# TITLE

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# Abstract

## Background and purpose

The comorbidity burden among THA patients has increased over time. Several studies have verified the connection between an increased comorbidity burden and a poorer outcome on a population level. Different comorbidity measures are used but there is no consensus. The aim of this study was compare the clinically used comorbidity measure ASA with the diagnosed based Charlson Comorbidity Index (CCI) and Elixhauser Score, and the prescription based RxRisk-V in regard to the risk of early postoperative mortality after THA. We also investigated the prediction value of each comorbidity measure and of their included dimensions separately, in order to find usable clinical “red flags” of high-risk patients.

## Patients and methods

We performed a nationwide retrospective cohort study analysing 44,214 patients between 18 and 100 years who hade received a THA due to primary osteoarthrosis. The Kaplan-Meier method was used to calculate unadjusted cumulative survival. Logistic regression models were fitted to calculate crude and adjusted odds ratios (OR) with 95% confidence intervals (CI). The performance of the logistic regression models was evaluated by its discrimination capacity using c-statistics.

## Results

Unadjusted cumulative 90-day survival was 99.7 (CI 99.68 to 99.78) number of events 115. As expected we found that age and male gender gave an increased risk of 90-day mortality. CCI, Elixhauser Score, and the RxRisk-V Score performedbetter in prediciting 90-day and one year mortality than the included dimensions separately.The RxRisk-V Scoreperformed better than diagnose based comorbidity measures in predicting 90-day mortality with an AUC= 0.66. Best predictive performance was found for the combination model of age, gender, ASA, presence of heart infarction or renal disease for the last 12 months prior to THA surgery (AUC 0.81).

## Interpretation

Our results of this nationwide cohort study indicate that, in research, a less data demanding comorbidity measure, i.e. the suggested combination of age, gender, ASA score, presence of heart infarction or renal disease for the last 12 months prior to THA surgery, serves us just as well if not better than the commonly used more complex diagnose based or prescription based coding algorithms.

# Introduction

Elective total hip Arthroplasty (THA) is a successful choice of treatment for advanced hip osteoarthritis (OA). The number of THA performed has increased in the past decades. ([1-4](#_ENREF_1)) The comorbidity burden among individuals undergoing THA procedures has also increased during the same period([5](#_ENREF_5), [6](#_ENREF_6)) while the early postoperative mortality after THA is low and has decreased over the last years.([7-10](#_ENREF_7)) The higher prevalence of comorbidity in patients undergoing THA may be multifactorial, i.e. caused by an ageing population, improved pre- and post-operative care, improved treatment of comorbid conditions, or a result of more comorbidities being registered. Several studies have verified the connection between an increased comorbidity burden and a poorer outcome on a population level, i.e. an increased risk of early postoperative mortality, an increased risk of revision([5](#_ENREF_5), [11](#_ENREF_11)) and poorer patient outcomes([5](#_ENREF_5), [12](#_ENREF_12)) for patients with more comorbidities. On existing data sources, i.e. in- and outpatient data and prescription data, diagnosed based (or prescription based) coding algorithms are often used to obtain a comorbidity measure([13](#_ENREF_13)) (i.e. Charlson Comorbidity Index (CCI), Elixhauser Score, and RxRisk-V). Inacio et al recently performed a study where the ability of Charlson Comorbidity Index (CCI), Elixhauser Score, and RxRisk-V to predict mortality after THA and TKA was evaluated([14](#_ENREF_14)). In our clinical departments comorbidity measures such as the American Society of Anesthesiologists physical status classification (ASA) are preferred.

However, an existing connection on a large population scale does not easily extrapolate to the individual level in our clinical practise. Several universal and arthroplasty specific risk prediction tools have been introduced but none has been broadly accepted.([15](#_ENREF_15))

In this study we aimed to investigate how the clinically used comorbidity measure ASA influence the risk of early postoperative mortality compared to the diagnosed based CCI and Elixhauser Score and the prescription based RxRisk-V. We also aimed to investigate the prediction value of each comorbidity measure and of their included dimensions separately, in order to find usable clinical “red flags” of high-risk patients.

