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Using the STS and Multinational Cardiac Surgical Databases to Establish Risk-Adjusted Benchmarks for Clinical Outcomes

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ABSTRACT

One of the purposes of collecting data on cardiac surgical procedures, at a national level is to enable individual surgeons to improve quality and benchmark their own practice by making more accurate prospective prediction of outcome of each individual patient by using risk stratification based on previous local and national experiences. The past decade has seen a dramatic increase in the development of national cardiac surgical initiatives in many countries around the world. The size and extent of these databases has successfully allowed their use for patient risk stratification and preoperative risk modeling in four main aspects: patient selection and informed consent, coherent analysis of the determinants of patient outcomes, rationalizing unit management, and negotiations with external agencies.

Approximately 610 cardiac surgical units presently contribute their patient data, containing pre-operative risk factors, to centralized national registries. There are currently nine different datasets used throughout the world to collect patient information. To harmonize the considerable diversity among these source materials, an International Dataset has been developed by a collaborative process among more than 50 cardiac surgeons around the world. Constructed around the Society of Thoracic Surgeons (STS) data format, the International Dataset brings in key elements from all the other datasets, allowing the sharing of data and cross-analysis, thus greatly expanding the pool of patients, and national sources, from which risk-stratified outcomes can now be analyzed and unified.

Unlike the STS dataset, the International Dataset incorporates EuroSCORE, a simple-to-use, validated patient risk stratification system, which has been rapidly adopted by large numbers of centers around the world for patient risk stratification, outcomes assessment, and improving patient informed consent.

There are several benefits to collecting and centralizing national and international data: (1) understanding and defining basic demographics of patients undergoing cardiac surgery; (2) patient risk stratification and risk prediction at both a national and center-by-center level; (3) unit benchmarking, and development of effective nationally oriented and center-oriented quality improvement programs; (4) understanding and rationalizing resource utilization; and (5) use of data to leverage governments and other healthcare providers to affect policy.

Cardiac surgical registries will soon attempt to track patients for longer follow-up periods after discharge in order to identify surgery-related deaths for more extended periods of time following surgery, thereby improving the monitoring and prediction of patient outcomes.

BACKGROUND

The field of cardiac surgery has long led the medical world in the collecting, centralizing, and analyzing of patient data on national and international stages, both in the breadth of information collected and the absolute numbers of patients [Grover 1999, National Adult Cardiac Surgical Database Reports 1998 & 2000, Wyse 1999a, Wyse 1999b, Ferguson 2000, Wyse 2000, Vogt 2000, Ferguson 2002, Stahle] (see Table 1 ◎).

Approximately 610 cardiac surgical units presently contribute their patient data, containing pre-operative risk factors, to centralized national registries. Globally, another 100+ centers are similarly planned to come on line during 2002. There are currently nine different datasets used around the world to collect preoperative, perioperative, and postoperative patient information (in most cases, this represents a large data set—up to 400-500 data elements per patient). Inevitably, these data sets have many similarities, but to harmonize the considerable diversity among them, an International Dataset has been developed by a collaborative process among more than 50 cardiac surgeons around the world, including the chairs of the Society of Thoracic Surgeons (STS) and European and Asian multinational database initiatives. Constructed around the STS data format, the International Dataset brings in key elements from all the other datasets, allowing the sharing of data and cross-analysis, thus greatly expanding the pool of patients, and national boundaries, from which risk-stratified outcomes

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Table 1. National Cardiac Surgery Database Initiatives.

	Dataset collected	Dataset includes risk stratification and outcomes	Approximate number of patients in national registry
USA & Canada (STS National Database)	STS	Yes	2,000,000
Germany	German	Yes	600,000
UK	UK (old STS)	Yes	140,000
Sweden	Swedish	Yes	90,000
Belgium	(minimal)	No, but planned	50,000
Czech Republic	old STS	Yes	30,000
Norway	(minimal)	No, but starting	25,000
Japan	International	Yes	5,000 (pilot phase)
France	International	Yes	Just started
Italy	UK (old STS)	Yes	Just started
Denmark	Old STS	Yes	Just started
Austria	STS	Yes	Just started
Israel	STS	Yes	Just started
Australia	Australian	Yes	Just started
Saudi Arabia	International	Yes	Starting 1/03

can now be analyzed and unified. The International Dataset has already been adopted by France (90 centers), Saudi Arabia (17 centers), and Japan. After a pilot phase, Japan, on behalf of the Asian Society for Cardiothoracic Surgery, plans to roll out this initiative to serve 22 Pacific Ring countries containing 1,000 cardiac surgery centers. Unlike the STS dataset, the International Dataset incorporates EuroSCORE [Nashef 1999, Roques 1999], a simple-to-use, validated patient risk stratification system, which has been rapidly adopted by large numbers of centers around the world for patient risk stratification, outcomes assessment, and improvement of patient informed consent.

