ASA classification and surgical severity grading used to identify a high-risk population, a multicenter prospective cohort study in Swedish tertiary hospitals

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Background: Identification of surgical populations at high risk for negative outcomes is needed for clinical and research purposes. We hypothesized that combining two classification systems, ASA (American Society of Anesthesiology physical status) and surgical severity, we could identify a high-risk population before surgery. We aimed to describe postoperative outcomes in a population selected by these two classifications system.

Methods: Data were collected in a Swedish multicentre, time-interrupted prospective, consecutive cohort study. Eligibility criteria were age ≥18 years, ASA ≥3, elective or emergent, major to Xmajor/complex (Specialist Procedure Codes used in United Kingdom), gastrointestinal, urogenital or orthopaedic procedures. Postoperative morbidity was identified by the Postoperative Morbidity Survey on postoperative days 3 ± 1, 7 ± 1, 10 ± 5 and graded for severity by the Clavien-Dindo system. Mortality was assessed at 30, 180 and 360 days.

Results: Postoperative morbidity was 78/48/47 per cent on postoperative days 3/7/10. Majority of morbidities (67.5 per cent) were graded as >1 by Clavien-Dindo. Any type of postoperative morbidity graded >1 was associated with increased risk for death up to one year. The mortality was 5.7 per cent (61/1063) at 30 days, 13.3 per cent (142/1063) at 6 months and 19.1 per cent (160/1063) at 12 months.

Conclusion: Severity classification as major to Xmajor/complex and ASA ≥3 could be used to identify a high-risk surgical population concerning postoperative morbidity and mortality before surgery. Combining the two systems future electronic data extraction is possible of a high-risk population in tertiary hospitals.
INTRODUCTION

As surgical techniques and perioperative medicine have developed, more elderly patients with significant co-morbidities are offered curative and complex surgical procedures in Sweden. Postoperative morbidity, that is, adverse events, is relevant from a patient perspective as it reduces the health-related quality of life up to 1 year\(^1\) and increases mortality during the first three years after surgery.\(^2\)

During the last decades, complex surgical procedures have been centralized into specialized hospitals which has led to a concentration of patients classified as ASA 3 (American Society of Anesthesiology physical status classification system) or more undergoing major to complex major surgery on tertiary hospitals. After this centralization process, it is reasonable to generate data on postoperative morbidity and mortality for clinical planning of resources, audit of performance and for research purposes.\(^3\) We hypothesize that a population classified as ASA 3 or more undergoing major to complex/major (AXA PPP/Specialist Procedure Codes; AXA-insurance company with Public-Private Partnership) gastrointestinal, orthopedic, or urogenital surgery in Swedish academic hospitals are at high risk with a mortality exceeding 5 per cent.\(^3\) The primary aim of this study is to describe the frequency and types of postoperative morbidities and mortality in a study cohort identified by surgical severity (AXA PPP) and ASA.

MATERIALS AND METHODS

The method section is written in accordance to the STROBE statement for transparent reporting of observational studies.\(^4\)

The cohort study was conducted per Handbook for Good Clinical Research Practice (GCRP/WHO). Compliance with GCRP provides public assurance that the rights and safety of study subjects are protected, consistent with the principles of the Declaration of Helsinki, the Swedish Personal Data Act and the Personal Data Ordinance. Processing of the personal data was authorized by the Swedish Data Protection Agency. The study was approved by the Regional Ethical Committee, Stockholm (ID: 2015/1128-31/4). The study was classified as a clinical follow-up study and written consent was waived by the Ethical committee. This was a multicentre observational closed study. The primary aim of this study was to describe the frequency and types of postoperative morbidities and mortality in a study cohort identified by surgical severity (AXA PPP) and ASA.

Baseline characteristics in prospective study cohort

Individuals were characterised by age, co-morbidities, types and urgency of surgery. All characteristics were accessed through electronic health records and operation planning system. The ASA classification\(^5\) as documented by attending anaesthesiologist during the pre-anaesthesia visit was used.
2.2 | Postoperative morbidity in prospective study cohort

Postoperative morbidities were identified by screening the medical records using the Postoperative Morbidity Survey (POMS) on postoperative days 3 ± 1, 7 ± 1 and 10-15. The POMS is validated in the United Kingdom and is recommended in European guidelines for reporting postoperative morbidities in clinical research in peri-operative medicine. The survey contains 18 items and it addresses ten domains: pulmonary, infection, renal, gastrointestinal, cardiovascular, neurological, wound, haematological, pain and mobility. For each domain, the presence of morbidity was recorded using objective criteria (Appendix Box 2). The severity of the morbidities was assessed by the Clavien-Dindo classification system (grades I–V), where grade I is a deviation from normal postoperative course without the need of not planned pharmacological treatment or surgical, endoscopic or radiological intervention. Criteria of the classification system are given in the Appendix 3.8

2.3 | Mortality in prospective study cohort

The postoperative mortality was assessed at 30, 180, and 360 days following surgery.

