Title of Study or Project:	The Interference of Anti-hemostatic Medication with Neuraxial Analgesia Use
Primary Institution:	University Medical Center Utrecht, The Netherlands
Principal Investigator:	Cor J. Kalkman MD PhD
Co-Investigators:	Elke M.E. Bos MD, Werner ten Hoope MD, Fabian Kooij MD PhD, Marcel de Quelerij MD, Markus W. Hollmann MD PhD, Wilton A. van Klei MD PhD, Philipp Lirk MD PhD
Type of Study:	Multicenter retrospective observational cohort study
IRB Number/Status:	Approved by the University of Michigan. The Medical Research Ethics Committee (MREC) of the University Medical Center Utrecht (UMCU) has reviewed and approved participation of the UMCU in the MPOG study database (12-253C). The MERC of the UMCU was asked for a waiver for documentation of consent for this study protocol as cases will not be subjected to investigational actions. The MERC confirmed that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study protocol and therefore an official approval of this study by the MREC of the UMCU is not required under the WMO (18/769). Patient confidentiality will be guaranteed according to the Dutch law on personal data protection.
Hypothesis:	The use of anti-hemostatic medication is a likely determinant of neuraxial analgesia use (i.e. epidural analgesia). We hypothesize that increased use of anti-hemostatic medication in the surgical and traumatic rib fracture population has led to a decreased use of neuraxial analgesia over time.
Number of Patients/Participants:	Inclusion: all adult patients (≥18 years of age) treated with neuraxial analgesia and all adult patients (≥18 years of age) with a valid indication for neuraxial analgesia for perioperative and trauma indications between January 1, 2008 to the present. Exclusion: • ear, nose, throat (ENT) surgery • ophthalmologic procedures • intracranial/extracranial neurosurgery • head or neck surgery

	• obstetric patients • neuraxial analgesia for chronic pain indications
Power Analysis:	Not applicable.
Proposed statistical test/analysis:	Descriptive analysis of the utilization of neuraxial analgesia and the utilization of anti-hemostatic medication in the perioperative and traumatic rib fracture population. Besides, we will develop a generalized linear mixed-effect model, to reduce confounding and random effects, with the goal to analyze the association between pre-procedure use of anti-hemostatic medication and utilization of neuraxial analgesia over time.
Resources (Brief summary of resources for data collection, personnel, financial):	De-identified case data from the Multicenter Perioperative Outcomes Group (MPOG) database will be acquired. Operational oversight and statistical analyses will be funded by the Department of Anesthesiology of the Amsterdam University Medical Center (Amsterdam UMC), the Netherlands and the University Medical Center Utrecht, the Netherlands. Cor J. Kalkman — Anesthesiologist, UMC Utrecht, the Netherlands Wilton A. van Klei — Anesthesiologist, UMC Utrecht, the Netherlands Elke M.E. Bos — Anesthesiology Resident and PhD candidate, Amsterdam UMC, the Netherlands Philipp Lirk — Anesthesiologist, Brigham & Women's Hospital, Boston, MA, USA Marcel de Quelerij — Anesthesiologist, Franciscus Gasthuis & Vlietland, Rotterdam, the Netherlands Markus W. Hollmann — Anesthesiologist, Amsterdam UMC, the Netherlands Werner ten Hoope — Anesthesiologist, Amsterdam UMC, the Netherlands Fabian Kooij — Anesthesiologist, MPOG coordinator Amsterdam UMC, the Netherlands Linda Peelen — Associate professor Epidemiology, UMC Utrecht, the Netherlands

Interference of Anti-hemostatic Medication with Neuraxial analgesia Use: A Report from the Multicenter Perioperative Outcomes Group

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Introduction

Despite the development of minimally invasive surgery and alternative analgesic techniques, epidural analgesia remains the preferred technique to provide postoperative analgesia for certain surgical interventions as well as for pain treatment in traumatic rib fracture patients.[1]

At the same time, there is increasing awareness of the patient-specific risks for complications after neuraxial analgesia, such as spinal hematoma, which may carry a significant burden in terms of morbidity and mortality.[2] There is evidence suggesting that the incidence of spinal hematoma after neuraxial analgesia is higher than reported in previous decades[3] and one prominent risk factor for developing such a complication is the use of anti-hemostatic medication.[4,5] The changes in anti-hemostatic medication use that occurred over the past 10 years - specifically in patients receiving neuraxial analgesia – is unknown. Furthermore, the use of such medication may influence the decision to apply a neuraxial technique, and therefore increased use of anti-hemostatic medication in the population might have reduced neuraxial analgesia use in the surgical and traumatic population over the past decade.