National registries that collect a patient dataset, which includes preoperative risk factors and outcomes, currently contain details on a total of approximately 2.9 million procedures. Over the next few years, this number will increase rapidly because national cardiac surgery registries are now planned in many other countries. International initiatives, such as the European Cardiac Surgery Registry (ECSUR) [Wyse 1999b], and the Asian Registry [Wyse 1999a], are attempts to collate further the information collected by centers in each geographic region, to understand the impact of local factors, such as epidemiological differences across a region [Nashef 2000, Roques 2000], referral patterns (see Figures 1 ◎ and 2 ◎), startling differences in patient demographics between centers (even within the same country) [National Adult Cardiac Surgical Database Reports 1998 & 2000], surgeon preferences, outcome patterns [Edwards 1999], and what preoperative elements most influence patient outcome within a country or region.

The German dataset, configured as a quality control program, was unexpectedly taken over by the government two years ago and releases for external publication very little data [Vogt 2000]. It represents the most comprehensive,

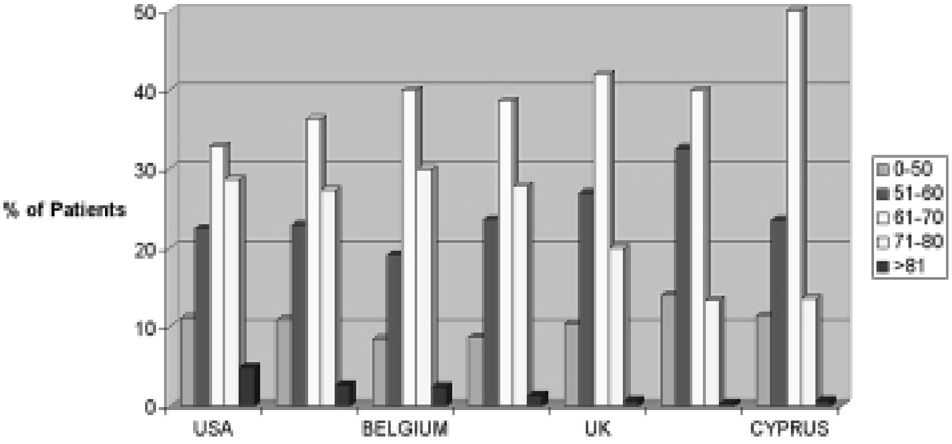

Figure 1. CABG Surgery by Nation—Analysis by Age Range. An analysis of ECSUR-compiled data showing the differences between selected countries in the age of patients undergoing CABG surgery, particularly showing substantial national differences in surgery patterns in the elderly.