2.4 | Data sources in prospective study cohort

Patient characteristics and postoperative morbidity were extracted manually from the medical notes by the research team. For mortality, the study cohort was matched with Swedish Personal Address Registry (SPAR).

2.5 | Background and eligible population

The cohort where selected manually, consequently there was a risk that not all eligible patients were included. To test whether the cohort was representative we derived the eligible population after the closure of the trial. This was done as follows; from the operation databases at each study site a background population (all patients undergoing any surgery but day-care and thoracic during the study period) and a subpopulation with ASA ≥3 was extracted. In the latter subset, the performed surgery was classified by the UK severity grading system (AXA PPP/Specialist Procedure Codes, United Kingdom) by one member of the research team. At last codes were constructed for the inclusion criteria (surgical subspecialties and severity) and a dataset of eligible patients was derived.

2.6 | Statistical methods

The number of eligible patients during the study period determined the sample size.

Descriptive patient data are presented by number and percent. Continuous data are presented as median and range. Kaplan Meyer plots were used to illustrate and Cox proportional hazard model with adjustment for sex and age, to analyse the relationships between categorical variables and survival.

Data was collected by the research team to a paper Case Report Form (CRF) which later was entered in an electrical CRF (Register Syd). Data output was in excel format. For analyses STATA version 13 (StataCorp 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP) and R (R Development Core Team R Foundation for Statistical Computing, Vienna, Austria, http://www.R-project.org) was used.

3 | RESULTS

3.1 | Prospective study cohort characteristics

The study cohort consisted of 1089 participants. Thirteen were excluded due to violation of inclusion criteria (misclassification of surgical severity), three were lost to follow-up at 30 days and ten were lost at one year. Consequently, 1063 patients entered the final analysis (Appendix Box 1, Consort diagram).

Demographic characteristics, co-morbidities and types of surgical procedures are displayed in Table 1. The number of females/males was about equal. None of the patients was classified as ASA 5. The most common co-morbidity was renal failure (mild to end stage), followed by ischemic heart disease and chronic obstructive pulmonary disease. The most common surgical procedure was orthopedic surgery, followed by gastrointestinal and urogenital surgery.

3.2 | Postoperative morbidity and mortality

The percentage of patients with one or more postoperative morbidities defined by POMS was 78/48/47 per cent on day 3/7/10 (Table 2). The point prevalence of postoperative morbidity given per POMS domain on day 3, 7 and 10 in elective/emergency surgery as well as categorized according to surgery; gastrointestinal, orthopaedic or urogenital surgery respectively, are displayed in Figure 1 and Appendix Tables A1-A4. Considering the whole cohort, the main source of morbidity on day 3 was mobilisation, renal and pain (Table 2). This pattern changed over time, as the incidence of observed morbidities decreased by half or more. Infectious and gastrointestinal morbidities lingered in hospitalized patients after elective/emergency surgery, 27/22/21 and 21/15/11 per cent respectively, on day 3/7/10 (Table 2). Pulmonary morbidity was observed in 24/10/8 per cent, and cardiovascular morbidity in 13/6/5 per cent on day 3/7/10.

Prevalence of in-hospital morbidity in patients undergoing emergency procedures was 85/81/61 per cent compared to 74/41/39 per cent in elective patients on day 3/7/10 (Appendix Table A1). In orthopaedic patients undergoing emergency surgery, morbidities were 85
per cent on day 3 compared to 72 per cent after elective procedures (Appendix Table A2). On day 3 the most common sources of morbidity for both emergency and elective orthopaedic surgery were mobilisation, renal, followed by infectious and pain (Appendix Table A2).

In gastrointestinal emergency/elective procedures the postoperative morbidities were almost similar 87/86 per cent on day 3 (Appendix Table A3). On day 3, the most common source was pain, renal and mobilisation in elective group with the addition of infectious morbidity in the emergency group. This pattern changed over time and gastrointestinal and infectious morbidities increased by day 7 and 10 in elective group and decreased in emergency group (Appendix Table A3).

In urogenital surgical procedures, the pattern of morbidity was different. Emergency procedures had lower risk for morbidity compared to elective procedures on day 3 (42 vs. 62 per cent, Appendix Table A4).

