FRAilty incidence in surGIcal European patients (FRAGILE) European prospective cohort study of the prevalence of frailty in surgical patients.

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Title of the project: FRAilty prevalence in surGIcal European patients
European prospective cohort study of the prevalence of frailty in surgical patients.

This study is endorsed by the Spanish Multimodal Rehabilitation Group (GERM), REDGERM, and the Spanish Society of Anesthesiology (SEDAR)

1. SUMMARY

Short title: FRAGILE

Methods: European prospective one day cohort study. Analysis of the prevalence of frailty and predefined 30-day postoperative complications in adult patients undergoing emergency or elective surgery.

Investigation sites: European hospitals where elective or emergency surgery is performed, where preoperative frailty index can be determined and patients can be followed for 30 days.

Objectives 1) To collect data on the incidence of patient frailty in elective and emergency surgery. 2) To evaluate the association between frailty and postoperative complications, hospital stay, quality of life (QoL) and mortality. 3)To evaluate whether the implementation of perioperative prehabilitation and early rehabilitation programs (posthabilitation) affects postoperative complications, QoL and frailty state at 30 days.

Number of patients: We aim to collect a sample size of 6500 in order to adequately represent the frailty prevalence (for a expected proportion de 0.1, with this sample, the total width of 95% confidence interval would be 0.015). For the second part of the study, this sample size was assessed in relation to the outcome with the lowest frequency, ie. thirty-day mortality. Assuming a global incidence of frail patients of 10% in our population with an expected 30-day mortality of 4% in the non-frail group, a sample size of 5000 patients allows us to significantly detect, two side 95% confidence interval and 80% power, a relative risk (RR) of 1.8 (7% of expected thirty-day mortality in frailty population).

Inclusion criteria: Patients over the age of 18 who will undergo emergency or elective surgery with an intended hospital stay of more than 24 hours and any type of anesthesia.

Statistical analysis: Continuous variables will be described by a mean and standard deviation if they present a normal distribution; by a median and interquartile range if they are not normally distributed. The comparison of continuous variables will be performed using one-way ANOVA or the Mann-Whitney test, as needed. Univariate analysis will be used to test factors associated with postoperative complications, hospital stay and in-hospital mortality. Univariate analysis and multivariate logistic regression models will be built in order to identify factors independently associated with these results and in order to adjust differences among confounding factors. Factors will be introduced into the model based on their relationship with the univariate result ($p < 0,05$), biological plausibility and low rate of missing data.

2. RESEARCH TEAM

2.1 CENTRAL COORDINATION

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3. BACKGROUND AND JUSTIFICATION

Frailty is defined by the deterioration of physiological functions of multiple systems in the body. This leads to an increased vulnerability for adverse events, increased dependence and medical complications including death, especially when the body is subjected to stress (1,2). Although numerous studies have described the prevalence of frailty and its association with age, specifically those over the age of 65 (3, 4, 5), there is an association between frailty and the incidence of complications in young patients, with an increase in the prevalence of comorbidities in patients under 40 years of age (6,7).

Therefore, frailty has been identified as an important risk factor that affects clinical outcomes in younger surgical patients (7). Several studies have suggested that high preoperative frailty scores are independently related to an increase in postoperative complications, length of hospital stay, 30 and 90-day mortality and the likelihood of institutionalization (8,9).

In a recent retrospective study including 232.352 patients above the age of 65, Mosquera et al (5) found that frailty increased mortality up to 6 times with respect to non-frail patients. This finding is consistent with other investigations in different surgical procedures (10). The association between frailty and surgical complications is consistent, frail patients have a risk of surgical complications up to twice as high as non-frail patients (5,9,11-13). Furthermore, an increase in hospital stay of up to 4 times of frail compared to non-frail patients has been found (5, 12).

For all these reasons, measuring preoperative frailty has a potential value in evaluating surgical risk and in applying pre and postoperative measures aimed at improving patient outcomes.