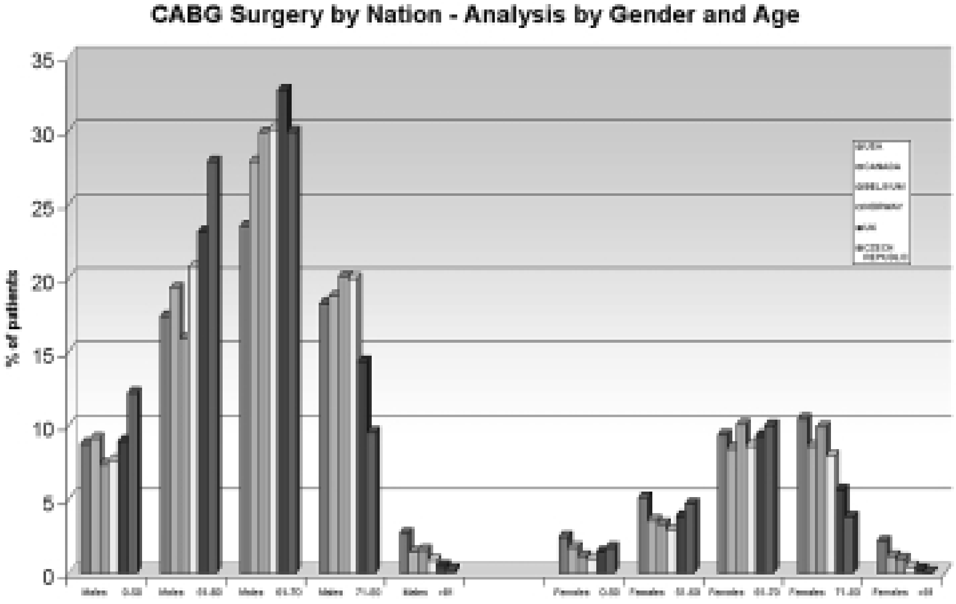

Figure 2. CABG Surgery by Nation—Analysis by Gender and Age. A more detailed analysis of the ECSUR data demonstrating large basic geographical, gender, and age differences, in particular between countries in the proportion of male (left section) and female (right section) patients over 71, and over 81 years of age, selected to receive CABG surgery.

sophisticated, and well organized national initiatives to emerge over the past decade. Although the STS publishes generously, the fact that it chooses not to publish its algorithms—the individual weights of the elements that comprise its risk models—is unacceptable to some [Sergeant 2001]; indeed most other national registries adopt a more open approach. The UK has now published two substantial national reports [National Adult Cardiac Surgical Database Reports 1998 & 2000]. Likewise, for those who read Swedish, Sweden has long published its results even, most recently, on the Internet (http://www.sos.se/mars/kva104/kv104doc.htm).

DISCUSSION

Why Collect and Centralize National and International Data?

Although it is intrinsically difficult to establish and manage such national initiatives, there are several benefits to collecting and analyzing this type of data:

1. Understanding and defining basic demographics of patients undergoing cardiac surgery, how they differ from center to center and from country to country, and how patient demographics (e.g., age at operation) change with the passage of time.
2. Patient risk stratification and risk prediction at both a national and center-by-center level. Adopting this approach generates verifiable data that enhances negotiating strength with payers (typically governments) by compiling accurate information and analyzing it appropriately. Although politicians and newspapers rarely acknowledge risk stratification, it forms a cornerstone of patient outcome interpretation at particular centers as well as nationally.
3. Patient risk stratification and risk prediction is also important for individual patients and may improve the consent process.
4. Unit benchmarking and developing effective nationally-oriented and center-oriented quality improvement programs for selecting and managing patients undergoing cardiac surgery. Adopting a national approach provides far more informative results with respect to risk assessment for mortality than any individual center could achieve because the annual numbers of patients at centers is too low for each to analyze their outcomes data as meaningfully as when a national perspective, involving many contributing centers, is adopted.
5. Understanding and rationalizing resource utilization on a center level, and also from a national perspective.

Practical Issues on a National and Unit Level

At a national level, patient risk stratification permits a more accurate performance assessment for individual units as well as individual surgeons. However, this can also be achieved at a single institution [Nashef 2001, Sergeant 2001] provided enough data can be collected over time and that the data remains relevant and consistent throughout the study. Patient risk stratification also assists with casemix/patient throughout decisions, since the length of stay of a group of incoming patients may also be predicted with some accuracy, probably even better than mortality. Risk prediction can be used directly with each new patient at initial consultation, and simplified software has been developed for this purpose. However, particularly when viewed across large numbers of patients, the use of the STS and other national cardiac surgical database registries to establish risk-adjusted benchmarks

Table 2. Abbreviated List of Risk Factors for Cardiac Surgery (STS Database).

