Prospective Assessment of Surgical Risk Using the POSSUM, P-POSSUM, Clinical Frailty Scale and Charlson's Comorbidity Index in Abdominal Surgery.

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Summary :

Abdominal surgery is the most common activity in the operating room. Advances in surgical techniques and improvements in postoperative care require greater monitoring of surgical results and the comparison of outcomes between similar departments using assessment scales.

A prospective observational study will be conducted at our hospital starting March 1, 2021. All patients undergoing both urgent and elective abdominal and digestive surgery will be included. Patients undergoing locoregional anesthesia, major outpatient surgery, discharged less than 24 hours postoperatively, and whose surgery is performed more than 24 hours after hospital admission will be excluded. Demographic variables, personal and surgical history, preoperative and intraoperative data, and surgery-related variables will be collected. Thirty days postoperatively, patients' medical records will be reviewed, and postoperative complications and mortality will be recorded. These data will be used to calculate the POSSUM, P-POSSUM, the Clinical Frailty Scale, and the Charlson Comorbidity Index.

Once this data has been collected, the following objectives will be met:

- To validate the POSSUM and P-POSSUM systems in patients undergoing gastrointestinal surgery at the Doctor Negrín University Hospital of Gran Canaria, comparing estimated morbidity and mortality with those observed 30 days postoperatively.
- To analyze the correlation of the estimated morbidity and mortality of the POSSUM and P-POSSUM and the Clinical Frailty Scale with respect to that observed in scheduled surgery *vs.* emergencies.
- To analyze the correlation of the estimated morbidity and mortality of the POSSUM and P-POSSUM and the Clinical Frailty Scale with respect to that observed in laparoscopic surgery *vs.* laparotomy
- To establish the relationship and predictive capacity of ICC with respect to morbidity and mortality at 30 days postoperatively .

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INTRODUCTION:

Abdominal surgery is the most common activity in the operating room of most hospitals. In Spain, there are no published records on the number of abdominal surgeries performed per year. In Catalonia, a study published in 2003 (1) on both elective and urgent anesthetic activity estimates an average of 89,370 gastrointestinal surgery procedures per year, carried out in 131 Spanish hospitals . More recent data from the 2019 activity report of the Doctor Negrín University Hospital of Gran Canaria highlights that 19.29% of scheduled patients correspond to the general surgery specialty (2222 of the 11,513 operated on) and, with regard to urgent surgical activity in the same year, general and digestive surgery accounts for 49.89% of all urgent procedures performed (1196 of 2397).

Abdominal surgery, in addition to its high frequency, carries a high morbidity and mortality rate. Specifically, the highest mortality rates correspond to emergency laparotomy, where the range is around 13% to 18% at 30 days postoperatively, as described by Saunders *et al* . (2) .

Advances in surgical techniques and improvements in postoperative care require greater monitoring of surgical outcomes. However, it is well known that the crude mortality and morbidity rates of healthcare centers are poor indicators of the quality of the service they provide, and it is recognized that morbidity and mortality rates as a single indicator are inadequate for comparisons between surgeons, departments, postoperative care units, or hospitals. This is because each surgical intervention, and therefore its outcomes, are subject to an inherent risk in each case. The use of scoring systems that capture variables related to both the patient's baseline condition and the severity of the surgical intervention would allow for more accurate comparisons between different hospitals and surgeons than crude morbidity and mortality rates alone. Thus, the POSSUM system (*Physiological and Operative Severity Score for the EnUmeration of Mortality and Morbidity*) was created to predict the morbidity and mortality of patients 30 days after surgery.

The POSSUM scale was developed by Copeland *et al* . (3) in 1991 to assess the risk of mortality and morbidity associated with a specific surgical procedure during the first month after surgery. It is one of the most widely used systems in healthcare centres to assess the risk of morbidity and mortality associated with a specific surgical intervention, taking into account the patient's physiological aspects as well as aspects of the surgery itself. Furthermore, its purposes include the ability to compare surgical outcomes between institutions, especially in cases where there was a significant difference in mortality and morbidity. However, this system was later expanded to compare outcomes between surgeons, surgical teams and between different surgical procedures.

