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SEVE project (Surgical Expertise Validity Evaluation) risk adjusted quality by standard data

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ABSTRACT

The SEVE project (Surgical Expertise Validity Evaluation) is a collaborative effort of the AEC (Spanish Association of Surgeons) and the Section of Surgery of the European Union of Medical Specialists (UEMS) that aims to develop a model and an on line application that can be used to evaluate surgical complications. The aim is to identify the optimal results that can be obtained in each intervention, in order to present them as a reference for our usual practice (benchmarking).

Proyecto SEVE (Evaluación de los resultados quirúrgicos en función de la experiencia del cirujano y complejidad de la intervención)

Palabras clave:
Evaluación
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RESUMEN

El proyecto SEVE, constituye un modelo de colaboración entre la Asociación Española de Cirujanos y la Sección de Cirugía de la Unión Europea de Médicos Especialistas, con el objetivo de establecer en la Unión Europea un modelo de evaluación de las complicaciones quirúrgicas en un proyecto piloto. El objetivo es identificar los mejores resultados que pueden obtenerse en cada intervención, y la posibilidad de presentarlo como referencia de la práctica quirúrgica habitual.

Introduction

Surgery is a science based on the synthesis between technique and knowledge aiming to save lives and improve quality of life. The indication for surgery refers to the decision that the surgeon must make related to the necessity of a procedure for a certain patient based on existing knowledge, experience and expertise and considering potential risks and benefits.

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Despite the amazing range of technical and therapeutic advances available today, possible surgical complications and their adverse post-operative effects remain a common issue related to surgical intervention. As no surgery is risk-free, no surgeon can offer guarantees to their patients apart from their commitment to work to the best of their ability to ensure optimum surgical treatment and patient safety.

Modern surgery in the context of today's evidence-based medicine (EBM), requires wealth of state-of-the-art data that safeguard quality assurance of surgical outcomes.[1,2] The standard parameters for evaluating the results of any intervention in surgery are morbidity, mortality, patient satisfaction and the cost of the procedure. Accordingly, a surgical scoring system and index that take into consideration all the above parameters need to be devised and observed as a guide that sets accuracy and validity of standards.[3–5]

The first step is to define the characteristics of each patient and the selected surgical operation in relation to surgical complications and risk factors. To understand the risk of complications of any surgical intervention, we must analyse a series of variables related to the following factors:

1 Patient: (age, obesity, comorbidities, anticoagulation, ASA grade etc.)
2 Disease: (benign, malignant, inflammatory, traumatic, urgent, etc.)
3 Level or grade of complexity of the intervention (1 – low; 2, 3, and 4 – high)
4 Surgeon who performs the intervention (skill, experience, clinical judgment)
5 Hospital where it takes place (level and experience)

Of these factors, 1 and 2 are related exclusively to the patient, and we can only improve them in elective surgery through adequate evaluation and preoperative preparation of the patient.[6,7]

Factor 5 (hospital), has value in relation to the characteristics of the centre for the performance of the proposed intervention, expressed in its portfolio of services.

However, both the level of complexity of the operation (factor 3) and the surgeon's expertise (factor 4), are determining and complementary factors for achieving the best possible surgical outcome.[8–10]

The surgeon as a risk factor

Determinants of outcome include technical skill, volume of work, and case mix

Surgery can be a risky business. Members of the public are now attuned to that fact and appreciate that their surgeon's performance is a key determinant of success. Outcome after surgery is of course relatively easy to assess; you survive the operation or you don't, the anastomosis holds or it doesn't, the hernia recurs or it doesn't, and so on. In an era of increased scrutiny it is perhaps no surprise that surgeons feel under pressure or that they account for a third of the referrals to the newly established National Clinical Assessment Authority in England.[1]

What then are the determinants of surgical performance, and is a poorly performing surgeon easy to spot? Technical skill is vital, but it is by no means the only essential ingredient for success. Thorough training, compassion, sound judgment, good communication skills, honed clinical skills, and knowledge are all critically important. Surgeons do not work in isolavalid comparison with their peers, particularly in low volume specialties such as neurosurgery.