Age	Previous Cardiac Surgery
Gender	Previous PTCA
Ethnicity	Congestive Heart Failure
Body Surface Area	Myocardial Infarction
Smoking	Cardiogenic Shock
Diabetes	Resuscitation
Renal Failure	NHYA Classification
Preoperative Creatinine	Use of Inotropes
Hypertension	Ejection Fraction
Hypercholesterolemia	Number of Diseased Vessels
Chronic Lung Disease	Left Main Disease
Peripheral Vascular Disease	Pulmonary Artery Mean Pressure
Cerebrovascular Disease or Accident	Aortic Valve Stenosis
Immunosuppression	Mitral Regurgitation
Infectious Endocarditis	Relative Urgency of Procedure

for clinical outcomes has proved outstandingly successful (see below), with certain qualifications. Regardless of whether centers are required to follow a mandatory report card system (several of these have been established in the United States) or are voluntary, collaborative initiatives between surgeons/ centers where best practices are identified and exchanged, Shahian et al. [Shahian 2001] recommend the use of a validated instrument, such as the STS dataset. Shahian was critical of the report card system, taking the view that it leads to an unjustified scientific complacency about the results it generates. The STS National Database is a voluntary system, with centers individually choosing to submit their cardiac surgery data to the STS Data Warehouse located at Duke University Clinical Research Institute (DCRI), which currently has the contract to collect and analyze the information twice a year on behalf of the STS.

Other countries have adopted a different strategy. All 84 cardiac surgical centers in Germany have been required by law for a decade to send in their data for analysis, and according to an extremely rigorous dataset, including preoperative risk factors. By 2004, all centers in the UK will similarly be required to submit to a central registry a large dataset on each of their patients; most are already complying voluntarily. Whether the adoption of mandatory legislation in the UK will generate any of the varieties of “gaming: strategies that centers sometimes adopt to their advantage [Shahian 2001] remains to be determined. Conversely, when there is inherent self-selection of centers, it is unproven how representative of reality the voluntary databases, such as the STS database, really are. Indeed, part of the rationale for establishing the STS database was to offer individual centers some protection against those managed care organizations who were trying to use sparse and inadequate outcomes data to leverage downward the fees they paid for cardiac surgery. Currently, approximately 450 centers in the United States, some 55% of the total, choose to send their patient data to the STS National Database for benchmarked analysis.

How Successful Have the STS and National Cardiac Surgical Databases Been in Establishing Risk-Adjusted Benchmarks for Clinical Outcomes?

Available Approaches

Various risk stratified systems have been developed over the years. Surgeons find it convenient to use a method that segregates patients into a relatively small number of groups, from low to high risk, and such approaches have now become widespread practice under several guises, particularly the Parsonnet [Parsonnet 1989] and EuroSCORE [Nashef 1999, Roques 1999] systems. A variety of alternatives to this approach include the use of neural networks [Lippman 1997], Bayesian mathematics [Marshall 1994, National Adult Cardiac Surgical Database Reports 1998 & 2000], and various forms of multivariate analysis (typically logistic regression for hospital mortality, and Cox proportional hazard models for long-term survival) [Parsonnet 1989, O’Connor 1992, Hannan 1994, Ferguson 2000, Ferguson 2002].

While multivariate risk models comprising patient preoperative risk factors are good at predicting continuous variables such as length of stay, Grunkenmeier pointed out the inherent difficulties in trying to predict a binary outcome (alive or dead) based on such complex multivariate models embracing a wide range of diverse preoperative risk factors [Grunkenmeier 2001]. Indeed, given identical data, it is intrinsically unlikely that any two statisticians would come up with the same multivariate model [Naftel 1994]. This is one reason why simple, risk-stratified approaches have been tenaciously used by cardiac surgeons for center-specific, and often national, requirements in deriving risk-adjusted benchmarks both for cardiac surgical practice and as a framework for developing quality improvement programs.

Risk Stratification and the Construction of Risk Models

The Parsonnet stratified approach [Parsonnet 1989] now over-predicts mortality in most situations, partly because elements of the system are subjective but mainly because cardiac surgery itself has improved substantially in the 10+ years since Parsonnet was first introduced. The STS generates CABG, valve, and length of stay models. The individual preoperative variables, each of which is predictive within these various risk models, are available from the STS website (http://www.sts.org), under the National Database section. The risk factors are briefly summarized in Table 2 (◎). While the univariate impact of each of these risk factors is also published on the STS website, together with individual values of relative risk, the actual STS multivariate algorithms for patient risk stratification and predictive modeling [Shroyer 1999, Ferguson 2002] are kept confidential and cannot be imported for patient-by-patient use outside the continental United States. Nevertheless, published STS annual reports do give good overall comparisons and benchmarks for risk assessment.