The POSSUM scale includes 12 physiological variables and 6 operative variables related to the surgical procedure, which, as Jones and de Cossart (4) already stated , are data collected in the routine preoperative evaluation of the patient or in the surgical procedure notes. All these variables are subdivided into 3 or 4 levels with an exponentially higher score of 1, 2, 4

and 8 points depending on the characteristics of each patient and each intervention. Therefore, there are 12 physiological variables whose data are obtained before the surgical intervention and the sum of their score ranges between 11 and 80, and, on the other hand, there are 6 variables called operative and related to the surgical intervention that are collected once the surgical procedure has been performed and their score ranges between 6 and 40. Finally, the score obtained is applied to the morbidity and predicted mortality equations described by Copenland et al, and we obtain a percentage of morbidity and mortality expected for each patient. The literature review shows that the POSSUM score, especially in gastrointestinal surgery, is a valid score for predicting morbidity and mortality at 30 days postoperatively, but in most series, it overestimates mortality in low-risk groups.

In 1998, Prytherch et al (5) developed a variation of the POSSUM called the Portsmouth -POSSUM (P-POSSUM) by adjusting logistic regression analysis. The objective of this adjustment was based on the correction of the overestimation of mortality in low-risk groups observed with the POSSUM score. The P-POSSUM presents the same physiological and operational variables as the POSSUM and the same equation is applied to calculate predicted mortality, but its result is subjected to a second correction calculation. It is important to keep in mind that the P-POSSUM is only useful for predicting mortality.

Apart from the POSSUM system and its variants, there are other scales for assessing the patient's baseline status, such as the Charlson Comorbidity Index (CCI), described by Charlson et al. in 1987 (6). It consists of 19 variables related to the patients' comorbidities that can be easily obtained during the preoperative assessment. It was initially used to predict patients' 10-year life expectancy, but it has subsequently been shown to be able to reliably predict postoperative morbidity and mortality.

Since the POSSUM and P-POSSUM scales are used worldwide, we consider their evaluation in our setting relevant, focusing on their ability to predict morbidity and mortality at 30 days postoperatively. This is the primary objective of our study. As a secondary objective, we aim to shed light on some questions surrounding these two scales, such as whether the original POSSUM overestimates mortality in low-risk patients and whether the P-POSSUM truly corrects this imbalance. Furthermore, given the large percentage of patients undergoing emergency surgery in our setting, it would be of interest to determine whether these scales are equally useful in patients undergoing emergency and elective surgery, as well as to establish their usefulness in open and laparoscopic surgery. Finally, we will attempt to establish a correlation between the CCI and the Clinical Frailty Scale and the morbidity and mortality observed at 30 days postoperatively.

GOALS:

Main objective:

- To compare the morbidity and mortality estimated by the POSSUM and P-POSSUM systems with those observed 30 days postoperatively in patients undergoing

gastrointestinal surgery at the Doctor Negrín University Hospital of Gran Canaria.

Secondary objectives:

- To analyze the correlation of the estimated morbidity and mortality of POSSUM and P-POSSUM with respect to that observed in scheduled surgery *vs.* emergencies.
- To analyze the correlation of the estimated morbidity and mortality of POSSUM and P-POSSUM with respect to that observed in laparoscopic surgery *vs.* laparotomy
- To establish the relationship and predictive capacity of the ICC and the Clinical Frailty Scale with respect to morbidity and mortality at 30 days postoperatively.

MATERIAL AND METHODS:

Study design:

A prospective observational study will be conducted, including all patients undergoing gastrointestinal surgery by the General and Digestive Surgery Service, both scheduled and urgent, starting March 1, 2021.

At 30 days postoperatively, patient medical records will be reviewed to determine the incidence of morbidity and mortality . Medical records will be reviewed digitally through the DRAGO® or TABAIBA® platforms of the Canary Islands Health Service. If necessary, physical medical records will also be reviewed.

