**Title**: Mortality, geriatric, and non-geriatric surgical risk factors among the eldest old: a prospective observational study

**Authors**:

Andres D. Pelavski,[[1]](#footnote-1)MD, PhD Universidad Autonoma de Barcelona, Vall d´Hebron University Hospital. Department of Anesthesia.

 (Design, analysis, writing)

Marcos De Miguel, MD Universidad Autonoma de Barcelona, Vall d´Hebron University Hospital. Department of Anesthesia.

 (Design, statistical anaysis)

Gabriela Alcaraz, MD Universidad Autonoma de Barcelona, Vall d´Hebron University Hospital. Department of Anesthesia.

 (Data collection, language editing)

Laura Villarino, MD Universidad Autonoma de Barcelona, Vall d´Hebron University Hospital. Department of Anesthesia.

 (Data collection, writing)

Albert Lacasta, MD Universidad Autonoma de Barcelona, Vall d´Hebron University Hospital. Department of Anaesthesia.

 (Statistical analysis, editing).

Lucía Señas, MD Universidad Autonoma de Barcelona, Vall d´Hebron University Hospital. Department of Anesthesia.

 (Data collection, editing)

María I. Rochera, MD Universidad Autonoma de Barcelona, Vall d´Hebron University Hospital. Department of Anaesthesia.

 (Design, editing).

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**Abstract**:

*Introduction*: Preoperative risk and postoperative outcomes among the elderly are the subject of extensive debate. However, the eldest old, i.e. the fastest growing and most vulnerable group, are insufficiently studied; even their mortality rate is unclear.

This prospective observational study was performed with a view to determining the mortality rate of this population, and establishing which preoperative conditions were predictors of which postoperative outcomes. It was undertaken between 2011-2015, in a major tertiary care university hospital.

*Methods:* all patients aged ≥85 years undergoing any elective procedure during the study period were included. Patients were followed up for 30 days postoperatively.

The preoperative conditions studied were demographic data, grade of surgical complexity (1 to 3), preoperative comorbidities, and some characteristically geriatric conditions (functional reserve, nutrition, cognitive status, polypharmacy, dependency, and frailty). The outcome measures were: 30­-day all-cause mortality (primary endpoint), morbidity, prolonged length of stay, and escalation of care in living conditions.

*Results*: Of 139 eligible patients, 127 completed follow-up. The 30­-day mortality was 7.9%, 95%CI [3.2-12.6]. It had 3 predictors: malnutrition (OR 15 95% CI: 3-89), complexity 3 (OR 9.1 CI: 2-52), and osteoporosis/osteoporotic fractures (OR 14.7 CI: 2­126). Significant predictors for morbidity (40%) were ischemic heart disease (OR 3.9 CI: 1-­11), and complexity 3 (OR 3.6 CI: 2-­9), while a non-frail phenotype (OR 0.3 CI: 0.1-­0.8) was found to be protective. Only two factors were found to be predictive of longer admissions, namely complexity 3 (OR 4.4 CI: 2-­10) and frailty (OR 2.7 CI: 2-7). Finally, risk factors for escalation of care in living conditions were: slow gait (a surrogate for frailty, OR 2.5 CI: 1-­6), complexity 3 (OR 3.2 CI: 1-­7) and hypertension (OR 2.9 CI: 1-­9).

*Conclusions*: The eldest old are a distinct group with a considerable mortality rate, and their own particular risk factors. Surgical complexity and certain geriatric variables (malnutrition and frailty), which are overlooked in ASA and most other usual scores, are particularly relevant in this population. Inclusion of these factors along with appropriate comorbidities for risk stratification should guide better decision-making for families and doctors alike, and encourage preoperative optimization of patients.

**Introduction**

The unprecedented increase in the elderly population has brought to the forefront the notion of frailty, an age-related multidimensional syndrome associated with increased vulnerability and decline in the physiological reserve.(1,2) Coined by geriatricians, frailty was originally approached through two models: Fried and coworkers established the ‘Phenotype of frailty’,(3) whereas the Canadian Study of Health and Aging devised the ‘Cumulative Deficit Model’.(4) Recently, researchers have expanded this notion to include various components of the Comprehensive Geriatric Assessment (CGA),(5-7) and several studies have suggested that frailty could be a useful predictor of surgical outcomes.(8-10) Accordingly, different groups have validated various scores as prognostic tools, each with a particular definition of frailty.(11,12)

