of medical decision-making over the conventional implicit method that uses statistics from accumulated sample data [11]. This type of method accounts for a rapidly growing dynamic knowledge base, as commonly seen in the medical field.

Another approach to a quantitative risk assessment is through simulation. Simulation models in medicine could predict health outcomes of treatments using probabilities of events impacting dose-response models. These models are advantageous because of their ability to depict iterated

■ Fig. 2.2 Risk assessment and risk probabilities: female with colon cancer

Chance of complication at surgical incision site	18 %
Chance of serious complication (i.e. cardiac arrest)	8 %
Chance of death	1 %



■ Fig. 2.3 Monte Carlo simulation of appendectomy dilemma

events or conditions that depend on time for more accurate representations. One such model includes Monte Carlo simulation, in which the probabilities of the best case, worst case, and best guess of an outcome are estimated and simulated thousands of times. Various methods of Monte Carlo assessment and imaging could be utilized to review a patient's risk for negative surgical outcome and could reduce uncertainty in surgical procedures by quantifying and communicating the many risks that affect a patient undergoing a surgical procedure that could yield a negative outcome.

To demonstrate how a Monte Carlo assessment would operate within this context, a surgical dilemma is noted below. A 28-year-old male patient is admitted with a perforated appendix, including a periappendiceal abscess along with acute inflammatory infiltration of the cecum. Though appendectomy is a relatively small operation, the presence of inflammation generates an increased risk of leakage from the appendiceal stump. In the presence of uncertainty, a simulation tool like Monte Carlo would be helpful to estimate the likelihood of surgical success along with an improved understanding of risk origin when paired with a decision support system such as multi-criteria decision analysis. Below, a normalized simulation is shown where a negative score indicates a negative surgical outcome, and

a positive score results in a surgical success (■ Fig. 2.3). Under the set risk criteria of the patient's age, history, surgical complications, and others, an approximate failure rate of 43% is expected.

Integration of expert and stakeholder views to the decision process has also been applied in a limited number of cases. Cairo et al. details an approach involving expert interviews that generate and assign risk scoring for each procedure [12]. This particular method utilizes the RAND appropriateness method (RAM) in order to determine whether or not a procedure or treatment option is applicable in a specific patient case. The output of the model is a scaled ordinal (1–3 inappropriate, 4–6 uncertain, 7–9 appropriate) system. This method establishes which alternatives may be the most appropriate, but may not clearly determine which method is optimal.

Formal decision methodologies have been used more recently in multiple publications. As a journal centered on discussions of risk and decision-making difficulties in a medical context, *Medical Decision Making* presents several decision models that involve more advanced quantitative methodologies which attempt to integrate subjective patient characteristics in a formal manner. For example, Pignone and Ransohoff [13] offer a cross-model comparison for colorectal

cancer screenings, asserting that modeling is an effective way to evaluate cost-efficiency, as well as to integrate subtle differences in time intervals and the intervention of more than one procedure.

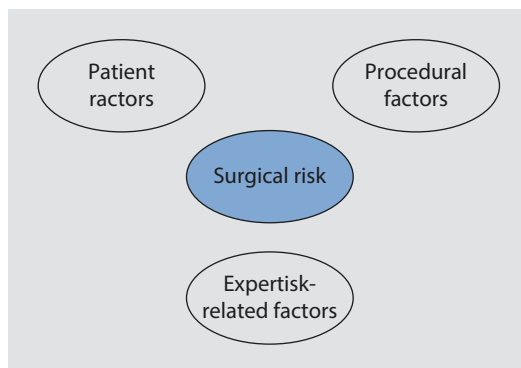
2.5 Risk-Based Decision Analysis for Application in Surgery

In any surgical procedure, various factors contribute to the risk of potential intra- and postoperative complications (■ Fig. 2.4). These factors can be associated with the traits of the individual undergoing the procedure, or with the procedure itself. Different patient characteristics such as age, body mass index (BMI), and medical history can affect a person's susceptibility to certain complications. Alternative procedures also have different propensities to induce particular problems. Though there are often additional risk factors to consider, such as those associated with the technical expertise of the surgeon, we will focus only on patient and procedural factors in our discussion of how surgical risk can be measured.