# Methods

## Study design and study population

We performed a nationwide retrospective cohort study (Figure 1). All patients operated between 2008 and 2013 for THA due to primary osteoarthritis from the Swedish Hip Arthroplasty Register (SHAR) were included. Only elective primary hip arthroplasty procedures were included.

Follow-up started on the date of surgery and ended on the day of death, emigration, or December 31st 2013, whichever came first. Only the first surgery was accounted for in bilaterally operated patients to avoid dependency issues. Potential reoperations within 90 days were not accounted for. Adjustment was made for age, gender, socioeconomic background, and type of hospital. Ninety days and one year mortality was the primary outcome measure.

## Sources of data

***The Swedish Hip Arthroplasty Register*** registers all patients undergoing THA in Sweden since 1979. The SHAR has a stable completeness of registration around 96-98% and has been validated repeatedly.([1](#_ENREF_1), [16](#_ENREF_16), [17](#_ENREF_17))

***Statistics Sweden*** is a state-owned registry collecting information on the entire Swedish population i.e. level of education, personal and family income. Thanks to the ten-digit personal identity number all Swedish citizens are assigned at birth, linkage between different Swedish official and medical databases is made possible.

***The Swedish National Patient Register*** was started in 1964. It contains information on medical comorbidities and admissions to hospital care for all individuals in Sweden. The positive predictive value of the Swedish National Patient Register is estimated around 90±5% which indicates high validity of data.([18](#_ENREF_18))

## Comorbidity measures

***The Charlson Comorbidity Index*** (CCI) is a diagnose based coding algorithm used in research.([19](#_ENREF_19)) It was developed to quantify the influence of comorbidities on survival. In this study the original weighting and the weighting according to Quan were investigated. ([19](#_ENREF_19), [20](#_ENREF_20))

***The Elixhauser Score*** is also a diagnose based coding algorithm used in research. ([21](#_ENREF_21)) The Elixhauser Score is more detailed than the more commonly used CCI.

***The RxRisk-V Score*** is a pharmacy based coding algorithm used in research.([22](#_ENREF_22), [23](#_ENREF_23)) Prescription based comorbidity measures have been increasingly used over the last years. It has been argued that a prescription based measure would be more reliable than a diagnosed based measure, not having the same limitations such as incomplete or inaccurate coding.([24](#_ENREF_24), [25](#_ENREF_25))

***The American Society of Anesthesiologists physical status classification*** (ASA) is a six-category physical status evaluation system developed in 1941 and it has remained virtually unchanged([26](#_ENREF_26)). The ASA grade was included in the Swedish Hip Arthroplasty Register (SHAR) in 2008 which is why our study period begins that year. The ASA grade is easily assessed in a clinical setting.

## Statistics

We adhered to the guidelines on statistical analyses of register data.([27](#_ENREF_27), [28](#_ENREF_28)) Means, medians and ranges were used to describe continuous data. 95% confidence intervals (CI) described estimation uncertainty. Categorical data were investigated by cross-tabulation and the Chi-square test. The Kaplan-Meier method was used to calculate unadjusted cumulative survival. In order to calculate crude and adjusted odds ratios (OR) with CI logistic regression models were fitted. Continuous variables were kept continuous when possible in order to strengthen the statistical analyses.([29](#_ENREF_29))

The performance of the logistic regression models was evaluated by its discrimination capacity using c-statistics. We performed no imputation for missing data. The level of statistical significance was set at p<0.05.

## Ethical approval

All patients registered in the SHAR have received written information about the register. Registered patients have been given the choice not to participate in the registry or associated research but written informed consent for participation was not obtained. This is in consistency with the Swedish Patient Data Law from 2009. Our ethical approval was obtained from The Regional Ethical Review Board in Gothenburg (2013: 360-13).

# Results

Participants and comorbidities:

After the selection process (Figure 1) 44,214 individuals between 18 and 100 years old who hade undergone THA due to primary OA were analysed. The mean age was 86,3 years (SD 10.02) and there were somewhat more women (56.8%) than men (43.2%).