A broadly similar spectrum of preoperative risk factors was predictive of mortality in a large series of German [Vogt 2000] and UK [National Adult Cardiac Surgical Database Reports 1998 & 2000] cardiac surgical patients.

The 2000 UK Report [National Adult Cardiac Surgical Database Report 2000] demonstrates clearly how, even in a single country, the presence of preoperative risk factors, such as operative priority, ejection fraction, angina status, and left main stem disease, varies widely between hospitals in each of their individual patient populations. As for outcomes, equally wide variations were reported in predicted and observed mortality rates for these hospitals [National Adult Cardiac Surgical Database Report 2000], with some centers doing much better than others, even when mortality rates were standardized across the group.

The UK report also provided a direct comparison of UK and STS preoperative risk variables, highlighting areas of different epidemiologies and disease expression that were observed despite the similarities in mortality rates of the two populations studied.

EuroSCORE [Nashef 1999, Roques 1999], a simple (16 variable) system, is increasingly recognized to be more accurate than the Parsonnet scoring system. EuroSCORE has been shown to provide accurate preoperative outcomes prediction across six different European countries, each with vastly different patient epidemiologies [Nashef 2000]. EuroSCORE also now forms an integral part of the International Dataset. As part of a global unification process in studying factors predictive of outcomes in different geographies, one of the authors (RW) has recently been involved in a study [Nashef 2002] of over 400,000 patients in the United States, which showed that the predictive capability of EuroSCORE compares extremely well to the far more complex, locally generated, STS multivariate models in predicting individual patient outcome in the large U.S. population. EuroSCORE works well both for valve surgery [Roques 2001] and for CABG [Nashef 2000]. Individual surgeons find EuroSCORE simple enough to use during initial patient assessment, as it very quickly produces a clear-cut percentage risk of mortality and likely length of stay [Stoica 2002] based on pre-operative risk factors [Nashef 2001]. At initial consultation, the level of individual risk quickly emerges from the patient history with the use of a very simple EuroSCORE computer program, which allows surgeons easily to incorporate a EuroSCORE prediction into the advice they give. The other value of EuroSCORE emerges over time, as surgeons are able to use it to determine if their patient casemix differs from other centers, and employ that information to support negotiations with their own hospital administrators and others. Another risk index, CABDEAL [Kurki 2002], is promising for its prediction of morbidity, rather than mortality, after cardiac surgery.

Refining Risk-Adjusted Benchmarks for Clinical Outcomes

Although EuroSCORE predicts patient outcome far better than Parsonnet, it does underestimate mortality in those of the highest risk, who comprise perhaps five to ten percent of the total. Some believe this is because insufficient weighting has been ascribed to the most serious situations, as there were too few of these in the initial cohort of patients that generated the reference dataset [Sergeant 2001]. The level of the "discriminatory" power of a risk-scoring system is normally assessed by measuring the receiver operating characteristic (ROC) value, which tests the sensitivity and specificity of the predictive power achieved. In their sophisticated analysis of the value of EuroSCORE in a single center, Sergeant et al. concluded that they needed a scoring system capable of outperforming the weather forecast, not merely matching it at a ROC value of 0.83 (unity would represent 100% outcomes prediction) [Sergeant 2001]. Very recently, the EuroSCORE group found that the inclusion of adverse intraoperative events enhanced their outcome predictive accuracy for patient length of stay and mortality beyond that of assessing only preoperative risk [Stoica 2002]. By adding the intraoperative information, they found that their ROC value for patient mortality increased to 0.87. This neatly ties in the elegant work of Marc de Leval in applying the notions of near misses and critical human factors to the processes, as well as the inevitable corrective measures adopted by all staff during cardiac surgery [de Leval 2000, Carthey 2001]. The recent discovery by van't Veer et al. sends a powerful message to all cardiac surgeons using local, national, or international registry data prospectively to predict outcomes in their patients [van't Veer 2002]. This group found that the gene expression profile of a selected group of breast cancer patients is a better predictor of their outcome than currently used clinical parameters. Thus, surgeons could, in effect, tear up all their patient notes and instead rely solely on the results of DNA microarray analysis for patient risk assessment. In view of the 400+ known enzymes and other biochemical factors involved in maintaining and restoring cardiovascular function after the physiological insult of cardiopulmonary bypass, it is hard to imagine that any future ROC score, in predicting patient outcome after cardiac surgery, would not be substantially enhanced by a detailed patient-by-patient analysis of alleles of (at least) those biochemical factors that are responsible for endothelial cell recovery and inflammation control. Incorporating findings on physiologically relevant polymorphisms should help to predict length of stay, and perhaps mortality, just that much better.