The standardization of perioperative care bundles, like intensified recovery bundles in surgical patients, has been associated with a decrease in complications and process costs (14-15). However, with regards to frailty, studies proving specific measures that reduce frailty indices and improve clinical outcomes are lacking.

Although the prevalence of frailty in patients older than 65 is estimated at about 20% (16), no prospective data evaluating the prevalence of frailty in the wider surgical population exists. In a recent retrospective study, Mrdutt M et al (17) observed a prevalence of frailty of 5.6% and an association with a significant increase in surgical complications, hospital stay, mortality and costs. The prevalence of pre-frailty states of frailty in this cohort was almost 47% which are also associated with poorer outcomes.

Our goal is to carry out a one day international point-prevalence multicenter cohort study in patients over the age of 18 who will undergo emergency or elective surgery in order to acquire detailed data that describes the prevalence of frailty and its association with postoperative complications, mortality, hospital stay and quality of life at 30 days. Furthermore, we will determine if the application or not of routine measures

during the perioperative period affects postoperative complications and quality of life at 30 days.

4. BIBLIOGRAPHY

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5. OBJECTIVES

Primary objective

To evaluate the incidence and degree of frailty in a population of patients undergoing programmed or emergency surgical interventions that require hospital admission.

Secondary objectives

1. To evaluate global frailty prevalence by age groups.
2. To evaluate the association between the presence and degree of frailty, and postoperative complications, hospital stay and 30-day mortality.
3. To describe the relationship between the degree of frailty and quality of life 30 days after surgery.
4. To describe the association between frailty and postoperative cognitive disorder and delirium by age groups.
5. To evaluate if the routine implementation of a preoperative prehabilitation program in the subgroup of patients programmed for surgery and its relationship with frailty and postoperative outcomes.
6. To evaluate the routine implementation of early rehabilitation measures in surgical patients and its relationship with frailty and postoperative outcomes.
7. To describe the relationship between each predefined item of prehabilitation and postoperative rehabilitation with clinical outcomes, including complications, hospital stay and quality of life at 30 days.

6. METHODOLOGY

TYPE OF STUDY

European observational prospective 1 day cohort study, with a 30 day follow-up of patients who meet criteria in participating hospitals. Each national group will select a single 1-day patient recruitment period during predefined months in 2020.

Inclusion criteria

All consecutive patients over the age of 18 who will undergo emergency or elective surgery under general anesthesia and/or locoregional anesthesia (central neuroaxial blocks or locoregional anesthesia) with an expected hospital stay of at least 24h.

Exclusion criteria

Outpatient (ie. day case) surgery, obstetric analgesia or anesthesia, organ transplant surgery, cardiac surgery, neurosurgery.

7. STUDY PROCEDURES

Consent procedures

Written informed consent will be obtained from all subjects who voluntarily participate in the study.

Specific regional procedures for the recruitment of patients and the request of consent. When necessary, the FRAGILE protocol will include appendices specific to each autonomous community or country describing specific procedures related to the utilization of data, the identification of patients, the procedures involved and the necessary regulatory approvals.

Study data

Data will be collected in all patients included in FRAGILE. All necessary data is included in an annex.

For the realization of sub-studies related to FRAGILE, each group or hospital may complete the basic data with a limited number of additional variables if they can be included in the case report form (CRF) as long as they meet the study regulations, and with the approval of the principal investigators and the FRAGILE Audit Directive Committee. All FRAGILE investigators will be informed of the selection process of related sub-studies ad hoc.

Data collection

Data will be collected in each hospital on an individual paper CRF for each patient recruited. Paper CRFs will be store in a locked office in each center. The local principal investigator or national coordinator will responsible of these CRFs will be. This will include patient identification data in order to allow follow-up of clinical results. Study data will be pseudonymized by encryption, generating a unique numerical code prior to entry to an online database via an electronic CRF (eCRF). The Castor EDC platform will be used to collect the data https://www.castoredc.com/. Castor EDC complies with all applicable laws and regulations: good clinical practice (GCP), 21 CFR Part 11, annexed 11 of the European Union and UE and the European Directive on data protection.