What current gaps exist in the understanding of this problem?

We hypothesize that in the context of an ageing society an increased proportion of patients use anti-hemostatic medication as part of primary or secondary prevention of cardiovascular disease,[6–8] which may have an impact on the use of neuraxial analgesia (i.e., anesthesiologists may be more reluctant to use epidural analgesia in patients using these drugs). The exact pattern of the changes

that occurred over the past 10 years in use of anti-hemostatic medication - specifically in patients receiving central neuraxial analgesia – is unknown. It is also not known what proportion of patients with a valid indication for neuraxial analgesia are current users of one or more anti-hemostatic drugs and whether such use influences the decision-making process regarding neuraxial analgesia in these patients.

How will this project address this gap and advance clinical care and/or research knowledge?

We intend to use the Multicenter Perioperative Outcomes Group (MPOG) database to examine patients with a valid indication for a neuraxial anesthetic technique in the surgical and traumatic population (domain) for patients using anti-hemostatic drugs (anticoagulant and/or antiplatelet medication) preoperatively (determinant), patients that received neuraxial analgesia for perioperative or trauma indications (outcome) and for the effect of anti-hemostatic medication on the use of neuraxial analgesia in surgical and traumatic patients (secondary outcome).

Our hypothesis is that over the last decade an increased proportion of patients use anti-hemostatic medication, which may be associated with a decrease in utilization of neuraxial analgesia. It is important to understand the proportion of patients using anti-hemostatic medication receiving neuraxial analgesia, to assess the magnitude of the problem concerning anti-hemostatic medication and alterations in medication use that may be necessary to perform neuraxial analgesia safely. We decided to exclude obstetric patients from analysis, as we expect no changes in anti-hemostatic medication use in the course of the past 10 years in this young and relatively healthy population and the occurrence of complications is seldom in this patient category.[1,9]

Methods

Study database and Population

We intend to use the Multicenter Perioperative Outcomes Group (MPOG) database. MPOG is a consortium of institutions formed in 2008 with a shared data set facilitating the investigation of

perioperative outcomes.[10] Details on the goals and structure of MPOG have been described in previous publications.[11,12] Data will be collected after routine medical care has been provided, therefore, the MREC of the University Medical Center Utrecht, the Netherlands (UMCU) approved a waiver for informed consent for this study protocol, as cases will not be subjected to investigational actions. We intend to extract data from anesthesia information system records that has been submitted electronically by participating institutions to the MPOG centralized database at the University of Michigan. Participating centers will be selected among MPOG contributing centers based upon the availability of structured documentation for key variables necessary for analysis: registration of neuraxial analgesia, description of medication use prior to neuraxial analgesia (home medication pre-operatively), performance of certain surgical procedures that are considered as major indications for epidural analgesia; i.e. thoracotomy, thoracotomy for pulmonary surgery, major upper abdominal laparotomy, cancer-related abdominal debulking procedures and epidural analgesia for trauma patients.[13,14] The participating institutions may require individual institutional IRB approval for creation and transmission of a limited dataset to the centralized coordinating center.[15]

We will perform this research consistent with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

Detailed Statistical Approach

IRB statement

The project was submitted to UMCU MERC for expedited approval with a limited de-identified dataset. The MERC confirmed that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study protocol and therefore an official approval of this study by the MREC of the UMCU is not required under the WMO (18/769).

Study type

The study design for this research is an international multicenter, retrospective observational cohort study.

Primary outcome

1. **Epidemiology of anti-hemostatic medication use in patients treated with neuraxial analgesia**

The primary outcome of this study is the use of anti-hemostatic medication in patients receiving neuraxial analgesia as a component of their anesthetic regimen within the surgical and traumatic rib fracture population in the course of the past 10 years. Databases will be queried from January 1, 2008 to the present. Differences will be evaluated by year of the procedure.