In a preoperative situation, a surgeon must evaluate the surgical approaches available and choose the most promising option that best meets the patient's needs. In an intraoperative situation, a surgeon could encounter a problem and must decide whether to continue with the intended operation or to deviate from the initially planned surgical approach to some alternative technique or procedure [14]. In either case, a well-informed decision must consider all the risk factors associated with both the patient and the different alternative procedures in order to select a course of action that minimizes the risk of potential complications.

Decision analysis provides a structured framework for evaluating patient and procedural risk factors to assess the risks of potential complications. Applied in a difficult surgical situation, MCDA can be used to support effective decision-making by integrating qualitative reasoning, such as the inference and experience of the surgeon, with quantitative data, such as empirical results from clinical studies, to measure the relative risk levels of alternative courses of action. MCDA decision models, such as the one pictured in ■ Fig. 2.5, offer a valuable tool for surgeons to quantify and analyze surgical risks.

The four-leveled decision model pictured in ■ Fig. 2.5 is a representation of how MCDA might



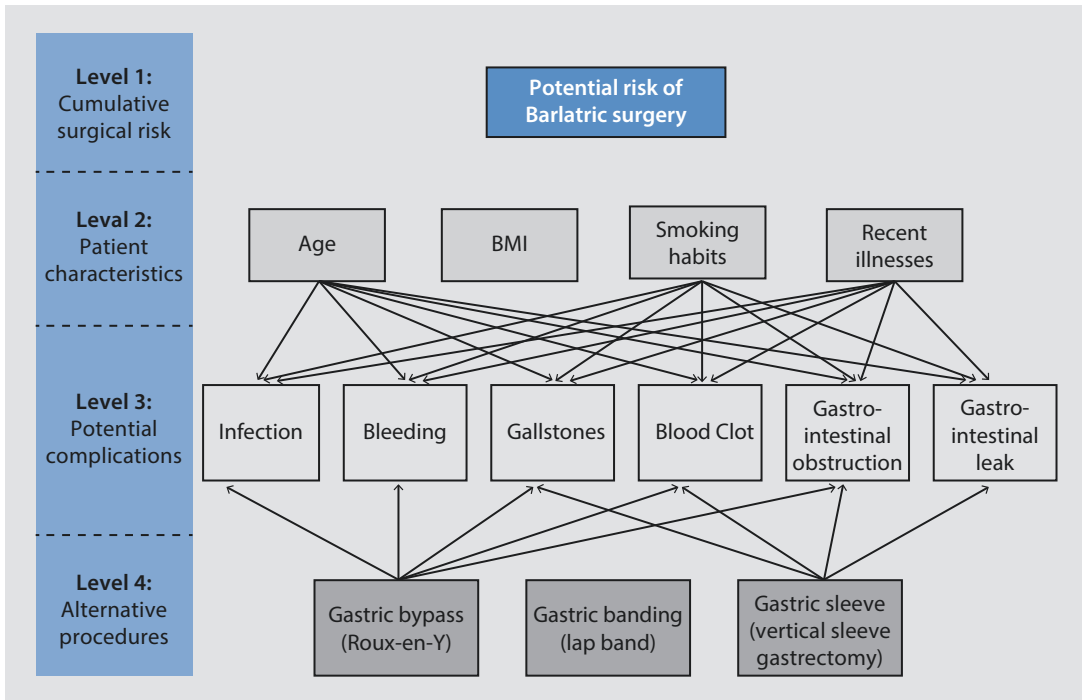
■ Fig. 2.4 Three types of factors that contribute to surgical risk

be applied to evaluate the potential risks of complications for different bariatric surgeries. While this general model is not meant to accurately represent the full complexity of a realistic surgical situation, it shows conceptually how factors associated with both the patient (level 2) and the procedure (level 4) contribute to the risk of potential complications (level 3) and thus affect the level of overall surgical risk (level 1) for a particular operation.