For data collection, a registration form (Annex I) has been developed to record demographic and preoperative data such as sex, height, weight, previous comorbidities of the patient, type of admission (urgent or scheduled) and whether or not the patient receives resuscitation prior to surgery. In addition, the following will be recorded: the physiological and operational variables necessary for calculating the POSSUM and the P-POSSUM as well as the variables necessary for calculating the ICC and the Clinical Frailty Scale. Finally, a review of the patients' clinical history will be made 30 days postoperatively and the cases in which there is postoperative mortality or morbidity will be noted, focusing on the number and type of morbidity recorded.

Subjects:

All ASA IV patients undergoing elective or urgent gastrointestinal surgery starting March 1, 2021, will be included in the study. These surgeries will be performed by our hospital's General and Digestive Surgery Department according to standard clinical practice and at their discretion. We estimate that approximately 350 patients will be included during this period.

Patients who meet any of the following criteria will be excluded from this study :

- Patients undergoing locoregional anesthesia.
- Patients undergoing major outpatient surgery (MAS) regardless of postoperative destination (home or hospital ward).

- Patients scheduled for surgery in the afternoon shift
- Patients who require surgery after the first 24 hours of hospital admission.

Method:

Data will be collected from all patients on the day of surgery and 30 days postoperatively. The data will be compiled using the "Data Collection Sheet" (ANNEX I) and will include demographic data, comorbidities, preoperative laboratory tests, diagnosis, type of surgery performed, as well as the approach and urgent/scheduled nature of the surgery, intraoperative surgical findings, intraoperative transfusion, physiological and operative variables required for calculating expected morbidity and mortality using the POSSUM and P-POSSUM systems, the variables required for calculating the CCI and the Clinical Frailty Scale, and, finally, morbidity and mortality observed 30 days postoperatively.

First, we will conduct a descriptive analysis of the study population, including demographic data and personal and surgical history. Second, we will conduct a descriptive analysis of surgical and intraoperative data, as well as morbidity and mortality observed 30 days postoperatively.

Third, we will calculate expected morbidity and mortality at 30 days postoperatively using the POSSUM and P-POSSUM scales, and we will calculate the ICC and the Clinical Frailty Scale . Finally, we will establish the correlation between the data obtained using these three scales and the actual observed data, with the aim of establishing the validity of these scales as predictors of morbidity and mortality in our setting.

Information systems:

The data will be obtained through a review of the digital medical record on the Canary Islands Health Service's TABAIBA® and DRAGO® platforms. If a review of the physical medical record is necessary, it will be done after obtaining the corresponding permission from the hospital's clinical records and documentation service.

Tools:

TABLA 2. **Sistema POSSUM**

Puntuación	**1**	**2**	**4**	**8**
Variables fisiológicas				
Edad	< 60	61-70	> 70	–
Sistema cardíaco	No	Fármacos	Edema, cardiopatía	Cardiomegalia
Sistema respiratorio	-	EPOC	EPM	Grave
PAS	110-129	130/170 o 10/9	> 170 o 90-99	< 90
Pulso	50-80	81-100 o 40-49	101-120	> 120 o < 40
Glasgow	15	12-14	9-11	< 9
Urea (mmol/l)	< 7,5	7,5-10	10,1-15	> 15
Sodio	> 136	131-135	126-130	< 126
Potasio	3,5-5	3,1-3,4/5,1-5,3	2,9-3,1/5,4-5,9	< 2,9 o > 5,9
Hemoglobina (g/l)	13-16	11,5-12,9/16,1-17	10-11,4/17,1-18	< 10 o > 18
Leucocitos	4-10.000	10,1-20/3,1-3,9	> 20 o < 3,1	–
ECG	Normal	–	F.A. Contr.	Otro
Variables quirúrgicas				
Grav. quir.	Menor	Moderada	Mayor	Mayor +
N.º interv. quir.	1	2	> 2	–
Transf. (µl)	< 100	101-500	501-1.000	> 1.000
Exudado peritoneal	No	Seroso	Pus local	Peritonitis difusa
Malignidad	No	Tumor localizado	Adenopatías	Metástasis
Tipo de cirugía	Programada	–	Urgente resuc. posible	Urgencia inmediata