The European carotid surgery trial provides a lesson in some of the pitfalls when assessing surgical performance.[8] In this trial the overall risk of major stroke and death within 30 days was 7%. Seventy one of the 147 participating surgeons did not encounter strokes or deaths during the operation. However, for a 0% risk of stroke or death to be significantly lower than the overall risk of 7% a surgeon would have had to operate on at least 50 patients, whereas most of the 71 had operated on less than five. At the other end of the spectrum, surgeons with the highest risks (50% and 33%) had operated on only two and three patients, respectively. Only surgeon X seemed to have a significantly increased operative risk (11 strokes or deaths in 50 patients), but after correction for case mix even he ceased to be a statistically significant "outlier." This is

In the above BMJ editorial published in April 2003, Professor David Carter from the University of Edinburgh, stressed the critical role of surgical performance as a prognostic factor and key determinant of success. Lessons learned from the above study, indicate the need for an objective and reliable index and scoring system that is operation-specific and enables clarity of comparison of surgical outcomes across surgical teams and hospitals in different countries.[11]

Among the existent available systems for the analysis and monitoring of surgical outcomes, there are several risk assessment models such as Acute Physiology and Chronic Health Evaluation II (APACHE II), the Surgical Risk Scale, the Charlson Comorbidity Index, and the Physiology and Operative Score for the enumeration of Mortality and Morbidity (POSSUM), with its variations CR-POSSUM, O-POSSUM, V-POSSUM, etc. All of them have important advantages, but also limitations in relation to two factors: individual surgical performance in relation to external audit of surgical outcomes.[12–19]

More recently we have two very useful tools to evaluate the results of surgical interventions in relation to complications: – the Dindo-Clavien Classification, which classifies possible complications into 5 degrees, depending on the treatment needed to resolve them, and – the Comprehensive Complication Index (CCI), which uses a mathematical model, with an algorithm that allows the various complications to be added together to obtain a final number that clearly expresses the result of the operation.[20–23]

Objectives

The SEVE project (Surgical Expertise Validity Evaluation) is a collaborative effort of the AEC (Spanish Association of Surgeons) and the Section of Surgery of the European Union of Medical Specialists (UEMS) that aims to develop a model and an on line application that can be used to evaluate surgical complications. The aim is to identify the optimal results that can be obtained in each intervention, in order to present them as a reference for our usual practice (benchmarking).

Methods

The development of this project consists of three steps:

Step 1:

The pilot study proposed by this project is based on five general surgery procedures:

1 Inguinal herniorrhaphy
2 Thyroidectomy
3 Cholecystectomy
4 Colectomy
5 Cephalic duodeno-pancreatectomy (DPC)

We apply to these interventions the criteria of risk on the part of the patient (A) by using the ASA classification, and (B) the levels of complexity of the suggested surgeries (SCx).

A – The classification established by the American Society of Anaesthesiologists (ASA), was initially proposed by Drs. Saklad,[6] Taylor and Rovenstein in 1941, and was later modified to 6, 5 or 4 grades. It is now set at four grades:

ASA 1: Normal healthy patient
ASA 2: Patients with mild systemic disease
ASA 3: Patients with severe systemic disease
ASA 4: Patients with severe, life-threatening systemic disease

B – Grades of complexity of the surgical operation (SCx): The classification is divided in four levels or categories of complexity for each surgical operation of those selected to be represented in the pilot project. Grade 1 being the simplest, increasing the degrees of complexity to grade 4 which are the most complex. This classification has been endorsed by the Surgical Sections of the AEC.