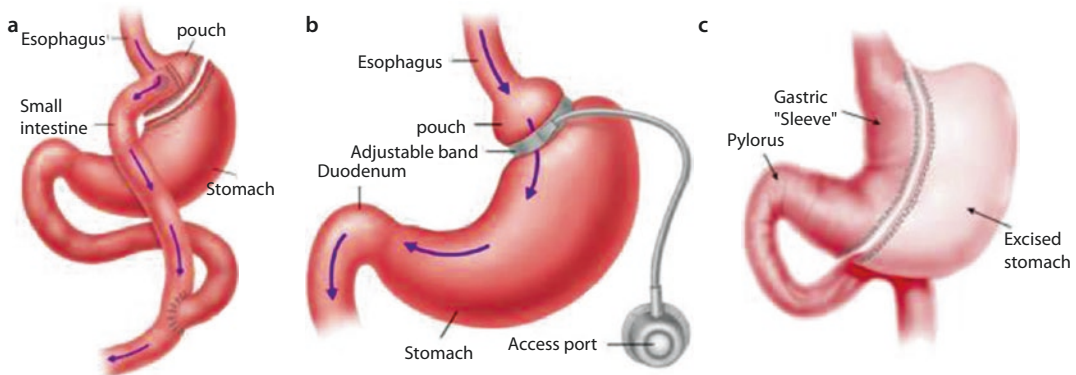
In any application of MCDA, decision models serve as a framework for organizing and analyzing all the criteria that is relevant to the decision at hand. These conceptual tools provide structure for a series of simple algorithms that describe mathematically how different criteria relate to each other and factor into the decision-making process. Used in conjunction, MCDA decision models and algorithms provide a transparent, systematic, and comprehensive approach to decision-making. To illustrate this approach, we explore below a hypothetical surgical case study that accompanies the decision model in ■ Fig. 2.5.

2.6 Case Study: MCDA Application for Risk Assessment in Bariatric Surgery

Consider a patient who wishes to undergo bariatric surgery and must choose between available surgical options. For the purpose of this case study, we will limit the patient's choices to three alternative procedures: a gastric bypass (Roux-en-Y) option, a gastric banding (Lap-Band) option, and gastric sleeve (vertical sleeve gastrectomy)



■ Fig. 2.5 Example MCDA decision model for assessing risks of alternative bariatric procedures



■ Fig. 2.6 Depictions of alternative bariatric procedures: (a) Roux-en-Y gastric bypass, (b) gastric banding, and (c) gastric sleeve

option. These three procedures are depicted in ■ Fig. 2.6 and on level 4 of the decision model in ■ Fig. 2.5. In order to make a well-informed decision, the patient should compare the overall surgical risk levels associated with each alternative operation.

For the surgeon to be able to provide the patient with cumulative measurements of risk for each alternative, he or she must consider all the potential complications for each procedure and

evaluate the relevant factors that could affect their possibility of occurring. For the purpose of this scenario, we will consider a limited number of potential complications: infection (at the surgical site), bleeding (internal), gallstones, blood clots, gastrointestinal obstruction, and gastrointestinal leakage. These complications are listed on level 3 of the decision model in ■ Fig. 2.5. Though a realistic surgical decision would likely need to consider a much wider array of potential complications, in

our example we will assume that there is zero possibility for any complications outside of these six.

The surgeon, having compiled a list of all potential complications, must now assess the risks of each one occurring for each of the three procedures. To do this, he or she must understand the different factors that contribute to the risks of the various complications. The risk factors associated with both the patient and with the specific procedures must be evaluated.

Suppose the surgeon chooses to first assess patient risk factors. He or she must determine which patient characteristics are relevant to the decision at hand. In other words, he or she must identify the qualities of the patient that influence his or her susceptibility to any of the potential complications. For the purpose of this scenario, we will assume that there are only four relevant patient characteristics (which are listed on level 2 of the decision model in **Fig. 2.5**): age, body mass index (BMI), smoking habits, and recent illness. The surgeon knows that each of these general patient characteristics have been proven to influence the chance of one or more potential complication occurring. Thus, he must evaluate the patient's "score" with respect to each of the four characteristics. This information for our hypothetical patient is shown below in **Table 2.1**.