Such a proliferation of scores and scales, however, usually overlooks the extremely old.(6,8,13) Patients ≥ 85 years of age are the fastest-growing group and most susceptible to poor outcomes,(14) but tend to be underrepresented in most series. So rarely are they studied that even their mortality rate is unclear, and recommendations about this group are based on extrapolations from research conducted in younger populations. Furthermore, the question of which postoperative outcomes are more relevant among the elderly is still a matter of debate.(15)

The following research is based on the hypothesis that the eldest old constitute a distinct group with their distinctive mortality rate, their own particular risk factors, and whose surgical outcomes depend on variables both specific and non-specific to their geriatric condition. This prospective observational study aimed to determine the mortality rate for this group, and to establish which preoperative conditions are the most robust predictors of important adverse postoperative outcomes.

**Methods**

*Patients*

The project was carried out between October 2011 and October 2015 in Vall d’Hebron University Hospital, a large tertiary care center. The study was approved by the Hospital Committee for Clinical Research Ethics, and the Board of Clinical Investigation Projects. All patients of ≥85 years undergoing any kind of elective surgery were included. Every recruited patient or their next of kin (when they were incapacitated) agreed to sign an informed consent form, and to provide a contact number for follow-up after discharge. Exclusion criteria were day-case surgery, emergency surgery (including deferred hip fractures), and patients scheduled for procedures under local anesthesia without any intervention by the anesthetist. In order to reduce inter-observer variability, every consenting patient was interviewed by a senior anesthetic resident specifically trained to deliver the questionnaires (3 trainees were involved). Interviews were performed before premedication and, to avoid bias, researchers who ascertained postoperative outcomes were blinded to preoperative health status.

*Preoperative data*

Apart from patients’ demographic characteristics and ASA score, information was gathered concerning the procedure. Participants were also questioned about their living conditions (LC), comorbid conditions, functional reserve and medication. The procedures were classified into three grades of complexity according to Donati’s simplified version of Johns Hopkins surgical criteria(16) (see table 1). Regarding LCs, we registered whether patients lived alone, with a partner, with their family, with a caregiver, or in an elderly-care institution prior to admission. Comorbidity was assessed both by recording diseases associated with higher risk in the general population,(17) as well as by assessing conditions frequently found among the elderly (supplemental Appendix A). We also calculated Charlson’s Comorbidity Index.(18) Functional reserve was measured in METS (supplemental Appendix B). A value of 3 or below was considered as reduced. Polypharmacy was defined as the concurrent use of 7 or more prescription drugs. (The definition of polypharmacy is still debated: different authors place it anywhere between 5 and 10).(19,20)

To assess the nutritional status we used the Mini-Nutritional Assessment (MNA) with scores ranging from 0 to 14:(21,22) 12-14 was considered normal, 8-11 nutritional risk, and 7 or less indicated malnutrition. Because some studies have demonstrated that albumin can be a useful proxy measure of the nutritional status, the preoperative albumin levels were also recorded when available. (Less than 3.5g/dl was considered as indicative of a poor status, according to the laboratory reference values).

The Mini Mental State Examination (MMSE), a 30 point tool was used to determine cognitive impairment.(23) A score of 27-30 was defined as intact cognition, and a score of 26 or less was considered impaired.

Physical functioning was measured with the Katz index of Activities of Daily Living (ADL).(24) This score, which ranges from 0 to 6, assesses the level of dependency of the patients: 0-2 means complete dependency, 3-4 partially independent, and 5-6 completely independent.

Frailty was calculated using Fried’s phenotype model, which assesses 5 criteria. This enables patients to be classified into 3 degrees of frailty according to the number of criteria involved. More than 3 is indicative of a frail condition, 2-3 factors indicate a pre-frail status, and 0-1 are considered non frail.(3) Although gait speed is one of the 5 factors defined in Fried’s phenotype, other studies have demonstrated that slow gait is a valid predictor of poor postoperative outcomes in itself (13). Therefore, we also registered it as an independent variable. (Timed up and Go was not used in order to prevent interference with Fried’s walking component.)