Central neuraxial analgesic procedures to be studied include:

- epidural catheter insertions
- spinal catheter insertions (for analgesic purposes)
- combined-spinal-epidural techniques

The following surgical procedures and patient categories are considered as specific indications for neuraxial analgesia:

- thoracotomy
- major upper abdominal laparotomy (esophagus, pancreas, liver, stomach, spleen, colon)
- cancer-related abdominal debulking procedures (e.g. urology/gynecology)
- trauma patients with one or more rib fractures

The cohort of patients who received neuraxial analgesia will then be screened for use of anti-hemostatic medication within a time frame of two weeks prior to the neuraxial block (vitamin K-antagonists, unfractionated heparin and low-molecular-weight heparins, fondaparinux, heparinoids, direct thrombin inhibitors, factor X inhibitors, Adenosine diphosphate (ADP) receptor-antagonists, and glycoprotein IIb/IIIa-inhibitors).

Secondary outcomes

We formulated the following secondary outcomes:

2. **Epidemiology of anti-hemostatic medication use in patients with a valid indication for neuraxial analgesia in the surgical and traumatic rib fracture population.**

   Use of pre-procedure anti-hemostatic medication (number of patients) by year in patients with a valid indication for neuraxial analgesia in the surgical and traumatic rib fracture population in the period January 1, 2008 to the present.

3. **Epidemiology of neuraxial analgesia use for specific surgical/traumatic indications.**

   Use of neuraxial analgesia (number of procedures) for each of the listed indications (see above) by year in patients with a valid indication for neuraxial analgesia in the surgical and traumatic rib fracture population in the period January 1, 2008 to the present (and then stratify the analysis for patients who were using anti-hemostatic medication preoperatively and those who did not receive such drugs).

4. **Effect of pre-procedure anti-hemostatic medication use on neuraxial analgesia utilization.**

   Effect of pre-procedure anti-hemostatic medication use (antiplatelet and/or anticoagulant medication) (determinant) on the utilization of neuraxial analgesia (outcome) in the course of the past 10 years in patients with a valid indication for neuraxial analgesia in the surgical and traumatic rib fracture population (domain).

5. **Incidence of spinal (epidural) hematoma after neuraxial analgesia in patients not using anti-hemostatic medication versus patients using anti-hemostatic medication.**

   We wish to study the incidence of spinal (epidural) hematoma (outcome) after neuraxial analgesia (domain) and compare the incidence in patients not using any anti-hemostatic medication versus patients using anti-hemostatic medication (determinant) within two weeks prior to neuraxial procedure or surgical case.

Hypotheses

For the **primary outcome** we developed the following hypothesis:

The prevalence of anti-hemostatic medication use (antiplatelet and/or anticoagulant medication) in patients who received neuraxial analgesia as part of their anesthetic regimen for perioperative indications or traumatic rib fractures changed in the course of the past 10 years.

For the **secondary outcomes** we developed the following hypothesis:

- The prevalence of anti-hemostatic medication use in patients with a valid indication for neuraxial analgesia in the surgical and traumatic rib fracture population changed in the course of the past 10 years.
- The use of neuraxial analgesia (number of procedures) changed in the course of the past 10 years for each of the valid indications for neuraxial analgesia in the surgical and traumatic rib fracture population.
- The prevalence of anti-hemostatic medication use (antiplatelet and/or anticoagulant medication) in patients receiving neuraxial analgesia as part of their anesthetic regimen for perioperative or trauma indications differs from the prevalence of anti-hemostatic medication use (antiplatelet and/or anticoagulant medication) in patients with a valid indication for neuraxial analgesia but treated with an alternative (analgesic) technique.
- Pre-procedure anti-hemostatic medication use (antiplatelet and/or anticoagulant medication) (determinant) influences the utilization of neuraxial analgesia (outcome) in the course of the past 10 years in patients with a valid indication for neuraxial analgesia in the surgical and traumatic rib fracture population (domain).
- The incidence of spinal (epidural) hematoma after neuraxial analgesia in patients without pre-procedure anti-hemostatic medication is different from the incidence of patients using anti-hemostatic medication.