Of more than 44,000 CABG patients operated upon between 1992 and 1998, the Swedish Heart Surgery Registry [http://www.sos.se/mars/kva104/kv104doc.htm] reported that 2.1% died within 30 days, and that females carried a higher risk for early mortality. The Swedish registry is unique as a national initiative in that it follows up all patients beyond hospital discharge, a far better measure of the quality of care than early mortality figures. They found that survival was 96.7% after one year and 90.5% at five years.

Achieving External Leverage

National cardiac surgical patient databases can be used to leverage governments and other healthcare providers. For example, STS data is used to document HCFA improved patient outcomes. These improved outcomes have been accomplished in spite of a progressive pattern in U.S. cardiac surgical units of operating on patients of increasingly higher risk. Thus, on behalf of its participants, it has been in the interests of the STS to demonstrate by logistic analysis that, while the expected mortality over the past decade has increased slightly, its members have been operating year-by-year on patients with progressively higher preoperative risk and yet have actually achieved relatively better results in spite of this. Using this approach, the STS was able successfully to defend the reimbursement level, the charges for cases, and decrease the amount by which the HCFA was planning to reduce fees for cardiac surgery. This serves as an excellent example of the value of large databases, such as the STS National Database, in using patient risk parameters in dealing with government and external agencies. The STS adopts a proactive view that, if they monitor their own results in a confidential manner, state governments and third party carriers will generally be pleased with the process and will not want to meddle in it themselves. It also serves as a way of checking the accuracy of government databases that are currently in place, since their methodology is often flawed.

The Use of Large National Datasets to Support Quality Improvement Measures

One of the purposes of collecting data on cardiac surgical procedures, at a national level, is to enable individual surgeons to improve quality and benchmark their own practice by making more accurate prospective predictions of outcome of each individual patient through the use of risk stratification based on previous local and national experiences. The experience of the Swedish national registry [http://www.sos.se/mars/kva104/kv104doc.htm] provided an exchange of information among cardiac surgeons that resulted in an increased openness and willingness to work with each other and was associated with improved results over the six years of its analysis.

Many might find EuroSCORE useful in conjunction with the cumulative sum (CUSUM) approach [Lovegrove 1997, Novick 1999] or the cumulative risk-adjusted mortality (CRAM) approach [Poloniecki 1998], which allow surgeons to track their yearly cumulative patient outcomes on the basis of actual versus anticipated mortality. In this way, they can plot lives saved against the EuroSCORE data as an adjunct to continuous quality improvement measures such as the New England initiative [Malenka 1995]. The current, ongoing STS quality initiative—the three-year AHRQ grant—looks to provide detailed feedback to specific centers from the large STS national dataset on several predefined quality issues as a test of whether such quality initiatives will be valuable in the future. The project has regular meetings and site visits (to learn best practices), and specifically shares data in a structured way for continuous quality improvement. Rather than simply collecting, analyzing, and reporting data, this attempt to start a proactive use of the database as a quality improvement tool represents a major maturation of the entire national STS initiative. Additionally, the STS is heavily involved with state activities, establishing liaison with regional initiatives such as the Northern New England Program, whose format of sharing data and round robin visits allows each participant to learn best practices from others. Future STS projects include the development of longitudinal patient follow-up (both authors serve on this STS database developmental subcommittee), with outcomes to include functional health status, quality of life, and patient satisfaction.

CONCLUSION

The past decade has seen a dramatic increase in the development of national cardiac surgical initiatives in many countries around the world. The size and extent of these databases have successfully allowed their use for patient risk stratification and preoperative risk modeling in four main aspects; patient selection and informed consent, coherent analysis of the determinants of patient outcomes, rationalizing unit management, and negotiations with external agencies.