The severity of postoperative morbidity was assessed by the Clavien-Dindo grading system. There was a deviation from normal course in 50 per cent of patients, 47 per cent within the ASA III group and 72 per cent within ASA IV group (Table 3). Majority of morbidities (67.5 per cent) were graded >1 by the Clavien-Dindo system (Table 3). Postoperative morbidity, classified as Clavien Dindo >1, and emergency surgery was associated with higher risk of death (Figures 2 and 3). After adjustment for age and gender the HR was 1.945 (95% CI 1.478; 2.558) and 2.558 (95% CI 1.950; 3.357) respectively. When we analyzed the association between death and postoperative morbidity detected on days (days 3, 7 and 10; Appendix Figures A1-A3), the HR was 1.779 (95% CI 1.103; 2.871), 1.597 (95% CI 1.188; 2.147) and 1.828 (95% CI 1.389; 2.405) respectively. After adjustment for age, gender and emergency, the association was still significant for morbidities detected on day 7 and 10, but not for those detected on day 3 (Appendix Tables A7-A9).

Mortality at 30 days was 5.7 per cent (61/1063), at 180 days 13.5 (143/1063) and at 360 days 19.1 (203/1063). The highest risk of death was observed following emergency procedures (Figure 3) except for urogenital surgical procedures (Appendix Table A5).

### 3.3 Background and eligible population

The background population, that is, those who underwent any type of surgery (with exception of thoracic and outpatient procedures) during the study period at the five study sites, consisted of 18 382 individuals (ASA 1-6). The mortality was 1.7/4.9/7.4 per cent at 30/180/360 days (Appendix Table A6).

Eligible population derived after the closure of the prospective Study cohort consisted of 1595 individuals. The proportion of different surgical subspecialties was comparable with the prospective Study cohort. The mortality was almost identical, as demonstrated by a mortality of 5.4/13.6/18.3 per cent at 30/180/360 days (Appendix Table A6).

### 4 DISCUSSION

This study demonstrates that using two tools, the physiological grading (ASA) and the surgical severity coding (AXA PPP/Specialist Procedure Codes, UK) we succeeded to select a high-risk cohort per definition, as the mortality was 5.7 per cent at 30 days and 19.1 percent at one year. The risk of death was increased for individuals undergoing emergency surgery, and for those who had any postoperative morbidity classified by Clavien Dindo >1.
We aimed to provide a means to a wider perspective where not only the type of surgery defines the planned postoperative care but rather the state of the patient, identified by the burden of disease and its effect on physical status as expressed by ASA-classification ≥3 and surgery severity that are identified as major to complex major. Currently, in Sweden the use of postoperative resources (nursing, physiotherapy, length of stay on postoperative care units) are rather based on the type of surgical procedure, than on individual needs.

An incorporation of the use of a surgical severity grading in a Swedish context requires attributing the Swedish surgical classification codes to relevant severity grading. In our study cohort this was done manually but could also be automatically generated for Swedish surgical procedure codes. We developed script codes (R script) that translated the Swedish surgical procedure codes into British codes, which enabled severity grading of procedures in the background population.

The translation and severity grading need to be validated and could then be plugged in any operation scheduling software, medical records, SPOR (Swedish PeriOperative Register) or other national registries. We suggest that providing such a ‘translation’ could be useful when describing case-mix and measuring outcome on a hospital level, when planning the postoperative care, and as hand-over information between levels of care.

This study is the first to use POMS screening tool in a Swedish health care context. The study provides estimates of postoperative morbidity using a validated tool (POMS) which could guide future outcome and prognostic research. The observed mortality is in line with previous publications on high-risk surgical patients.

The postoperative morbidity in this cohort is higher than postoperative complications reported in Swedish surgical quality registers. This is due to the differences between the criteria of morbidity and complications. The POMS capture adverse events, deviations from expected postoperative course in ten domains, and is a sensitive tool.