Search strategy

A search will be performed in the anesthesia information system records of participating institutions to identify cases. Specific search terms will be determined in collaboration with the MPOG investigators, and will roughly comprise: 'neuraxial block', 'neuraxial analgesia', 'spinal', 'epidural', 'CSE' and synonyms. Furthermore specific surgical procedures will be identified using the appropriate CPT (or equivalent) codes for procedures classified as 'thoracotomy', 'major upper abdominal laparotomy' (including, but not exclusively, gastrectomy, liver resection, esophagectomy, open hiatus hernia repair, pancreatic surgery, PPPD/Whipple, adrenalectomy (open), nephrectomy (open), and cancer-related abdominal debulking procedures (i.e. gynecology, radical cystectomy (open), radical cystoprostatectomy (open)). The International Classification of Diseases (ICD) procedure coding system may be used to identify appropriate interventions and patient categories "*(for inclusion as a major abdominal operation, organ-specific resections can be categorized as follows: esophagus, codes 42.4 and 42.40 through 42.42; stomach, codes 43.5 through 43.7, 43.81, 43.9, 43.91, and 43.99; liver, codes 50.22 and 50.3; and pancreas, codes 52.5, 52.51, 52.52, 52.53,52.59, 52.6, and 52.7. Diagnoses for malignant neoplasms within each organ were also categorized as follows: esophagus, codes 150.0 through 150.5, 150.8, and 150.9; stomach codes 151.1 through 151.6, 151.8, 151.9, and 209.23; liver, codes 155.0, 155.2, 197.7, 235.3, and 209.72; and pancreas, codes 157.0, 157.1, 157.2, 157.8, and 157.9.)*".[16] Definitive search terms will be determined in consultation with collaborating MPOG investigators.

Patient inclusion/exclusion criteria

All adult patients (≥18 years of age) treated with neuraxial analgesia and all adult patients (≥18 years of age) with a valid indication for neuraxial analgesia for perioperative (elective and urgent procedures) and acute pain (rib fractures) indications between January 1, 2008 to the present.
We will exclude ear, nose, throat (ENT) surgery, ophthalmologic procedures and head or neck surgery, since these procedures are not applicable for neuraxial analgesia use. Furthermore, obstetric patients will be excluded, as we expect no changes in anti-hemostatic medication use in the

course of the past 10 years in this young and relatively healthy population and severe complications are seldom in this patient category. Also patients receiving neuraxial analgesia for chronic pain indications will be excluded if chronic pain is the primary indication for neuraxial analgesia, however, if patients receive a neuraxial procedure for perioperative or acute pain (trauma) purposes the patient will be included in analysis.

Data source

MPOG Database.

Confounders

We composed a Directed Acyclic Graph to identify possible confounders that may influence both the outcome (utilization of neuraxial analgesia) and the exposure (anti-hemostatic medication), see Figure 1. Possible confounders are: cardiovascular disease, cardiomyopathy and/or cardiac valve morbidity (mitral, tricuspid, aortic, pulmonary valve stenosis/insufficiency), hypertension, Diabetes Mellitus type 2, obesity, osteoporosis, cancer, age, major surgery and trauma/rib fractures. Based on the Directed Acyclic Graph, the minimal sufficient adjustment set for estimating the total effect of anti-hemostatic medication on neuraxial analgesia utilization is: Cardiovascular Disease, Major Surgery (valid indication Neuraxial Analgesia), Rib Fractures (trauma)

We intend to evaluate perioperative patients and trauma patients separately, which will reduce the bias in our analysis. Nevertheless, we will have to control for the presence of cardiovascular disease.