*Outcome variables*

Altogether, 4 indicators of poor postoperative outcomes were considered. The primary endpoint was all-cause 30-day mortality rate and its risk factors. Secondary outcome measurements included in-hospital morbidity, escalation of care in the LC, and prolonged hospital length of stay (LOS). Postoperative morbidity was defined as the occurrence of at least one clinically significant complication after surgery during the same hospitalization (full description in supplemental Appendix C). Reoperation within the same admission, and readmission after discharge within the first postoperative month were also included within this category. Patients were contacted by telephone 30 days after the procedure in order to assess survival and LC. An escalation was considered whenever a patient who lived on his own prior to surgery had to move in with a relative or required a caregiver afterwards; and all cases living in the community who had to go into some form of institutionalized care (in an elderly home or in a convalescent center) once discharged from hospital. In all cases, living conditions were assessed on the thirtieth day after surgery. Finally LOS was considered prolonged whenever the number of days of hospitalization – from admission until discharge or death –was above the 75th percentile for the sample.

*Statistical analysis*

To carry out this observational study the STROBE guidelines were followed.(25) The analysis was performed with IBM SPSS statistics 22.0. Continuous variables are presented as mean ± standard deviation, discrete variables as median [range], and categorical variables as count (percentage). Patients lost to follow up were excluded from the study.

A power analysis was used to estimate the sample size necessary to provide a precision of ±5% (width of the 95% CI) at an alpha of 0.05, assuming an expected mortality of 10% in the study population (based on the available data) (26,27). Given that our primary outcome was 30-day all-cause mortality 139 patients were needed.

After the descriptive analysis, potential risk factors were compared between patients with poor outcomes and patients without them, by using t-tests for continuous variables, and χ2 or Fisher’s exact test for dichotomous categorical variables. Mantel and Hänsel’s linear association was chosen for variables with 3 or more categories. These comparisons were made for each of the outcome variables. For non-parametric correlations Spearman’s coefficient was used.

Subsequently, forward stepwise multivariable logistic regression analysis was performed to identify independent risk factors for poor outcomes. The aim was to develop four equations, one for each outcome variable under investigation (i.e. mortality, morbidity, prolonged LOS, escalation of care in LC). A univariate cutoff of p<0.1 was used for inclusion, and a p value < 0.05 as the threshold for statistical significance within each model.

A covariate analysis with Cramer’s V was performed to ensure that there were no strong correlations between frailty and the other variables.

*Missing data*

Main outcome variables were complete for all participants. Structural missing variables, such as patients who could not walk, and those in pain who were unwilling to do so (17 individuals, 13.4%) were counted as as positive for this component of Fried’s frailty phenotype and as abnormal gait. We assumed that those that did not meet this criterion were the most frail patients. (In other words, they were considered Missing Not At Random). As far as the Missing At Random are concerned, preoperative albumin levels were not present for all participants (15 missing, 11.8%), and 1 patient did not complete Katz’s ADL questionnaire. Such cases were excluded from the corresponding analysis.

**Results**

127 out of 139 eligible individuals were included (exclusions, losses and the reasons behind them are shown in figure 1). The median age was 87 [85-96], with a majority of women 70 (55.1%), and most patients were classified as ASA III, 68 (53.1%). There were 56 (44.1%) individuals considered as ASA II, and only 3 (2.4%) as ASA IV. A large percentage of this cohort lived with their family prior to surgery 55 (43.3%). Among the rest, 33 (26%) lived on their own, or with their partner, 24 (18.9%). Only 6 (4.7%) lived in an elderly institution and only 7 (5.5%) required a caregiver before the procedure. Inasfar as outcome measurements are concerned, 10 patients died during the first postoperative month, which yielded an all-cause 30-day mortality rate of 7.9%. Of those, 7 died while still hospitalized, and their median LOS was 24 days [4-30]. Among the 3 that were discharged – median stay 14 days [4-20] – 1 patient had to be readmitted.

60 patients sustained one or more complications during admission (in-hospital morbidity of 47.2%). The median LOS was 10 days [1-54] (See supplemental Figure 1), and 31 patients had to stay longer than 19 days, which was the 75th percentile –prolonged LOS 24.4%. Finally, 46 patients required an escalation of care in their living conditions after surgery (36.2%).

No significant statistical relationship was found between the patients’ demographic characteristics and any of the outcome measurements (see supplemental Table 1). Furthermore, there was no significant correlation between outcome variables and Charlson’s index, nor was the number of comorbidities statistically correlated to any outcome except for morbidity: a weak though significant correlation between the number of preoperative comorbidities and the occurrence of postoperative complications was found (correlation coefficient 0.25, *p* 0.05). However, this variable was not found significant in any of the logistic regression models.