ECG: electrocardiograma; EPM: enfermedad pulmonar moderada; EPOC: enfermedad pulmonar obstructiva crónica; Grav. quir.: gravedad de la cirugía; N.º interv. quir.: número de intervenciones quirúrgicas; PAS: presión arterial sistólica; POSSUM: Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity; resuc.: reanimación previa a cirugía; Transf.: transfusión sanguínea.

- ASA Physical Status Classification System (2014)

- ASA I: Healthy patient.
- ASA II: Patient with mild systemic disease.
- ASA III: Patient with severe systemic disease.
- ASA IV: Patient with severe systemic disease that is a constant threat to life.
- ASA V: Moribund patient who is not expected to survive the next 24 hours with or without surgery
- ASA VI: Patient declared brain dead whose organs will be removed for donation

- Physiological and Operative Severity Score for the EnUmeration of Mortality and Morbidity (POSSUM): The POSSUM scale collects 12 physiological variables and 6 operative (surgical) variables related to the surgical procedure (Table 1) which, as Jones and de Cossart (4) said , are data collected in the routine preoperative evaluation of the surgical patient or in the surgical procedure notes. All these variables are subdivided into 3 or 4 levels with an exponentially higher score of 1, 2, 4 and 8 points depending on the characteristics of each patient and each intervention. Therefore, there are 12 physiological variables whose data are obtained before the surgical intervention and the sum of their score ranges between 11 and 80 and, on the other hand, there are 6 variables related to the surgical intervention that are collected after the surgical procedure has been performed and whose score ranges between 6 and 40. Finally, the score obtained indicates a percentage of morbidity and mortality specific to each patient by applying the equations described by Copeland *et al* . (3) which are detailed below:

Mortality: Ln[R1/(1-R1)]=-7.04+0.13·physiological evaluation)+(0.16·surgical severity evaluation).

R1: mortality risk, Ln: natural logarithm.

Morbidity: Ln[R2/(1-R2)]=-5.91+(0.16·physiological evaluation)+(0.19·surgical severity evaluation)

R2: risk of morbidity, Ln: natural logarithm.

Table 1. Physiological and surgical variables of the POSSUM scale.

- Portsmouth- Physiological and Operative Severity Score for the EnUmeration of Mortality and Morbidity (P-POSSUM): The P-POSSUM scale is a variation of the POSSUM scale developed in 1998 by Prytherch *et al* (5) with the intention of correcting the overestimation of mortality of the POSSUM scale in low-risk patients observed in many studies. The physiological and operative variables are the same but, in this case, only the correction to obtain the expected mortality is applied. The P-POSSUM is calculated with the equation described by Copeland *et al. (3)* and, subsequently, is subjected to this corrective equation, where R is the expected mortality risk calculated by POSSUM.

P-POSSUM mortality : Ln (R/(1 - R)) = -9.37 + (0.19 x Physiological Score) + (0.15 x Operative Severity Score)

R: mortality risk, Ln: natural logarithm.

- Clinical Frailty Scale: is a tool developed by Rockwood and colleagues (Dalhousie University, 2005) to rapidly and clinically assess the degree of frailty in older people or those with chronic illnesses. Its main purpose is to assess a patient's vulnerability to adverse health events (such as hospitalization, surgery, or infections), beyond chronological age . The scale classifies individuals into nine categories , based on their level of independence, comorbidities, and physical and cognitive function.

Punctuation	Category	Summary description
1	Very Fit	Active, vigorous, healthier than most his age.
2	In shape (Well)	No active disease, but less vigorous than those in level 1.
3	Managing Well	Diseases under control, but does not do regular physical activity.
4	Vulnerable	Not dependent, but tires easily or is limited in activities.
5	Mildly Frail	Needs help with complex tasks (shopping, transportation, etc.).
6	Moderately Frail	Needs help with basic daily activities (bathing, dressing).
7	Severely Frail	Totally dependent, although stable and with no imminent risk of dying.
8	Very Severely Frail	Completely dependent and nearing the end of life.
9	Terminally ill	Life expectancy <6 months, but not necessarily frail beforehand.