The validity of our cohort is supported by that the case-mix of the PROFS cohort is comparable with the ASA 3-4 subpopulation of the POMS validation study. However, the main sources of morbidity were different in the POMS validation population and the PROFS cohort. The most common source in the PROFS cohort was mobilisation, renal and pain (needing treatment), in the POMS validation study infectious, gastrointestinal and renal. This difference could be explained by that mobilisation was not reported in the ASA 3-4 group in the POMS validation cohort. The high prevalence of pain related morbidity on day 3 could be attributed to the use of postoperative regional anaesthesia, that is epidurally administered pain-relief (Appendix Box 2, definition of pain related morbidity) which is a clinical routine for both elective and emergency major

### TABLE 2 Prevalence of observed postoperative morbidity in the cohort

| Morbidity type | Postoperative day | Number (% of participants) |
|----------------|-------------------|-----------------------------|
|                | 3 ± 1             | 7 ± 1                       | 10-15                      |
| Mobilisation   | 645 (60.7)        | 399 (37.5)                  | 336 (31.6)                 |
| Renal          | 519 (48.8)        | 231 (21.7)                  | 182 (17.1)                 |
| Pain           | 406 (38.2)        | 155 (14.6)                  | 88 (8.3)                   |
| Infection      | 283 (26.6)        | 235 (22.1)                  | 221 (20.8)                 |
| Pulmonary      | 254 (23.9)        | 107 (10.1)                  | 83 (7.8)                   |
| Gastrointestinal | 226 (21.3)      | 159 (15.0)                  | 113 (10.6)                 |
| Cardiovascular | 133 (12.5)        | 58 (5.5)                    | 51 (4.8)                   |
| Haematological | 92 (8.7)          | 20 (1.9)                    | 31 (2.9)                   |
| Neurological   | 81 (7.6)          | 45 (4.2)                    | 28 (2.6)                   |
| Wound healing  | 14 (1.3)          | 18 (1.7)                    | 30 (2.8)                   |
| Cumulative number of observed morbidities | 2653 n.a | 1427 n.a | 1163 n.a |
| Patients with any morbidity | 829 (78.0) | 512 (48.2) | 503 (47.3) |
| Patients discharged | 90 (8.5) | 431 (40.5) | 643 (60.5) |
| Patients with any missing data in the POMS dataset | 72 (6.8) | 86 (8.1) | 24 (2.3) |

Note: Morbidity was extracted from medical records by using the Postoperative Morbidity Survey (POMS) on postoperative days 3 ± 1, 7 ± 1 and 10-15. The prevalence of each type of morbidity is expressed by number and by percentage of participants with the observed morbidity within the whole cohort (n = 1063). The cumulative number of observed morbidities, number of patients with any of the morbidities, (ie, composite morbidity), discharged patients and patients with any missing data in the morbidity dataset are also displayed.
gastrointestinal surgeries in Sweden. The presence of morbidity in all domains declined over time, except for infections, which had an almost unchanged level around 27/22/21 per cent between days 3 and 10.

The POMS screening tool has been described as a robust method. The advantage of POMS is that it is validated for both prospective and retrospective screening of medical records and in the present cohort the study sites could choose to use any of the screening methods. The POMS tool has been reported to have low inter-rate variability and is recommended in reporting guidelines of perioperative outcome studies. The Clavien-Dindo grading system was initially proposed to grade the severity of surgical complications.
**TABLE 3** Classification of the severity of postoperative morbidity (numbers and %) according to Clavien-Dindo\(^8\) after identification of morbidity according to POMS\(^7\)

| Clavien-Dindo grade | ASA 3 (n = 939) Number (%) | ASA 4 (n = 124) Number (%) | Total (n = 1063) Number (%) |
|---------------------|-----------------------------|-----------------------------|-----------------------------|
| No deviation from normal course | 495 (52.7) | 35 (28.2) | 530 (49.9) |
| Any deviation from normal course | 444 (47.3) | 89 (71.8) | 533 (50.1) |
| 1 | 116 (26.1) | 9 (10.1) | 125 (23.5) |
| 2 | 220 (49.6) | 36 (40.5) | 256 (48.0) |
| 3a | 34 (7.7) | 7 (7.9) | 41 (7.7) |
| 3b | 24 (5.4) | 6 (6.7) | 30 (5.6) |
| 4 | 20 (4.5) | 10 (11.2) | 30 (5.6) |
| 5 | 25 (5.6) | 19 (21.4) | 44 (8.3) |
| Missing data | 5 (1.1) | 2 (2.3) | 7 (1.3) |

Note: The whole cohort and ASA 3 and 4 patients are displayed. Grade 1. Any deviation from normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside. Grade 2. Requiring pharmacologic treatment with drugs other than such allowed for grade 1 complications. Grade 3. Requiring surgical, endoscopic and radiological interventions. (a) Interventions not under general anaesthesia and (b) interventions under general anaesthesia. Grade 4. Life-threatening complication requiring intensive care management. Grade 5. Death of the patient.