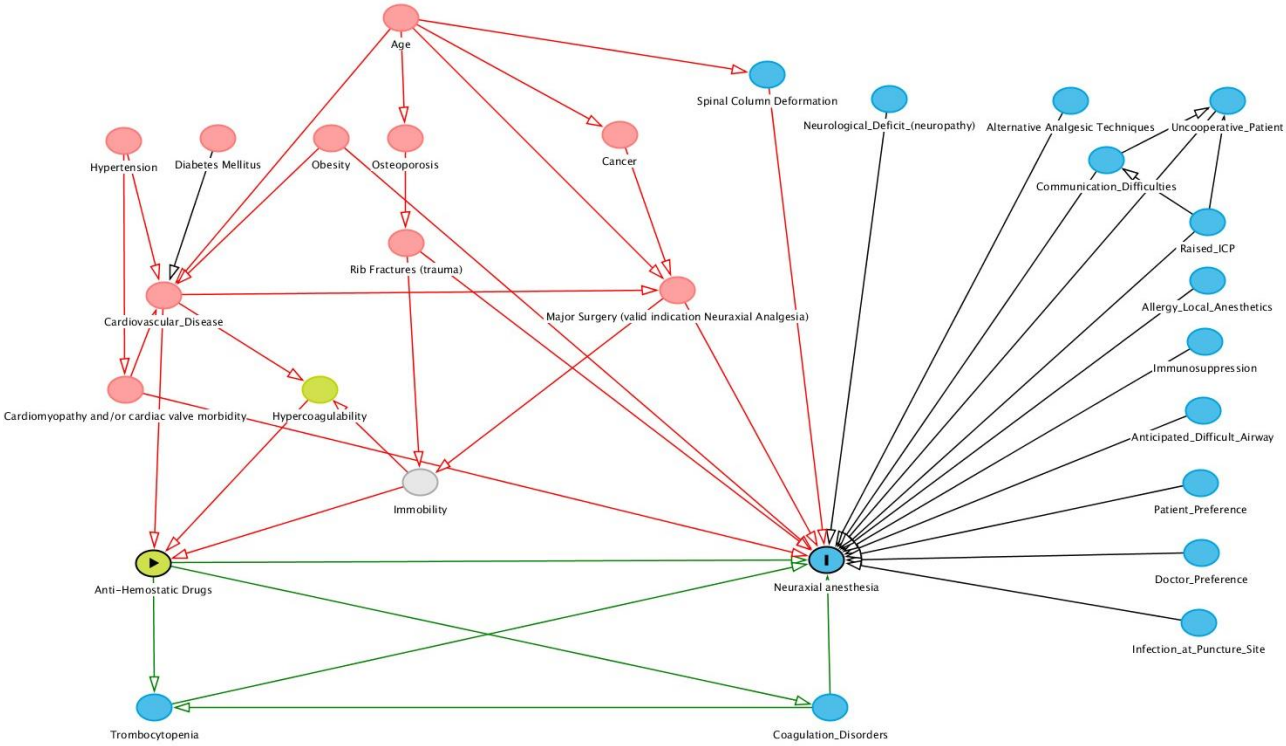

Figure 1. Directed Acyclic Graph for the association between anti-hemostatic drugs and neuraxial analgesia. Possible confounding variables are displayed in red.

Statistical analysis

The unit of analysis is the anesthesia case, thus if a patient requires multiple interventions within the study period, possibly with the use of neuraxial analgesia in some procedures, this patient will be included more than once. We wish to perform separate analyses for the perioperative population and for traumatic rib fracture patients. Within those two populations, two cohorts (domains) will be analyzed; patients with a valid indication for neuraxial analgesia (ultimately treated with alternative analgesic techniques), and patients treated with neuraxial analgesia within this population (see stratified analysis below).

Descriptive statistics

Demographics will be described with categorical data presented in numbers (quantity) and continuous data with mean and standard deviation or median and interquartile range based on

normal or non-normal distribution. To explore differences between patients treated with neuraxial analgesia and patients treated with alternative analgesic techniques (but with a valid indication for neuraxial analgesia), categorical variables will be compared using Pearson's $\chi 2$ tests or Fisher's exact tests; continuous variables will be compared using unpaired t-tests or Mann-Whitney U Tests, for non-normally distributed variables, as appropriate. Proportions will be represented with 95% Confidence Intervals. A *p*-value of <.05 is the criterion for statistical significance.

Stratified analysis. We will stratify our analysis for patients who were using anti-hemostatic medication preoperatively and those who did not receive such drugs.

Generalized linear mixed-effects model. To examine the effect of anti-hemostatic medication on neuraxial analgesia use within patients with a valid indication for neuraxial analgesia, we will conduct a generalized linear mixed-effect model for the dichotomous outcome 'utilization of neuraxial analgesia'. This model will include confounding variables, random effects (stratification for the variable 'center' as random effect), and the interaction term (time * anti-hemostatic medication).

The statistical tests and analysis will be performed using SPSS version 24 (IBM Corporation, Armonk, NY, USA). A two-sided *p*-value of <.05 is the criterion for statistical significance.

Power analysis

Not applicable.

Variables to be collected

Patient characteristics: age, sex, ASA physical status, weight, height, body mass index (BMI), medical history, specifically cardiovascular disease (comprising coronary heart disease, cerebrovascular

disease, peripheral arterial disease, rheumatic heart disease, congenital heart disease, deep vein thrombosis), medication use (home medication).