At present, most national cardiac surgical registries only follow patients to the point of discharge from the hospital. However, it is well known that as many patients die in the year following CABG and heart valve surgery as succumb in their first few postoperative days. A comprehensive risk stratification system needs to embrace these late, but surgery-related, deaths. The new International Adult Cardiac Surgical Dataset already includes some follow-up information in anticipation of this vitally important new trend. The STS will proactively address these patient tracking issues shortly. Long-term patient tracking will eventually represent a far superior way to use large, multinational datasets to monitor and predict patient outcomes, quality of care, and quality improvement in cardiac surgery.

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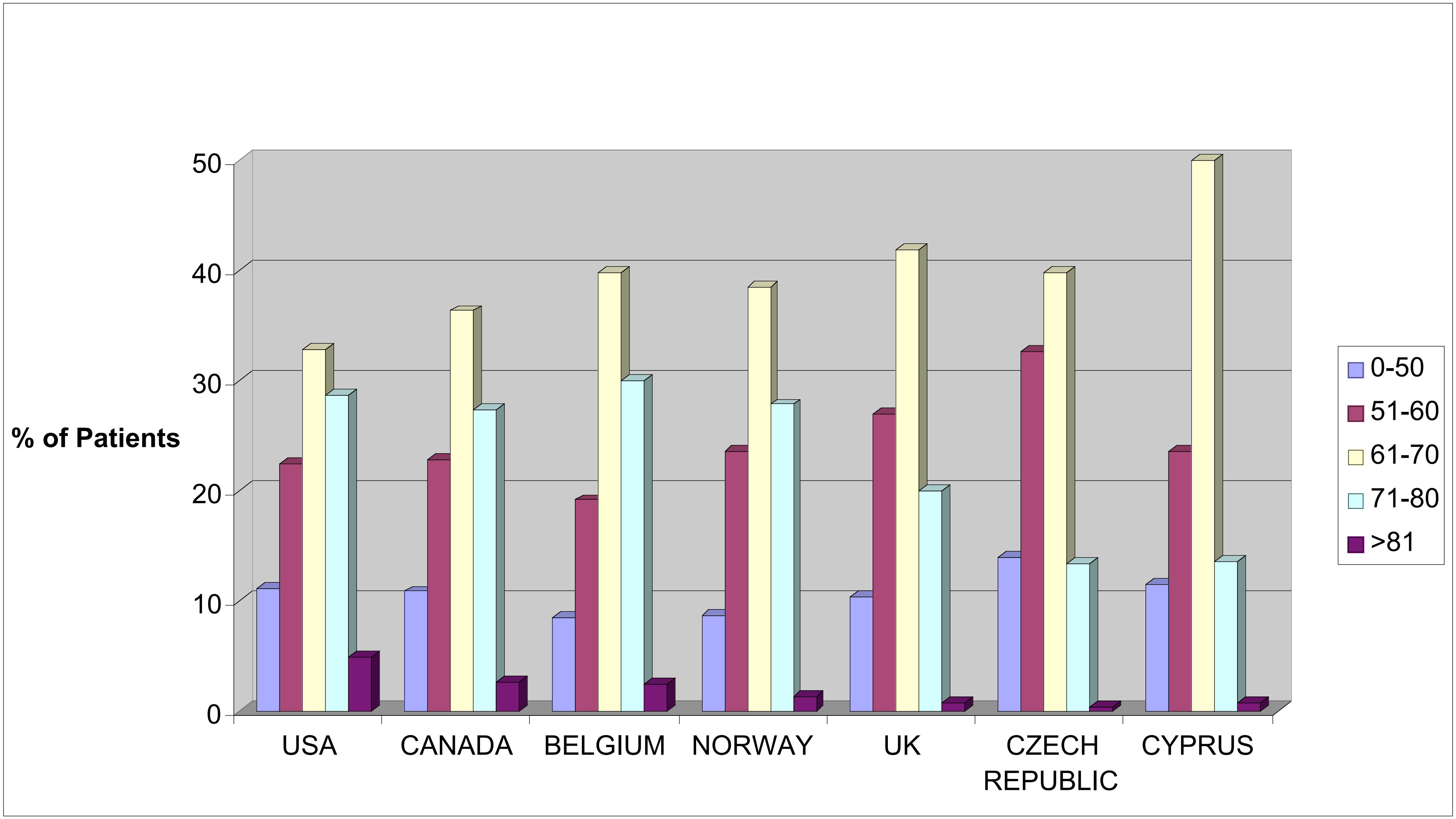