- Charlson Comorbidity Index (CCI): The CCI is a scale described by Charlson et al (6) in 1987 with the aim of establishing a morbidity scale useful for use in cross-sectional studies. Initially, it was used to predict the life expectancy of patients 10 years after its calculation, but subsequently, it has been established as one of the predictive scales of postoperative morbidity and mortality. It consists of 19 items with a variable score depending on comorbidity, all of them easily identifiable in the preoperative period as shown in Table 2.

Comorbidity	Punctuation
Acute myocardial infarction	1
Congestive heart failure	1
Peripheral vascular disease	1
Cerebrovascular disease	1
Dementia	1
Chronic lung disease	1
Connective tissue disease	1
Peptic ulcer	1
Benign liver disease	1
Diabetes	1
Hemiplegia	2

Moderate/severe kidney failure	2
Diabetes with organic involvement	2
Cancer	2
Leukemia	2
Lymphoma	2
Moderate or severe liver disease	3
Metastasis	6
AIDS	6

Table 2. Charlson Comorbidity Index (CCI). Comorbidity and score.

- Definitions proposed by the European Society of Anesthesiology (ESA) and the Society European Intensive Care Unit (ESCIM):
    - Atelectasis: One of the following three criteria will be used to diagnose atelectasis: Radiographic: Opacification with deviation of the mediastinum, hilum, or hemidiaphragm toward the affected area, and compensatory hyperinflation of the adjacent parenchyma. Chest ultrasound/CT
    - Mild Respiratory Failure: PaO2 < 60 mmHg, PaO2/FiO2 < 300 mmHg, SpO2 < 90% requiring supplemental oxygen treatment during the postoperative period.
    - Severe Respiratory Failure: PaO2 < 60 mmHg, PaO2/FiO2 < 300 mmHg, SpO2 < 90% requiring treatment with non-invasive (including CPAP) or invasive mechanical ventilation.
    - Acute Respiratory Distress Syndrome: The gasometric and radiological criteria of the Berlin definition will be used for diagnosis: Mild: PaO2/FiO2 < 300 mmHg with CPAP ≥ 5 cmH2O and FiO2 ≥ 0.5. Moderate: PaO2/FiO2 < 200 mmHg with PEEP ≥ 5 cmH2O and FiO2 ≥ 0.5. Severe: PaO2/FiO2 < 100 mmHg with PEEP ≥ 5 cmH2O and FiO2 ≥ 0.5. With bilateral alveolar-interstitial infiltrate on the chest X-ray of recent appearance.
    - Pulmonary Infection: Patient who has received antibiotics for a suspected respiratory infection and who meets the following criteria: Presence of a new pulmonary infiltrate and/or progression of previous pulmonary infiltrates on chest X-ray. Leukocytosis > 12,000 WBC/mm3. Fever > 38.5°C. Increased secretions with purulent sputum. Positive bronchoaspiration.
    - Pleural Effusion: Radiological: chest X-ray shows pinching of the costophrenic sinus, displacement of adjacent anatomical structures, and blurring of the hemidiaphragmatic silhouette in the supine position. Ultrasonographic
    - Cardiogenic Pulmonary Edema: Evidence of alveolar fluid accumulation secondary to cardiac dysfunction/failure.
    - Weaning Failure: Reintubation of the patient within ≤ 48 h after postoperative extubation.