For **Hernia**, 3 categories of complexity have been coded at grade 1; 5 at grade 2; 10 at grade 3; and 7 at grade 4. Examples: Grade 1: 1.1 – Lateral inguinal hernia (indirect) with content in the inguinal canal with limit on the pubis; 1.2 – Medial (direct) inguinal hernia with destruction of the transverse fascia and limit on the pubis; Grade 2: 2.1 – Lateral (indirect) inguinal hernia with hernia sac in the scrotum; 2.2 – Medial (direct) or lateral (indirect) inguinal hernia in an obese patient 25–30 BMI; Grade 3: 3.3 – Medial (direct) or lateral (indirect) groin hernia in an obese patient >30 BMI; 3.4 – Recurrent inguinal hernia (first recurrence) in a patient operated without previous mesh; Grade 4: 4.1 – Slipped left inguinal hernia; 4.2 – Medial (direct) or lateral (indirect) inguinal hernia in an obese patient >40 BMI.

For **Thyroidectomy**, 3 categories have been coded in Grade 1; 3 in Grade 2; 4 in Grade 3; and 4 in Grade 4. Examples: Grade 1: 1.1 – Hemithyroidectomy; 1.3 – Hemithyroidectomy in an obese patient 25–30 BMI; Grade 2: 2.1 – Hemithyroidectomy in an obese patient >30 BMI; 2.3 – Total thyroidectomy for benign pathology; Grade 3: 3.1 – Hemithyroidectomy in an obese patient >35 BMI; 3.2 – Total thyroidectomy in obese patient 25–30 BMI; 3.3 – Thyroidectomy in intrathoracic goitre; Grade 4: 4.1 – Thyroidectomy for thyroid cancer with lymphadenectomy; 4.2 – Intrathoracic goitre thyroidectomy with sternotomy; 4.3 – Thyroidectomy in recurrent goiter.; 4.4 – Thyroidectomy with previous recurrent paralysis.

For **Cholecystectomy**, 2 categories have been coded in grade 1; 5 in grade 2; 5 in grade 3; and 2 in grade 4. Examples: Grade 1: 1.1 – Elective cholecystectomy for asymptomatic cholelithiasis; 1.2 – Elective cholecystectomy with previous biliary colic; Grade 2: 2.1 – Elective cholecystectomy after previous cholecystitis; 2.2 – Elective cholecystectomy after cholelithiasis with biliary pancreatitis; Grade 3: 3.1 – Cholelithiasis with wall widening and inflammation; 3.2 – Elective cholecystectomy with previous supra-mesocolic surgery; 3.3 – Cholecystectomy in acute cholecystitis; Grade 4: 4.1 – Cholecystectomy in Child B; 4.2 – Cholecystectomy in scleroatrophic gallbladder.

For **Colectomy**, 1 complexity category has been coded in grade 1; 4 in grade 2; 5 in grade 3; and 5 in grade 4. Examples: Grade 1: 1.1 – Ileocecal resection; Grade 2: 2.1 – Right colectomy; 2.2 – Sigmoidectomy; Grade 3: 3.1 – Transverse colon resection; 3.2 – Anterior resection; 3.3 – Total colectomy; Grade 4: 4.1 – Ultra-low anterior resection; 4.2 – Colectomy in obese patient >30 BMI; 4.5 – Total pan-proctocolectomy with ileoanal pouch.

For the **DPC**, 2 complexity categories have been coded at grade 1; 3 at grade 2; 4 at grade 3; and 2 at grade 4: Examples: Grade 1: 1.1 – DPC for Ampuloma; 1.2 – DPC for distal biliary tumour; Grade 2: 2.1 – DPC for duodenal tumours; 2.2 – DPC for Ampuloma, in obese patient 25–30 BMI; Grade 3: 3.1 – DPC for pancreatic head tumour; 3.2 – DPC for distal biliary tumour in obese patient >30 BMI; 3.3 – DPC for Ampuloma, in patient with previous surgery; Grade 4: 4.1 – DPC for pancreatic head tumour in patient with previous Surgery; 4.2 – DPC for pancreatic head tumour with vascular infiltration.

In order to reflect numerically the risk factors corresponding to the patient (ASA) and to the surgical intervention (degree of complexity SCx) a formula is established where the ASA value increases 1/2 point in each category, (ASA 1 has 0.5 point, ASA 2 is 1 point, ASA 3 is 1.5 points, and ASA 4 is 2 points), adding it to the degree of complexity of each intervention. For example, a grade 3 intervention in a patient with ASA 3 the predicted risk of complication is 3 + 1.5 = 4.5.