Tables 1, 2, and 3 show our findings regarding the complexity of the procedures, comorbidities, and specific geriatric variables, respectively. From all the items of the CGA assessment studied, only a few were statistically related to poor outcomes in the univariate analysis, and only frailty was significant for all four. As for comorbidities, a small number from the whole list was linked to the outcome measurements under investigation.

Finally, the logistic regression models are presented in table 4. As shown, the assessment of frailty (or its surrogate indicator, slow gait) proved to be a relevant predictor for 3 of the 4 outcome measurements explored. Regarding the covariate analysis, the correlation between frailty and all the other variables was weak (Cramer’s V ≤0.3), except for slow gait, which was deliberately used as a proxy measure of frailty (supplemental Table 2). Similarly, the correlation between malnutrition as measured by the MNA and abnormal albumin did not show to be significant (supplemental Table 2).

**Discussion**

This study suggests that the mortality rate in the extreme elderly undergoing elective procedures is 7.9%, 95%CI [3.2-12.6], and that there are three main types of risk factor. They include complex surgery, certain preoperative comorbidities, and two specifically geriatric conditions, namely, frailty and malnutrition. A specific blend of these components can predict each particular indicator of poor postoperative outcomes. Although none of these groups of risk factors is surprising, the extent to which they contribute had never been established, particularly amongst the eldest old.

In terms of general findings, the all-cause 30-day mortality rate was considerable, even if it was lower than expected as compared with previous studies in similar populations (8.4 to 35.3%).(26-28) Such studies were based on nonagenarian patients and included emergency cases, or a substantial percentage of individuals with hip fractures (which we excluded). There have also been publications with lower rates than ours; however, the types of procedures were less comprehensive, and they seldom distinguished between the third age (65 to 84 years old) and the fourth (85 and older). (29),(30,31) Indeed, comparisons are difficult because the epidemiology in the ≥85 group is limited. Few researchers have focused on the eldest old, as a result of which the evidence available is either retrospective, or out of date, or mixes both emergency and elective cases. The high percentage of patients (43.3%) that lived with their families prior to surgery is, perhaps, a Spanish-cultural feature, which may not be easily extrapolated to other populations.

These findings showed that invasive surgery (grade 3) was the most significant independent risk factor for poor outcomes. Not only was it present in all four outcomes, but it also showed a high odds ratio in each of them. Intuitively obvious though it may seem, complexity is normally overlooked in studies that assess frailty, for the majority of them are based on a single type of surgery, or on procedures of similar complexity.(6,8,32) Moreover, the most widely used preoperative tool, the ASA score (American Society of Anesthesiologists’ physical classification system) does not take it into account either. Our outcomes are also supported by McIsaac’s findings in a retrospective cohort of patients ≥65 years old,(31) and the EUSOS study in the general population. They both found that complex surgery was an independent predictor of mortality.(33)

As for specific geriatric variables, each of the outcomes had at least one. However, contrary to most scales published in the literature, only malnutrition and frailty were statistically related to poor outcomes. While the former was a risk factor for postoperative mortality, various forms of frailty were involved in the other models. The lowest degree of frailty (non-frail phenotype) was found to be a protective factor (OR 0.3) for morbidity; the frail phenotype a predictor of prolonged LOS, and its surrogate measure (slow gait) was an independent risk factor for escalation of care in the LC. In light of these findings, the non-frail phenotype could also be framed as a marker of resilience, successful ageing, or positive physiological reserve.(10) In other words, in a population where 74% of the patients are frail or pre-frail (table 3), the patients who were able to avoid these frailty traits seem to be better equipped than the others to handle the stress of surgery. Additionally, once multicollinearity was ruled out (supplemental Table 2a), the fact that frailty was not a risk factor for mortality – as in other series – (9,13,34) could be explained if we consider that old age might be acting as a confounder. In other words, very old age is directly related to both the outcome measure (mortality) and the exposure variable (frailty) without actually being on the causal pathway. The studies where such a relationship was found were based on cohorts of younger patients (older than 65), where the extremely old only represented a small percentage, and fewer patients were found to be frail (10.4% in Makary’s series and 3.1% in McIsaac’s).(9,31) Moreover, McIsaac has observed in a ≥65-year-old retrospective cohort that frailty was a stronger mortality factor among his younger patients, which is in line with our hypothesis.(31) Another feasible explanation as to why frailty failed to predict mortality could be its low incidence. Indeed, mortality had the lowest incidence of all four outcomes.