Each patient will only be identified in the eCRF by their numerical code. Therefore, the research coordination team will not be able to associate data to an individual patient without contacting the local team. In each center there will be a list of individual patients and their identification codes in the database in order to track clinical results and provide any data that might be missing. Once the local coordinator has confirmed the data entry is complete for their hospital, they will receive a spreadsheet with unprocessed data, this will allow more data integrity and precision controls. Individual data at each hospital may be used by local investigators, however, they may not be published on an individual basis under any circumstance.

All identifiable data collected, processed and stored for the purposes of the project will be kept confidential at all times and will comply with the guidelines of Good Clinical Practice for Research (GCP) and the General Regulation of Data Protection (GDPR) (Regulation (EU)) 2016/679).

Study organization

FRAGILE will be directed by the study management group, that will be responsible for the administration of the study, the communication among project partners, monitoring and data management.

The coordinators of each European country will manage and lead the project in their respective countries and will play the following roles:

- Identifying local coordinators in participating hospitals.
- Ensuring the distribution of documentation, bibliography and other study material.

- Ensuring that necessary regulatory approval is obtained before the start date.
- Ensuring good communication among the participating sites in their community. (In large communities more than one coordinator may be appointed).

Local coordinators in individual institutions will have the following responsibilities:

- Providing leadership for the study in their institution.
- Ensuring that necessary regulatory approval is obtained for their particular institution.
- Guaranteeing adequate training of all participating personnel before data collection.
- Supervising daily data collection and helping in problem solving.
- Acting as a guarantor of the integrity and quality of the data collected.
- Ensuring the appropriate termination of CRFs by supervising the data entry on a local level.
- Communicating with the coordinator of the correspondent national coordinator.

Definition of study completion

The completion of the study is defined at 30 days of follow-up for the last patient included in FRAGILE. The data analysis will be adjusted accordingly.

STATISTICAL ANALYSIS

Sample size calculation

Our plan is to recruit as many European centres as possible and ask them to include in the study all elegible patients with inclusion criteria. Only those centres that include at least 10 valid patients will be included in the analysis.

The sample size was calculated to detect the effects of frailty over the outcome with the lowest prevalence: thirty-day mortality (4% prevalence in no-frail patients). Estimating a global incidence of frail patients at 10% in our population, a simple size of 5000 patients allows us to significantly detect with a relative risk (RR) of 1.8, 80% power, two side 95% confidence interval and 97% accuracy. Taking into account a possible loss of patients of 30% during the follow-up period, the final simple size will be adjusted to 6500 patients

Statistical analysis

Data will be presented at European level. All data will be anonymized prior to publication.

Categorical variables will be presented as proportions and will be compared using chi-square or Fisher exact tests. Continuous variables will be presented as mean and standard deviation or as median and interquartile range, depending on the distribution of the variables. Continuous variables will be compared using one-way ANOVA or Mann-Whitney U test. A univariate analysis will be performed in order to test variables associated with postoperative complications, hospital length of stay and in-hospital mortality. Univariate analysis and hierarchical multivariate logistic regression models will be built in order to identify which variables are independently associated with these results and to adjust for confounding variables. Variables will be introduced into the models based on their relation to the univariate analysis ($p<0,05$), biological plausibility and the low rate of missing data. A step by step approach will be adopted to introduce new terms. Logistic regression results will be presented as adjusted odds ratio (OR) with 95% confidence intervals. The models will be evaluated through sensitivity analyses in order to explore possible interacting variables and to examine any effect on the results. Only one final analysis is planned at the end of the study.

Data will be analyzed using the percentage of frail patients and both the

principal and secondary outcome variables. It will be evaluated the influence of the recorded variables. Initially, a univariate analysis will be performed in order to evaluate the relation between each factor and the outcome variables. Comparisons will be performed using chi-square tests for the categorical variables, whereas T tests and Kruskall-Wallis tests will be used to compare differences between normally and non-normally distributed continuous variables respectively. Hospital length of stay will be analyzed through the normal distribution logarithmic transformation and independent T tests with exponentiation, given its non-normal distribution. The multivariate analysis, using binary logistic regression for the postoperative complications and using linear regression with logarithmic transformation for the length of hospital stay, will be performed afterwards, to all variables that had a statistically significant difference or almost significant (P<0,1). P<0,05 will be considered as statistically significant.