Moreover, with regard to the list of complications, a numerical classification (SVCIx) has been developed which expresses the severity of the complications that occur in each type of surgery, ranking from a value of 1, which corresponds to the minor complications, to a value of 10. This assessment is important because, using an algorithm model, it is possible to obtain a final numerical result of the complications that have occurred during the operation, which allows it to be statistically related to the degree of complexity of the operation (SCx) and the patient's risk factors (ASA).

Step 2:

The second step consists of the development of an online application to enter the data of the operations, collect the information of the results, and perform the statistical analysis. Computer application: Cloud application for recording surgical operations performed by surgeons participating in the SEVE project. The Cloud application will enable access and use from any location and device with internet access. It consists of a front-open access for surgeons and a back-office for auditors and administrators. The project's computer application is simple and intuitive, and can be viewed on the computer, phone and tablet.

Step 3:

The third step concerns the selection of a group of surgeons who are experts in each corresponding area of surgery and who represent different countries of the European Union in the UEMS. The number of operations to be performed by each surgeon will be between 50 and 100 consecutively and will be classified according to the levels of complexity in relation to the specific pathology and ASA of the patient. The agreement to take part in this project is made voluntarily and confidentially, accepting the protocol corresponding to the selected interventions, and the rules required in the audit of the project. The project auditors will also be selected through the national delegates of the Section of Surgery of the UEMS.

- Internal audit: each surgeon will carry out an audit of their own results, through the computer application, using the SEVE classification (SVCIx). Finally, the application collects

the data corresponding to morbidity, mortality, hospital stay, cost of the procedure, etc.
- External audit: external audit at the end of the series of interventions that will be carried out by the Evaluation Committee of each participating country together with the Technical Committee.
- Statistical analysis: the risk factors will be evaluated by a binary logistics regression model in order to identify those data that relate significantly to each type of complication, the multiple risk factors, their interactions and the clustering of adverse outcomes in the interventions. We will then use the coefficients derived from multivariate analysis to interpret the results.

Conclusion

We believe that the SEVE project would be a real breakthrough in setting the standards of surgical outcomes and for quality assurance in surgical practice. This will be done not through the commonly used individual or departmental audits but through a pan-European collaboration and robust data selection and analysis.

Surgeons would be able to know and reflect on their own results, surgical capabilities and limitations in relation to the difficulties of the interventions. This in turn will allow them to optimise their practice and improve patient care and surgical outcomes.

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Conflict of interest

The authors declare that they have no conflict of interest.