The fact that none of the other geriatric variables investigated constituted an independent risk factor in the analysis might be an arbitrary finding due to the modest sample size, but it could conceivably also be a consequence of our approach. Most researchers developed scales based on different combinations of geriatric assessments, where the results were added to yield a final score that predicts the risk of certain undesirable outcomes.(6,8,11) In other words, they used the ‘cumulative deficits’ principle to build their tools. The present study, by contrast, explores the independent statistical relationship between certain comorbidities, certain geriatric variables and certain degrees of surgical complexity, with particular individual indicators of postoperative outcomes. In this way, it offers a more general idea of the independent risk factors, and their specific weight in the outcomes. The cumulative effect was only explored for comorbid conditions through correlations, and only the number of preoperative comorbidities (i.e. multi-morbidity)(10) was correlated with postoperative morbidity. Yet, in the logistic regression model the cumulative effect was not significant.

As far as comorbid conditions are concerned, although some of them were significant, they did not dominate the risk factors of adverse outcomes as in younger cohorts. It seems as though beyond a certain age, the success in the aging process, which is better reflected by the degree of frailty and the nutritional state, acquire a higher weight for predicting postoperative outcomes. To be sure, most preoperative comorbidities included in the predicting models are well-known risk factors about which patients are always questioned during the pre-anesthesia consultation, and which are often assessed in the most relevant surgical risk scales (ASA, POSSUM, EuroSCORE, etc.). Therefore, the finding of osteoporosis/osteoporotic fractures in the mortality-predicting model was rather unexpected. Although the relationship between osteoporosis, fractures and mortality is well documented –mortality rates are increased during the first 5 years after a fracture – (35) such a condition can easily be overlooked and not explicitly investigated during the preoperative assessment. Furthermore, it could also be framed as a manifestation of unsuccessful aging. Also of note is that no comorbidities were found to be predictive of a prolonged LOS, which yielded a regression model with only 2 predictive variables, namely frailty and surgical complexity.

Some of this study’s limitations must be mentioned. First of all, the sample size was insufficient to reach a reasonable precision in our multi-variable model for mortality (hence the wide 95%CIs). Furthermore, the limited number of patients precluded the possibility of exploring whether complexity could be acting as a potential effect modifier. It should be noted, nonetheless, that this study group still represents a minority segment among the general surgical population, even if their number is rapidly growing (according to EuSOS Spain, elective surgery in ≥85-years old only represents 3% of the total surgical volume). Secondly, given the finding of osteoporosis/fractures as an independent risk factor for mortality, the syndrome of falls should also have been explored.(11) Certainly, fractures in elderly patients are usually caused by falls; nevertheless, it is possible that we might have missed some potentially valuable information.(36) Thirdly, continuous variables were dichotomized according to the standard values used for the general population. As a result, some cutoff points may under- or overestimate the limits of normality, especially in a group so scarcely studied. As a matter of fact, the specific boundaries between normality and abnormality are seldom defined for the eldest old. Additionally, we did not have a control group. A comparison with a younger population would make clearer the extent to which poor outcomes are a consequence of a particular risk factor, and the extent to which they are a consequence of ageing. A further limitation is that patients were only recruited from a single center. Consequently, their number was limited and some findings might not be generalizable to other communities. On the other hand, some strengths are also worth mentioning. This is, to our knowledge, the largest prospective study in such an elderly population that looks independently at both geriatric and non-specifically geriatric risk factors. It is neither procedure- nor specialty-specific, as is the case with the majority of the research in the literature. Additionally, it provides a distinct predictive model for each specific indicator of poor outcomes.

In summary, the prediction of adverse outcome was dominated by the complexity of the surgery and the presence of frailty or its surrogates, even when comorbidities demonstrated an influence. The strong impact of the severity of surgery on outcome reinforces the concept that many elderly patients have insufficient physiological reserve to withstand the stress of truly major surgery. As a result, our findings confirm the need to consider certain geriatric variables in this population: the assessment of frailty and nutritional status could, additionally, encourage prehabilitation to optimize the patients’ condition and, conceivably, improve postoperative outcomes.(1,37) It can also help to tailor the best anesthetic technique for each patient.(10) Finally, by paying proper attention to these risk factors, a more realistic prospect can be offered to the patients and their relatives, thereby allowing for better-informed decisions.(10)

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Figure 1: Flow diagram

1. Corresponding author**:** Joaquin Costa 46, 3º 3º (08001), Barcelona. Spain. Tel: (+34)679372504. Email: pelavski@yahoo.es [↑](#footnote-ref-1)