**FIGURE 2** Cumulative risk of death (Kaplan-Meier plot) between postoperative days 0-360 after emergency or elective surgical procedures included in the prospective Study cohort of ASA ≥3 patients undergoing major to complex major surgery according to AXA PPP/Specialist Procedure Codes (AXA-insurance company with Public-Private Partnership).\(^5\) Number at risk and cumulative number of events are given

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We graded the severity of postoperative morbidity (by POMS\textsuperscript{8} criteria) in the postoperative period and found increased risk for death with any POMS defined morbidity grade >1.

Protocolized care to achieve enhanced recovery in patients undergoing high-risk surgery have been widely implemented. Those protocols are currently designed per type of surgery. During the last decade, older patients with several comorbidities are offered curative or reparative major and major complex surgery. We suggest that these patients rather need individually tailored care and that the first step to prepare for introducing individual decisions is to identify groups with the high risk. A further argument for individual tailored care is that the ethical platform for prioritization process of health care in Sweden, states that those who are at greatest risk/need have the highest priority. This raises the question whether the currently used protocols and allocation of resources need to be refined and individualized for the current high-risk patients in tertiary hospitals.\textsuperscript{11,12}

The prospective study cohort have several limitations. One is that not all eligible patients entered the cohort. The difference between the manually obtained prospective Study cohort and the electronically obtained eligible population, was approximately 30% (1089 included vs 1595 eligible). The case mix and postoperative mortality of the eligible population was comparable with the prospective Study cohort which suggest that the cohort could be described as representative.

Another possible limitation of the study could be any misclassification in either the ASA categories and/or in the UK surgical severity coding system. The ASA classification is subjective but has been found to be robust in large populations.\textsuperscript{13} To minimize researcher induced selection bias the ASA classification was done by attending clinicians and was not revised by the research team. In Sweden there is no uniform grading system of size and severity of surgery. As a uniform grading is required if fair comparisons are aimed for, we applied UK surgical severity grading for the selection of the population. The Swedish and UK surgical procedure codes, ie the name of the surgical procedures, are not identical. So, major surgery could erroneously have been classified as major complex or vice versa as in any categorization/translation. A possible flaw in using the UK surgical severity grading system, in this study not attended to, is that the UK coding system of surgery was developed to establish reimbursement in independent UK hospitals. Besides the magnitude and severity of surgery, reimbursement also must consider technical requirements for the surgery. This is illustrated by the low morbidity and mortality in the emergency urologic group that in the system is classified having a high severity.

We suggest that the results are generalizable to other academic hospitals in Sweden, but also to countries with similar health care system as the Scandinavian countries as this is a multicentre study including 4 tertiary hospital on 5 sites. It would be highly interesting to perform a new study in a multinational context. Such an initiative
could be supported by ESA guidelines who recommend a more uniform postoperative follow-up, by for example POMS,14 and the excellent article from Kappen TH et al15 about lessons learnt when pursuing the track of clinical prediction.

It could also be reasonable to study if protocolized or individual designed interventions triggered by the occurrence of any POMS graded as >1 by Clavien-Dindo, that is, demonstrating a deviation in the clinical course, could affect long-term mortality in this high-risk group. A further line of interest would be to investigate how this cohort would be described if classified by NSQIP16 or other individualized scores or in relation to the level of postoperative care.

This study adds basic information about the morbidity and mortality in patients who are offered major to complex major surgery and presenting with an ASA classification of 3 or more in the context of academic hospitals in Sweden.

5 | CONCLUSIONS

Preoperative severity classification as major to complex major according to AXA PPP/Specialist Procedure Codes and ASA:3 could be used to identify a high-risk surgical population concerning postoperative morbidity and mortality before gastrointestinal and orthopaedic but not urological surgery. Combing the two-classification systems provides a future possibility for electronic data extraction of a high-risk population in tertiary hospitals.

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Erzebet Bartha: Conception, design and planning of the study, data analyses, manuscript preparation and revisions; Rebecka Ahlstrand: Design and planning of the study, interpretation of data, manuscript revisions; Max Bell: Design and planning of the study, manuscript revisions, data interpretation; Olof Brattström: Design and planning of the study, manuscript revisions, data interpretation; Håkan Björne: Design and planning of the study, manuscript revisions, data interpretation; Johan Helleberg: Design and planning of the study, data collection, data extraction, data interpretation, data analyses and manuscript revision; Lena Nilsson: Design and planning of the study, manuscript revisions, data interpretation; Egidijus Semenas: Design and planning of the study, manuscript revisions, data interpretation;Sigridur Kalman: Conception, design and planning of the study, data analyses, manuscript preparation and revisions.

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**SUPPORTING INFORMATION**

Additional supporting information may be found online in the Supporting Information section.

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