In order to evaluate how the patient's characteristics affect the overall risk levels of alternative procedures, the surgeon must not only know how the patient scores for each characteristic but must also understand how exactly these characteristics influence the patient's susceptibility to the various complications. For example, it is not exactly useful for the surgeon to know that the patient's BMI is 32 unless he or she also knows the propensity of BMI to influence the chance of surgical infection. Thus, for each of the potential complications, our surgeon must assess all relevant characteristics

and integrate the patient's characteristic score with the characteristic's general propensity to induce the complication.

In a realistic application, there might be multiple ways of integrating a patient's score with the characteristic's propensity to determine the influence of the specific patient attribute on the risk of a given complication. These could range from purely mathematical algorithms to more qualitative approaches that place the patient in a "bin" or category, along a scale from one to ten, along a spectrum from "low susceptibility" to "high susceptibility," etc. The MCDA approach can be adapted to accommodate any and all methods of integration, which may vary with the context and/or with the medical data that is available.

As our case study is hypothetical and intended primarily to illustrate the larger MCDA approach, we will not explicitly define or integrate characteristic propensities but will instead randomly assign each patient characteristic and "influence score" from one to five with respect to each potential complication, representing the magnitude with which the patient's attribute increases his or her susceptibility to that complication. Our surgeon can combine these scores to derive our patient's "susceptibility score" for each potential complication. The results of these evaluations are pictured below in **Table 2.2**.

The surgeon has now completed a comprehensive assessment of the patient-related risk factors involved in the surgical decision. Having considered all relevant patient characteristics and determined the patient's own susceptibility to each potential complication, he or she must now assess the risk factors associated with the surgical procedures being considered. The distinct steps involved with each of the three bariatric operations might present varying levels of potential risk for different complications. Thus, the surgeon has to determine the propensity of each procedure to induce each of the potential complications.

Various sources of information can be utilized to determine the propensity of a particular procedure to induce a specific complication. The surgeon's own intuition, grounded in his or her experience performing the operation, might be a reliable gauge. Documented medical data and the results of clinical trials might also be potentially useful sources. Although the data that is available

Table 2.1 Patient characteristic "scores"

Patient characteristic	Patient score
Age	36
BMI	32
Smoking habits	None
Recent illness	None

■ **Table 2.2** Patient characteristic influence scores and susceptibility scores for each potential complication

Patient characteristic	Patient score	Characteristic influence scores					
		Infection	Bleeding	Gallstones	Blood clot	Gastrointestinal obstruction	Gastrointestinal leak
Age	36	1	2	3	2	1	1
BMI	32	3	2	2	4	3	2
Smoking habits	None	0	0	0	0	0	0
Recent illness	None	0	0	0	0	0	0
<i>Final complication susceptibility score</i>		4	4	5	6	4	3

■ **Table 2.3** Alternative propensity scores for each potential complication

Surgical alternative	Procedure propensity scores					
	Infection	Bleed ing	Gallstones	Blood clot	Gastrointestinal obstruction	Gastrointestinal leak
Gastric bypass (Roux-en-Y)	2	1	3	2	4	3
Gastric banding (Lap-Band)	1	1	2	1	3	2
Gastric sleeve (vertical sleeve gastrectomy)	3	4	2	2	1	2

in different surgical contexts may vary, it is important that the propensity scores for different procedures and complications are derived with as much fidelity as is possible.

For the purpose of our case study, we will randomly assign the three alternative procedure propensity scores from one to five for each potential complication. These propensity scores, displayed below in ■ Table 2.3, represent the tendency of the procedure to induce the particular complication.

The surgeon has now comprehensively assessed both the patient and procedural risk factors that could contribute to the possibility of encountering potential complications during the bariatric surgery. He or she must now aggregate the patient's susceptibility scores with each procedure's propensity scores to produce cumulative measures of surgical risk that the patient can use to compare alternatives.

Before he or she can derive these final risk levels, however, the surgeon must perform one

last assessment that explicitly considers the severities of each potential complication. In order for the patient to make a well-informed decision regarding which surgical alternative to pursue, he or she must not only understand his or her own susceptibility to potential complications and the procedures' varying propensities for inducing them, but he or she must also take into account the severity of the potential complications that could arise. Suppose the patient would favor a procedure with a high risk for a minor complication (i.e., gallstones) over a procedure with a low risk for a major complication. This preference must factor into the surgeon's calculations.