The highest proportion of patients with multiple comorbidities (i.e. three or more) was identified by the RxRisk-V measure (69.5%). For the Charlson Comorbidity Index the proportion of three or more comorbidities was 3.4% and for the Elixhauser Score it was 4.9%.

A vast majority of patients had an ASA score below three (85.2%). Individuals with an ASA score of 5 and 6 were excluded since those values describe moribund individuals.

See Table 1 for more characteristics of the study population.

## Ninety day mortality after THA

Unadjusted cumulative 90-day survival was 99.7 (CI 99.68 to 99.78) number of events 115. As expected we found that age (OR 1,1 [CI 1.06-1.12]) and gender (female gender adjusted OR 0.4 [CI 0.28-0.64] gave a statistically significant influence on the adjusted risk of death. Crude values indicated an increased risk of 90-day mortality for all three comorbidity indexa but only CCI remained statistically significant (adjusted OR 1.3[CI 1.09-1.45]) after adjustment was made as did the clinical ASA score. Within the social background variables only being a widow/-er (adjusted OR 1.7[CI 1.05-2.70]) fell out statistically significant after adjustment. Crude and adjusted odd ratios for 90-day mortality with 95% confidence intervals are presented in Table 2.

## One year mortality after THA

The unadjusted cumulative survival was 99.1 (CI 98.99 to 99.17) for 1 year and the number of events 363. For the whole study period the number of events was 1412 and the unadjusted cumulative survival 91.3 (CI 90.44 to 92.12). Age (OR 1,1 [CI 1.06-1.09]) and gender (female gender adjusted OR 0.6 [CI 0.44-0.69]) still gave a statistically significant influence on the adjusted risk of death. CCI remained statistically significant (adjusted OR 1.3[CI 1.2-1.45]) after adjustment was made as did the clinical ASA score. Within the social background variables marital status fell out statistically significant after adjustment (Data not shown).

## Prediction strength of investigated comorbidity measures

***The Charlson Comorbidity Index*** When examining the CCIs different dimensions we found that the total CCI performed better in predicting 90-day and one year mortality than the included dimensions separately. (See Table 3 A.) The original weighting (90-d c=0.65, 1-y c=0.65) was somewhat better in predicting both 90-day and one year mortality than the weighting according to Quan (90-d c=0.61, 1-y c=0.63). The original weighting of Charlson performed best of all investigated comorbidity measures better in predicting 90-day mortality. (See Table 3 A-C.)

***The Elixhauser Score*** was better in prediciting 90-day and one year mortality than the included dimensions separately (See Table 3B) with a 90 d AUC=0.63 and a 1 year AUC=0.65.

***The RxRisk-V Score*** performed better than diagnose based comorbidity measures (CCI and Elixhauser Score) in predicting 90-day mortality with an AUC= 0.66. (See Table 3 A-C.) The RxRisk-V Score performed better in prediciting 90-day and one year mortality than the included dimensions separately.

***The American Society of Anesthesiologists physical status classification***

OK, tänkte inte på det. Men visst tog vi fram prediktivt värde för ASA variabeln ensam? Annars kan vi ju inte saga att vår slut modell är bättre än ASA ensamt.

***Age, gender, ASA score, presence of heart infarction or renal disease combined the last 12 months*** After trying combinations of dimensions included in the different comorbidity measures and clinically accessible data we found that the combination of age, gender, ASA score, presence of heart infarction and renal disease the last 12 months gave the best prediction strength for 90-day and one year mortality)(AUC = 0.81). (See Table 4 and Figure 2 . Adding socioeconomic variables such as education level and civil status increased marginally the predictive power to 0.82, an insignificant increase (p =0.287).