Medication use: anticoagulant/antiplatelet drugs, (possibly all drugs), within 2 week prior to surgery.

- **vitamin K-antagonists**: *warfarin, coumatetralyl, phenprocoumon, acenocoumarol, dicoumarol, tioclomarol, brodifacoum, pindone, chlorophacinone, diphacinone, anisindione, fluindione, phenindione*
- **unfractionated heparin**
- **low-molecular-weight heparins**: *enoxaparin, dalteparin, nadroparin, tinzaparin, certoparin, reviparin, ardeparin, parnaparin, bemiparin*
- **heparinoids**: *danaparoid*
- **fondaparinux**
- **direct thrombin inhibitors**: *hirudin, bivalirudin, lepirudin, desirudin, argatroban, dabigatran, inogatran, melagatran, ximelagatran*
- **factor X inhibitors**: *rivaroxaban, apixaban, betrixaban, darexaban, edoxaban, otamixaban, letaxaban, eribaxaban.*
- **ADP receptor-antagonists**: *ticagrelor, clopidogrel, prasugrel, ticagrelor, cangrelor, elinogrel, ticlopidine.*
- **Glycoprotein IIb/IIIa-inhibitors**: *abciximab, eptifibatide, tirofiban, roxifiban, orbofiban.*

Procedure characteristics: elective/urgent, duration of intervention, intervention (e.g. gastrectomy, liver resection, esophagectomy, open hiatus hernia repair, pancreatic surgery, PPPD/Whipple, adrenalectomy (open), nephrectomy (open), and cancer-related abdominal debulking procedures (i.e. gynecology, radical cystectomy (open), radical cystoprostatectomy (open)).

Analgesic technique characteristics: neuraxial analgesia (epidural catheter, spinal catheter, and combined-spinal-epidural procedures), intravenous analgesia (PCA), wound catheters, peripheral nerve blocks (axillary, supraclavicular, infraclavicular, interscalene, popliteal sciatic, sciatic (anterior, transgluteal, subgluteal), femoral, saphenous, adductor canal, fascia iliaca, obturator).

Spinal hematoma: hematoma below C0 in the epidural, subdural, subarachnoid, and/or intraspinal space, or in the paraspinal muscles.

Element	**Source**
MPOG case identifier	General_Case_Information.MPOG_Case_ID
MPOG patient identifier	General_Case_Information.MPOG_Patient_ID
MPOG institution identifier	General_Case_Information
Case Date (or year)	General_Case_Information.AIMS_Scheduled_DT
Scheduled procedure description from AIMS text	General_Case_Information.AIMS_Scheduled_Procedure_Text – see appendix for search terms
Actual procedure description from AIMS text	General_Case_Information.AIMS_Actual_Procedure_Text – see appendix for search terms
Primary Surgical Service	General_Case_Information. MPOG_Primary_Procedural_Service_Concept_ID
Primary Surgical Service	General_Case_Information. MPOG_Primary_Procedural_Service_Concept_Desc
Anesthesia CPT code	General_Case_Information. Charge_Capture_Primary_Anesthesia_Code – 01961, 1961, 01967, 1967, 00600 – 00700
Surgery CPT code	General_Case_Information. Charge_Capture_Primary_Surgery_Code – 63000 - 70000
ICD code	General_Case_Information.Charge_Capture_Primary_Diagnosis_Code – 286.xx, 287.0, 287.1, 287.31, 287.8, 287.9
ASA class	ASA_Class.ASA_Class
Emergent	ASA_Class.Emergent
Height in cm	Anthropometrics.MPOG_height_cm
Weight in kg	Anthropometrics.MPOG_weight_kg
BMI	Anthropometrics.Body_Mass_index
Age	Patient_Demographics.AIMS_Patient_Age_Years
Gender	Patient_Demographics.AIMS_Sex
Medical history	
Smoking	Smoking_yn
Cardiovascular disease	Cardiovascular disease_yn (see below); coronary heart disease, cerebrovascular disease, peripheral arterial disease, rheumatic heart disease, congenital heart disease, deep vein thrombosis
Coronary heart desease	Coronary heart desease_yn
Cerebrovascular disease	Cerebrovascular disease_yn
Peripheral arterial disease	Peripheral arterial disease_yn
Congential heart disease	Congential heart disease_yn
Rheumatic heart disease	Rheumatic heart disease_yn
Deep vein thrombosis	Deep vein thrombosis_yn
Hypertension	Hypertension_yn
Diabetes Mellitus	DM_yn
Cardiomyopathy	Cardiomyopathy_yn
Mitral valve morbidity	Mitral valve morbidity_yn
Tricuspid valve morbidity	Tricuspid valve morbidity_yn
Aortic valve morbidity	Aortic valve morbidity_yn
Pulmonary valve morbidity	Pulmonary valve morbidity_yn
Block_yn	Anesthesia_Technique.Block_yn
Epidural_yn	Anesthesia_Technique.Epidural_yn
General_yn	Anesthesia_Technique.General_yn
Spinal_yn	Anesthesia_Technique.Spinal_yn
POC – Coulter counter – Platelets	Laboratory or Testing Observations - 3445
Formal lab- Platelets	Laboratory or Testing Observations - 5004
Hematologic – Anticoagulation	Preoperative Observations - 70243
Hematologic – Bleeding Disorder	Preoperative Observations - 70064