Outcomes

Outcome definitions are described in the annex 2.

Primary outcome

The percentage of patients with frailty identified in the preoperative assessment in both elective and emergency surgery, as well as frailty's severity.

Secondary outcomes

- The incidence and severity of frailty stratified by age groups and type of surgery (elective and emergency surgery).
- The presence of in-hospital postoperative complications.
- All-cause in-hospital mortality (censored at 30 days after surgery).
- The compliance with preoperative and postoperative prehabilitation programs.
- Length of hospital stay (length of hospital stay after the primary surgery).
- Quality of life 30 days after surgery.
- Presence and severity of frailty 30 days after surgery.

Blinding

Because of the study characteristics assessors will not be blinded. Data will be obtained extracting it from the clinical records and asking patients through a personal interview or by phone call.

Planning:

	Pre-operative	Day of Surgery	30 postoperative day
Demographic and baseline data	x		
Morbidity scales*	x		x
Intraoperative data		x	
Postoperative outcomes			x

*Includes clinical frailty scale, frail questionary, Barthel scale, Charlson index, cognitive evaluation and EuroQOL. In the supplement is specified which ones are done preoperatively and/or postoperatively.

ETHICS

This trial has been designed in accordance with the fundamental principles established in the Declaration of Helsinki, the Convention of the European Council relating to human rights and biomedicine, and the Universal Declaration of UNESCO on the human genome and human rights, and with the requirements established by Spanish legislation in the field of biomedical research, the protection of personal data, and bioethics.

National coordinators and principal investigators at each participating centre will be responsible for clarifying the need for approval by the local Ethics Committee.

The principal investigator shall ensure that the study will be performed according to the ethical principles in the 2005 second edition of the "Marco de Gobierno de Investigación para la Salud y Asistencia Social" and its subsequent amendments, as well as to comply with the current legal and regulatory requirements applicable. The ethical approval of the study may not be necessary in every participant nation. The Steering Committee, community and local investigators will be responsible to clarify whether there is the need of ethical or other regulatory approvals; and in case they are needed they will also be responsible to guarantee that they are approved before data collection.

Data registration without confirmation of ethical or other regulatory approvals will not be permitted. This study is, in fact, a large scale clinical audit. We expect that in most, if not in every, participant communities and countries the need of individual patient consent is not required, given that data will be anonymous and that data are already registered in everyday clinical care. In communities and countries which require individual patient consent, collection of data that describe mid-term (e.g. one year) outcomes could be possible using data from the health recording system. Regardless of whether there is a need of informed consent, the Steering Committee will provide the informed consent form approved by the regulatory CREC (Clinical Research Ethics Committee) and it encourages all investigators to inform patients about their participation in the study.

SAFETY CONSIDERATIONS

There are no safety considerations related to the FRAGILE study. There is no risk of harm neither to patients nor to investigators.

SAFETY

The study presents no risk to patients and investigators. Adverse events are not monitored and they do not need to be reported in a different way than that of the

usual clinical practice.

MONITORING AND AUDIT

The FRAGILE study master files will be audited by the sponsor (Grupo Español de Rehabilitación Multimodal) to ensure that the study's activities are performed in accordance with the protocol, the sponsor's standard operating procedures, Good Clinical Practices and the applicable regulatory requirements. In the participating hospitals, local study documents can be selected to perform a local audit. Nevertheless, the FRAGILE study team will not routinely supervise the participating hospital's individual data collection or data verification.