In the field of risk analysis, risks are described by measures of "likelihood" and "consequence." In this scenario, the combined patient susceptibility and procedural propensity scores describe the "likelihood" of potential complications occurring, and severity scores describe the "consequence." Thus, the surgeon

Table 2.4 Severity scores for potential complications and cumulative surgical risk level for the gastric bypass alternative

Complication	Severity score ("consequence")	Patient susceptibility score	Gastric bypass (Roux-en-Y)		
			Procedure propensity score	Susceptibility × propensity ("likelihood")	Complication risk level
Infection	2	4	2	8	16
Bleeding	3	4	1	4	12
Gallstones	1	5	3	15	15
Blood clot	4	6	2	12	48
Gastrointestinal obstruction	3	4	4	16	48
Gastrointestinal leak	2	3	3	9	18
<i>Cumulative surgical risk score:</i>					157

Table 2.5 Cumulative surgical risk levels for the gastric band and gastric sleeve alternatives

Gastric band (Lap-Band)			Gastric sleeve (vertical sleeve gastrectomy)		
Procedure propensity score	Susceptibility × propensity ("likelihood")	Complication risk level	Procedure propensity score	Susceptibility × propensity ("likelihood")	Complication risk level
1	4	8	3	12	24
1	4	12	4	16	48
2	10	10	2	10	10
1	6	24	2	12	48
3	12	36	1	4	12
2	6	12	2	6	12
<i>Cumulative surgical risk score:</i>		102	<i>Cumulative surgical risk score:</i>		154

must first combine the susceptibility and propensity scores for each complication and then integrate these combined likelihood scores with their associated severity, or consequence, scores. Only then can cumulative risk levels be defined for the alternative surgeries.

Although these scores could be integrated in different ways, for the purpose of our hypothetical case study, we will simply take the product of

each complication's likelihood score (which is itself a product of its susceptibility and propensity scores) and randomly assigned consequence score (1–5) to derive the risk score for the complication. We will then sum the risk scores across all complications to calculate the final, cumulative risk level for the surgical procedure. The results of these evaluations are shown below in

■ Tables 2.4 and 2.5.

2.7 Discussion

It is important to note that the decision model and hypothetical scenario we present in this chapter are simplified examples meant only to demonstrate how MCDA can be applied in a difficult surgical situation. Our model's lists of complications, procedures, and patient characteristics are incomplete and are intended to be specific to the limited field of bariatric surgery. Realistically, the relevant factors and alternatives that must be considered when measuring risk and making decisions would be defined by the objective of the surgery. Additional patient characteristics, potential complications, and alternative procedures might need to be evaluated in order to fully comprehend associated risks and make a well-informed decision. Moreover, both the preferences of the patient and the surgical policies of the hospital must be taken into account.

Also worth noting is the fact that our model and scenario are specific to a preoperative surgical context, where risks can be evaluated before the operation takes place and the patient generally has a say in the decision that is made. MCDA can also be applied in an intraoperative context, when an unanticipated difficulty is encountered mid-procedure. In these scenarios, new risks can develop that often require a reassessment of the initial surgical strategy.

Ultimately, doctors and surgeons must be able to understand and evaluate risk in order to meet the needs of their patients. There are many ways to measure risk, and risk and decision analysis is just one way to facilitate comprehensive and efficient risk assessment. Medical MCDA could better inform patients and surgeons as to the potential risks of a procedure and could also improve surgical success rates through responsible mitigation of complications. Though decision analysis methods such as MCDA are no replacement for a skilled surgeon and the diagnostic abilities of medical professionals, they may act as tools to prioritize surgical procedures for a particular patient based upon cumulative measurements of relative risk.

In the field of surgery, decision models like the one described in this chapter would not replace, but rather support a surgeon's own expertise and intuition. With so many interrelated risk factors to consider in a difficult surgical situation, a structured approach to organizing, integrating, and interpreting these factors could help surgeons make better informed, risk-minimizing decisions.

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