General- Medications – Anticoagulation	Preoperative Observations - 70073
Epidural	Anesthetic Technique View – 2005
Neuraxial – spinal performed	Anesthetic Technique View – 50680
Neuraxial technique – Combined Spinal/Epidural technique note	Anesthetic Technique View – 50614
Neuraxial – spinal catheter	
Peripheral nerve block	
Wound catheter	
Intravenous analgesia	

Handling of missing data

In retrospective epidemiologic research, data are often missing at a random pattern. Based on the amount of missing data we will decide whether it is appropriate to use the observed data and perform a complete case analysis, or to perform multiple imputations to limit the amount of bias.[17,18] If more than 5-10% of data is missing we will perform multiple imputation, otherwise we will perform the statistical analysis using the observed data.[19]

Areas for discussion/known limitations

- Validity of the registration of medication use (home medication)
- Validity of the registration of neuraxial analgesia
- Completeness of indications for neuraxial analgesia; inclusion or exclusion of specific types of procedures, adequacy of CPT/ICD code
- Completeness of anti-hemostatic medication, (i.e. addition of other medication types that may increase bleeding risk)
- Inclusion/exclusion of trauma population
- Inclusion/exclusion of patients treated with spinal catheter
- Inclusion/exclusion of patients with genetic connective tissue disorders (Marfan/ Ehlers Danlos syndromes)
- Missing data and resulting unknown selection bias

- Time variable: analysis per year, per 6 months, per month
- MPOG population may differ from general population undergoing anesthesia

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Case report form

MPOG Case ID: _____

(1) Description of surgery:

Intervention _____

Emergency surgery (as defined by ASA status) Yes ____ No ____

Duration of surgery _____hrs _____min (from incision to time out of OR)

(2) Description of trauma:

Which organs are damaged:

___head and neck

___face

___chest

___abdomen

___extremity

___external

Injury Severity Score _____

Emergency surgery (as defined by ASA status) Yes ____ No ____

Ribfractures: Yes ____, No ____

Level and number of fractures: _____

Laterally: Rt._____, Lt. _____, Bilateral _____

(3) Description of neuraxial analgesia placement:

Type of neuraxial analgesia: epidural _____ spinal _____ CSE ____ Spinal catheter ____

Time of neuraxial analgesia placement: _____ (0 to 24:00)

Needle gauge/type_____

Number of placement attempts_____

Approach: Midline _____, paramedian _____

Loss of resistance to: Air _____, Saline _____

Bloody placement: Yes ____, No ____ (blood dripping from needle at any time during placement procedure)

Initial intravascular placement: Yes ____, No ____

Level of placement (eg L2/3 T9/10, etc): _____

Length of catheter left in space (cm) _____

Place catheter was placed (operating room, labor and delivery room)_____

INR when: (1) catheter placed_____, (2) catheter removed_____

Partial thromboplastin time when: (1)catheter placed_____, (2)catheter removed_____

Platelet count when: (1) catheter placed_____, (2) catheter removed_____

Length of time catheter is left in place (hours) _____hrs.