- Surgical wound infection: CDC criteria will be followed for the diagnosis of surgical wound infection.
    - Superficial wound infection: Infection occurring within the first 30 days that involves only skin and subcutaneous tissue and the patient has at least one of the following signs: Purulent drainage from the superficial incision, Isolation of microorganisms from the superficial incision, Superficial incision deliberately opened by the surgeon with a positive culture, or without culture but with at least one of the following signs: pain, heat, swelling, inflammation, redness. Diagnosis made by a surgeon regardless of diagnostic criteria.
    - Deep wound infection: Infection occurring within the first 30 days (or 1 year if there is an implant) that involves deep soft tissue (fascia, muscles, etc.) and the patient has at least one of the following signs: Purulent drainage from the affected area, not the specific organ or surgical site. Isolation of microorganisms from the deep incision. Deep incision opened spontaneously or by the surgeon with a positive culture, or without a culture but with at least one of the following signs: fever > 38ºC, pain or loss of sensation localized in the affected area. Abscess or other evidence of infection on direct surgical examination or with imaging techniques. Diagnosis made by the surgeon regardless of the diagnostic criteria.
    - Wound infection in an organ or surgical site: Infection occurring within the first 30 days and involving any part of the body (surgical area) but excluding superficial and deep wounds. The patient has at least one of the following signs: Purulent drainage from the affected area. Abscess or other evidence of infection on direct surgical examination or imaging. Diagnosis made by the surgeon regardless of diagnostic criteria.
- Suture dehiscence: Leakage of intraluminal contents from a surgical connection between two viscera. The luminal contents may escape through a wound or a drain, or a collection may develop (diagnosed with imaging techniques) causing fever, sepsis, or shock.
- Sepsis: Life-threatening organ dysfunction caused by an uncontrolled host response to infection. Organ dysfunction is defined as an increase in the SOFA score of two or more points.
- Septic shock: Sepsis with vasopressor requirements to maintain a mean arterial pressure greater than or equal to 65 mmHg and serum lactate greater than 2 mmol/l in the absence of hypovolemia.
- Reoperation: Surgery within the first 30 days after the primary intervention as a result of a complication of the latter.
- Urinary Tract Infection: Positive urine culture with more than 105 colony-forming units per ml with at least one of the following signs or symptoms: Fever > 38°C. Urgency. Frequency. Dysuria. Increased suprapubic tenderness. Costovertebral angle pain.
- Heart Failure: HF < 2.5 mL/min/m2 or > 2.5 with dobutamine requirements ≥ 5

μg/kg/min. It may also be diagnosed as the appearance of new signs and symptoms (dyspnea, fatigue, orthopnea, paroxysmal nocturnal dyspnea, edema) along with a proBNP level > 13 pg/ml or echocardiographic diagnosis.

- Arrhythmia: Newly occurring heart rhythm disturbance evidenced by electrocardiography.
- Acute Myocardial Infarction: A gradual rise and fall in troponin levels associated with electrocardiographic abnormalities such as Q waves and ST-segment elevation or depression. It is also diagnosed without electrocardiographic abnormalities when troponin mobilization cannot be justified by any other cause.
- Acute Renal Failure: AKIN Classification: Stage I: Diuresis < 0.5 mg/kg (6h) or Cr increase > 0.3 mg/dl. Stage II: Diuresis < 0.5 mg/kg (12h) or baseline Cr x 2 mg/dL. Stage III: Diuresis < 0.3 mg/kg (24h) or anuria (12h) or baseline Cr x 3 mg/dL, Cr levels > 4 mg/dL or renal replacement therapy.
- Paralytic ileus: Intolerance to solids or absence of defecation for three or more days after surgery.
- Delirium: Defined as the presence of four or more items on the Intensive Care Delirium Screening Checklist. Patients will receive one point for each of the following criteria: Inattentiveness; Disorientation; Hallucination/psychosis; Psychomotor agitation/retardation; Inappropriate mood/language. Alteration or fluctuation of the circadian rhythm.
- Postoperative nausea and vomiting

- Data collection sheet (ANNEX I)
- Medical records in paper and digital format

Operational definition of variables:

To carry out this study, a series of variables will be collected, which are shown in the data collection sheet (ANNEX II).