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REFERENCES

1. Korenkov M, Troidl H, Sauerland S. Individualized surgery in the time of evidence-based medicine. Ann Surg. 2014;259:e76–7. http://dx.doi.org/10.1097/SLA.0b013e31820757e3 [PMID: 21209589].
2. Meakins JL. Evidence-based clinical practice. Can J Surg. 2000;43:404–5 [PMID: 11129823].
3. Cima RR, Lackore KA, Nehring SA, Cassivi SD, Donohue JH, Deschamps C, et al. How best to measure surgical quality? Comparison of the Agency for Healthcare Research and Quality Patient Safety Indicators (AHRQ-PSI) and the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) postoperative adverse events at a single institution. Surgery. 2011;150:943–9.
4. Bosch DJ, Pultrum BB, de Bock GH, Oosterhuis JK, Rodgers MGG, Plukker JTM. Comparison of different risk-adjustment models in assessing short-term surgical outcome after transthoracic esophagectomy in patients with esophageal cancer. Am J Surg. 2011;202:303–9.
5. Aguiló J, Soria V. Gestion Clinica en Cirugia. Ed Aran 2018; Guias Clínicas AEC.
6. Saklad M. Grading of patients for surgical procedures. Anesthesiology. 1941;2:281–4.
7. Davenport DL, Bowe EA, Henderson WG, Khuri SF, Mentzer RM Jr. National Surgical Quality Improvement Program (NSQIP) risk factors can be used to validate American Society of Anesthesiologists Physical Status Classification (ASA PS) levels. Ann Surg. 2006;243:636–44.
8. Rebasa P, Mora L, Vallverdu H, Luna A, Montmany S. Andreu Romaguera y Salvador Navarro a Efectos adversos en cirugıa general. Analisis prospectivo de 13.950 pacientes consecutives. Cirugia Española. 2011;89:599–605.
9. Brennan TA, Leape LL, Laird N, Hebert L, Localio AR, Lawthers AG, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med. 1991;324:370–6.
10. Judez Legaristi D, Aibar Remon C, Ortega Majan MT, Aguilella Diago V, Aranaz JM, Andres JM, et al. Incidencia de efectos adversos en un servicio de cirugía general. Cir Esp. 2009;86:79–86.
11. Carter D. The surgeon as a risk factor. BMJ. 2003;326:832–3. http://dx.doi.org/10.1136/bmj.326.7394.832 [PMID: 12702596].
12. Whittemore AD. The competent surgeon: individual accountability in the era of ''systems'' failure. Ann Surg. 2009;250:357–62. http://dx.doi.org/10.1097/SLA.0b013e3181b28c93 [PMID: 19730172].
13. Tekkis PP, Kocher HM, Bentley AJ, Cullen PT, South LM, Trotter GA, et al. Operative mortality rates among surgeons: comparison of POSSUM and p-POSSUM scoring systems in gastrointestinal surgery. Dis Colon Rectum. 2000;43:1528–32.
14. Ko CY, Hall BL, Hart AJ, Cohen ME, Hoyt DB. The American College of Surgeons National Surgical Quality Improvement Program: achieving better and safer surgery. Ann Surg. 2006;243:636–44.
15. Keller DS, Reif de Paula T, Kiran RP, Nemeth SK. Evaluating the association of the new National Surgical Quality Improvement Program modified 5-factor frailty index with outcomes in elective colorectal surgery. Colorectal Dis. 2020. http://dx.doi.org/10.1111/codi.15066.
16. Feldman L, Barkun J, Barkun A, Sampalis J, Rosenberg L. Measuring postoperative complications in general surgery patients using an outcomes-based strategy: comparison with complications presented at morbidity and mortality rounds. Surgery. 1997;122:711–9.
17. Charlson M, Szatrowski TP, Peterson J, Gold J. Validation of a combined comorbidity index. J Clin Epidemiol. 1994;47:1245–51. http://dx.doi.org/10.1016/0895-4356(94)90129-5 [PMID: 772256].
18. Sundararajan V, Henderson T, Perry C, Muggivan A, Quan H, Ghali WAJ. New ICD-10 version of the Charlson comorbidity index predicted in-hospital mortality. Clin Epidemiol. 2004;57:1288–94. http://dx.doi.org/10.1016/j.jclinepi.2004.03.012 [PMID: 15617955].
19. Osler TM, Rogers FB, Glance LG, Cohen M, Rutledge R, Shackford SR. Predicting survival, length of stay, and cost in the surgical intensive care unit: APACHE II versus ICISS. J Trauma. 1998;45:234–7. http://dx.doi.org/10.1097/00005373-199808000-00006 [PMID: 9715178].

20. Dindo D, Demartines N, Clavien P-A. A new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg. 2004;240:205–21.
21. Clavien PA, Barkun J, de Oliveira ML, Vauthey JN, Dindo D, Schulick RD, et al. The Clavien-Dindo Classification of surgical complications five-year experience. Ann Surg. 2009;250:187–96.
22. Clavien P-A, Vetter D, Staiger RD, Slankamenac K, Mehra T, Graf R, et al. The Comprehensive Complication Index (CCI). Ann Surg. 2017;265.
23. Slankamenac K, Graf R, Barkun J, Puhan MA, Clavien P-A. The comprehensive complication index. a novel continuous scale to measure surgical morbidity. Ann Surg. 2013;258.