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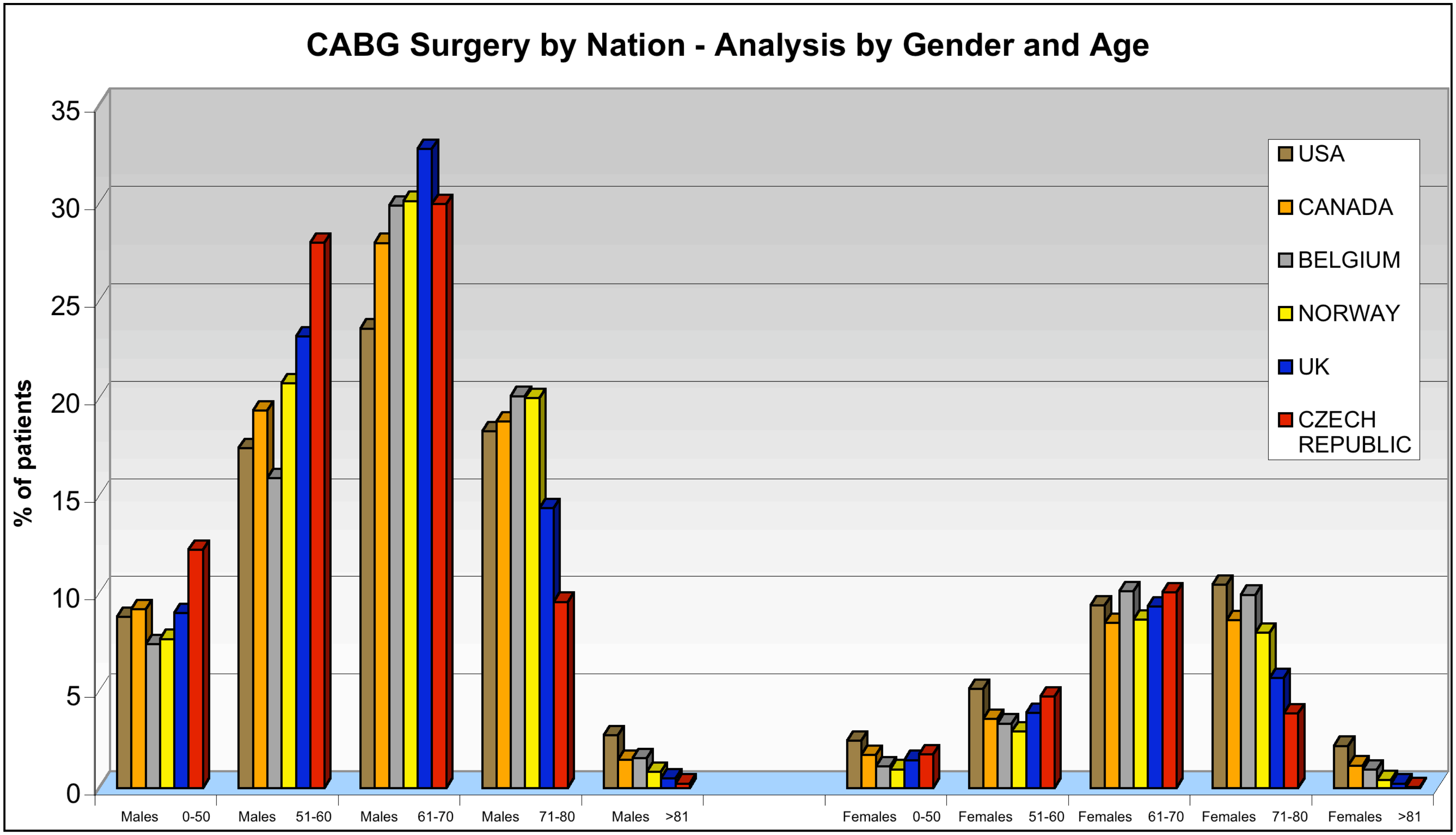

Figure 2. CABG Surgery by Nation—Analysis by Gender and Age. A more detailed analysis of the ECSUR data demonstrating large basic geographical, gender, and age differences, in particular between countries in the proportion of male (left section) and female (right section) patients over 71, and over 81 years of age, selected to receive CABG surgery.