# Discussion

## The impact of comorbidity on early postoperative mortality after THA

In this nation wide cohort study we wanted to investigate the performance of commonly used diagnosed based comorbidity coding algorithms (i.e. CCI and Elixhauser Score), an increasingly used prescription based comorbidity coding algorithm (i.e. RxRisk-V) with a clinically widely used comorbidity measures (i.e. ASA) with adjustment for other relevant factors such as age, gender and socioeconomic background. We found that the original CCI (AUC 0.65) performed somewhat better than the Elixhauser Score (AUC 0.63) in predicting 90 day mortality but in predicting 1 year mortality the performed equally (AUC 0.65). The prescription based RxRisk-V Scoreperformed better than the diagnose based comorbidity scores (CCI and Elixhauser Score) in predicting 90-day mortality with an AUC of 0.66 but worse in predicting one year mortality (AUC 0.62). This differs from earlier findings by Inacio where the RxRisk-V did not perform as well as the CCI and Elixhauser Score and where the C- values generally were higher than in our study.([14](#_ENREF_14)) The study population of our study was younger and included more women and we only included diagnoses and prescriptions registered one year prior to surgery which perhaps could at least partly explain the differences in the results.

Comorbidities are known to influence the outcome after THA.([5](#_ENREF_5), [11](#_ENREF_11), [12](#_ENREF_12)) In order to include the effect of comorbidity in research different comorbidity measures are used; either diagnosed based or prescription based. However, these comorbidity measures are not used in clinical settings and not seldom they demand a merge of information from several data sources. Patient administrative data are easily accessible to researchers but are known to be incomplete. Coding errors and underreporting of certain conditions are common.([13](#_ENREF_13))

ASA

## The prediction strength

Risk prediction may be useful in the patient selection process, in the preoperative risk mitigation process of a patient and in research settings. A number of risk prediction tools for adverse outcomes after total joint replacements have been introduced on the market with various validation and performance measures. ([15](#_ENREF_15)) Using c-statistics we evaluated the prediction strength of different comorbidity measures intended for research and their included dimensions with that of a comorbidity measure intended for clinical use. Overall the predictive strength of the total index of the diagnose and prescription based measurements was better than the individual predictive strength of the included dimensions separately. However, the best predictive strength was found for a model including age, gender, ASA score and presence of cardiac infarction or renal disease the last 12 months prior to THA surgery (AUC 0.81). In regard to trauma outcome prediction tools are common and it is has been shown that a clinical evaluation tool with few variables included tend to have stronger prediction capacity than more complex ones.([30](#_ENREF_30)) Our results indicate that also for THA we should try to find risk prediction models not more detailed and complex but rather simpler and including the right variables. A risk prediction measurement of this kind would also have a smaller risk of coding errors etc.

## Strengths and limitations

A strength of this study is that it is nationwide with a large cohort with a reasonable number of events. The sources of data have been shown to a have a high validity of data and the risk of missing data or cohort attrition was low. ([1](#_ENREF_1), [16-18](#_ENREF_16)) Limitations are the potential bias at different levels associated with observational data and the risk of coding errors as expected when dealing with patient administrative data.

It is important to make a distinction between explanatory research and prediction research. In the latter, prediction research, the investigated temporal context is another i.e. *futurum*. In order for a risk factor to be considered a predictor, the investigated effect needs to be tested in a different sample of individuals to capture the “*futurum*” aspect. This has not been done. Hence it is only with extreme caution we can extrapolate our findings into predictions in the clinical setting. Our results indicate that, in research, a less data demanding comorbidity measure, i.e. the suggested combination of age, gender, ASA score, presence of heart infarction or renal disease for the last 12 months, serves us just as well if not better than the commonly used diagnose based or prescription based coding algorithms. It would be interesting to evaluate the effect on adverse events and revision rate within 2 years in the Swedish setting and validate the combination comorbidity measure on other populations in the future.

## Conclusion

Our results of this nationwide cohort study indicate that, in research, a less data demanding comorbidity measure, i.e. the suggested combination of age, gender, ASA score, presence of heart infarction or renal disease for the last 12 months prior to THA surgery, serves us just as well if not better than the commonly used more complex diagnose based or prescription based coding algorithms.

## Contribution of authors

AG, NH: initiated the study and managed the ethical review board application. SN and AG performed the statistical analyses. GG: Assisted in preparing the review board application. AG drafted the manuscript. AG, SN, NH and GG took part in designing the study and editing the manuscript.

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