8. STUDY COMMITTEES

Study management group

The FRAGILE study will be managed by RedGERM, belonging to Grupo Germ,

Steering Committee

The study's Steering Committee shall appoint an independent president on behalf of the GERM's Scientific Committee (Alfredo Abad Gurumeta) and the independent members (Jesús Villar). There is no role for a Data Monitoring Committee.

The Scientific Committee will be composed of the study's principal investigators.

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9. FUNDING

The FRAGILE study lacks external funding.

10. COMPENSATION

The FRAGILE study will be promoted by the Grupo Español de Rehabilitación Multimodal (GERM), which has an insurance. Even though given the study's characteristics, an insurance is not considered necessary.

11. DISSEMINATION OF THE RESULTS

The Steering Committee will appoint a Drafting Committee to edit the scientific report(s), which will be disseminated in due course. The performance of secondary analysis is foreseen. FRAGILE investigators will have priority over the conduction of these analysis and they will be encouraged to do so. Participation will be based on the contribution to the primary study. The Steering Committee will consider the scientific validity and the possible impact on the participating centres' anonymity before granting any request. If necessary, prior written agreement will establish the terms of this type of collaboration. The Steering Committee shall approve the final version of all manuscripts before their presentation. In the event of disagreement within the Steering Committee, the head of the research project will make a choice. Any data of the analysis of

FRAGILE that includes two or more venues will be considered to perform possible secondary analyses and will be subject to predefined rules.
All study participants will be included as co-authors under the FRAGILE Network Group.

Data management and data property

The sponsor of the study, the **Grupo Español de Rehabilitación Multimodal**, will act as the custodian of data. In line with data preservation and data exchange principles, after the publication of the general database, the Steering Committee will consider all reasonable requests to conduct secondary analyses. Its decision will be based on the quality and validity of the proposed analysis. Only summary data will be publicly presented and all European, national, institutional and patient data will be absolutely anonymous. Individual patient data provided by the participant hospitals are the property of their respective institution. Once each local coordinator has confirmed that the provided data are both complete and exact, raw data will be transferred to spreadsheet. Complete datasets, concerning patients participants, hospitals and communities will be codified, nevertheless, they will be at public disposal during two years after the publication of the main scientific report. Before this, the Steering Committee is under no obligation to provide data for any participant investigator if the Committee considers that it is not in line with the overall objectives of the FRAGILE study.

12. STUDY TIMELINE

Data collection will start with the first recruited patient, once all required regulatory approvals are obtained.
The study will start the day of the surgery. Patients will be followed up for 30 days. The 30 days follow-up will be done through a patient phone call. The study will last 30 days from the inclusion of the patient. (Onset is yet to be determined).

13. EXPECTED RESULTS

The incidence of frailty within the overall surgical patients is not yet defined. The incidence of frailty according to age group also remains unclear. It has never been described whether or not there are differences between patients undergoing elective and urgent surgeries in terms of frailty. In general, the published reviews performed in patients older than 65 years old show that the prevalence of frailty in this age group is more than 20%; and it is associated with

an increase in postoperative complications, hospital length of stay and institutionalization. The relation between the application of prehabilitation protocols in frail patients and their postoperative evolution has been scarcely investigated and its association with postoperative quality of life remains unknown.

Likewise other large international cohort studies, the expected results of this study are:

1. To identify the incidence and severity of frailty in patients undergoing elective as well as urgent surgeries.
2. To identify whether the application of perioperative prehabilitation programs is associated with an improvement in the frailty state and in the clinical outcomes 30 days after surgery.
3. To identify postoperative complications in frail patients both at a national level and an international level.
4. To identify the differences in postoperative quality of life 30 days after surgery between frail and non-frail patients, and between the different degrees of frailty after urgent and elective surgery.
5. Overall, a high international participation is anticipated. Therefore, the obtained data will allow not only to clearly define the prevalence of frailty in different age groups, in different types of surgery and in urgent or elective surgery, but also to identify which are the key elements to patients' recovery of a prehabilitation or posthabilitation program as well as to establish which patients could benefit most of the aforementioned programs. Additionally, it will identify those areas of knowledge that need further study.