Data analysis:

will be calculated to describe the quantitative variables, and the Shapiro-Wilk test will be used to check the normality of the data for the quantitative variables. Frequency and percentage will be used for qualitative variables, and Fisher's exact test will be used to compare the observed and expected frequencies. The observed (O) and expected (E) mortality and morbidity ratios (O:E ratio) will be calculated. A ratio of 1 will indicate a perfect correlation between the expected and the observed; a ratio < 1 indicates that the results obtained are better than expected; and a ratio > 1 indicates that the results obtained are worse than expected. To evaluate the goodness of the test, the area under the curve (AUC) will be calculated for both mortality and morbidity, with their 95% confidence intervals (CI), using Receiver *Operating Characteristic (ROC*) curves. These curves can take values between 1 (perfect test) and 0.5 (useless test), so that a test will have greater discriminatory capacity when its AUC is closer to

1. To determine if there are statistically significant differences between the results obtained and those expected, according to the POSSUM and P-POSSUM systems, a p-value less than 0.05 will be considered statistically significant. To compare different quantitative variables with each other, Pearson's correlation will be used. To compare different qualitative variables between different groups, the Chi-square test will be used. To compare quantitative variables between different groups, the Student t-test will be used for two groups or the Analysis of Variance (ANOVA) for three or more groups. A p-value less than 0.05 will be considered statistically significant. The statistical program used will be SPSS 24.1.

Limitations of the design, data source, and analysis methods:

One of the limitations of the study may be the inaccuracy when determining the variable "severity of the intervention" of the POSSUM and P-POSSUM systems, since there may be current surgical techniques that were not described in the work of Coperland et al (3) so that the classification of the severity of these surgeries will be at the discretion of the research team.

ETHICAL ASPECTS/PROTECTION OF PARTICIPATING SUBJECTS:

The study will be conducted in accordance with the requirements expressed in the Declaration of Helsinki (Seoul revision, October 2008) and current Spanish legislation (Ministerial Order SAS/3470/2009) regarding the conduct of observational studies. The processing, communication, and transfer of personal data of all participating subjects will comply with the provisions of Organic Law 15/1999 of December 13 on the protection of personal data.

BENEFIT-RISK EVALUATION

This study does not pose any additional risk to the patient, as its observational and prospective design is based on standard clinical practice regarding the indication of the surgical plan, as well as on the standard practice of the anesthesiologist in charge of the patient, both in the preoperative, intraoperative, and postoperative periods.

The benefit that this study would offer to our routine clinical practice is to understand and analyze the validity of the POSSUM, P-POSSUM, Clinical Frailty Scale, and ICC scales in our setting. The first two are essential for predicting 30-day postoperative morbidity and mortality in our patients, as well as for establishing inter- and intra-hospital comparisons between different surgeons and general surgery departments. Likewise, establishing the validity of the ICC scale as a prognostic tool for postoperative morbidity and mortality could be key to improving the individualized prognostic information provided to patients and to improving therapeutic decisions by the surgical team.

INFORMATION SHEET AND INFORMED CONSENT FORM

Prior to the intervention, patients will be given and explained the informed consent form from our hospital's Anesthesiology and Resuscitation Department. Once they have read and

understood all sections, they will sign their consent form. This consent form includes a section authorizing us to collect and analyze data derived from the clinical procedure, provided that this is for educational and/or academic purposes. Furthermore, prior to inclusion in the study, patients will be asked for their written informed consent (Annex IV) for their participation in this study.

DATA CONFIDENTIALITY

To ensure the confidentiality of the study data, only the researcher and his or her team of collaborators, the CEIC, and the relevant health authorities will have access to them.

INTERFERENCE WITH PRESCRIPTION HABITS

The project proposed here does not interfere in any way with the physician's prescribing habits, as it is limited to prospective data collection, in which all procedures, follow-up, and diagnostic methods are derived from routine clinical practice.

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ANNEXES:

- Annex I: Evaluation Request
- Annex II: Data Collection Sheet (CRD)
- Annex III: Commitment of researchers
- Annex IV: Patient information sheet and informed consent.
- Annex V: Exemption from fees
- Annex VIII: Economic report