(4) Description of alternative analgesic technique:

Wound catheters: Yes ____, No ____

Intravenous analgesia: Yes ____, No ____

Peripheral nerve block: Yes ____, No ____

Type of peripheral nerve block: axillary _____ supraclavicular _____ infraclavicular _____ interscalene _____ popliteal sciatic _____ sciatic (anterior, transgluteal, subgluteal) _____ femoral _____ saphenous _____ adductor canal _____ fascia iliaca _____ obturator _____

Needle gauge/type_____

Number of placement attempts_____

Bloody placement: Yes ____, No ____ (blood dripping from needle at any time during placement procedure)

Initial intravascular placement: Yes ____, No ____

Length of catheter inserted (cm) _____

(5) Description of patient:

Patient age_____

ASA Status 1 ___ 2 ____ 3 ____ 4 ____ 5 ____ E Yes ___ No ___

Body mass index (kg / m2) _____

Presence of comorbidity (check all that apply):

___ coronary heart disease

___cerebrovascular disease

___peripheral arterial disease

___rheumatic heart disease

___congenital heart disease

___deep vein thrombosis and pulmonary embolism

___ cardiomyopathy

___ mitral valve morbidity (stenosis/insufficiency)

___ tricuspid valve morbidity (stenosis/insufficiency)

___ aortic valve morbidity (stenosis/insufficiency)

___ pulmonary valve morbidity (stenosis/insufficiency)

___ Hypertension requiring chronic medication

___Chronic renal disease, baseline creatinine_____

___Acute renal failure, peak creatinine_____

___Congenital coagulopathy, describe type_____

___History of spinal surgery including kyphoplasty/laminectomy, describe procedure:

_____, and level_____

Preoperative antiplatelet/anticoagulation medications and dose (check and write dosing for all that apply, and the time stopped (day, hour) prior to surgery)

Warfarin Dose_____ Time stopped, days before surgery:_____

Coumatetralyl Dose_____ Time stopped, days before surgery:_____

Phenprocoumon Dose_____ Time stopped, days before surgery:_____

Acenocoumarol Dose_____ Time stopped, days before surgery:_____

Dicoumarol Dose_____ Time stopped, days before surgery:_____

Tioclomarol Dose_____ Time stopped, days before surgery:_____

Brodifacoum Dose_____ Time stopped, days before surgery:_____

Pindone Dose_____ Time stopped, days before surgery:_____

Chlorophacinone Dose_____ Time stopped, days before surgery:_____

Diphacinone Dose_____ Time stopped, days before surgery:_____

Anisindione Dose_____ Time stopped, days before surgery:_____

Fluindione Dose_____ Time stopped, days before surgery:_____

Phenindione Dose_____ Time stopped, days before surgery:_____

Enoxaparin Dose_____ Time stopped, days before surgery:_____

Dalteparin Dose_____ Time stopped, days before surgery:_____

Nadroparin Dose_____ Time stopped, days before surgery:_____

Tinzaparin Dose_____ Time stopped, days before surgery:_____

Certoparin Dose_____ Time stopped, days before surgery:_____

Reviparin Dose_____ Time stopped, days before surgery:_____

Ardeparin Dose_____ Time stopped, days before surgery:_____

Parnaparin Dose_____ Time stopped, days before surgery:_____

Bemiparin Dose_____ Time stopped, days before surgery:_____

Danaparoid Dose_____ Time stopped, days before surgery:_____

Fondaparinux Dose_____ Time stopped, days before surgery:_____

Hirudin Dose_____ Time stopped, days before surgery:_____

Bivalirudin Dose_____ Time stopped, days before surgery:_____

Lepirudin Dose_____ Time stopped, days before surgery:_____

Desirudin Dose_____ Time stopped, days before surgery:_____

Argatroban Dose_____ Time stopped, days before surgery:_____

Dabigatran Dose_____ Time stopped, days before surgery:_____

Inogatran Dose_____ Time stopped, days before surgery:_____

Melagatran Dose_____ Time stopped, days before surgery:_____

Ximelagatran Dose_____ Time stopped, days before surgery:_____

Rivaroxaban Dose_____ Time stopped, days before surgery:_____

Apixaban Dose_____ Time stopped, days before surgery:_____

Betrixaban Dose_____ Time stopped, days before surgery:_____

Darexaban Dose_____ Time stopped, days before surgery:_____

Edoxaban Dose_____ Time stopped, days before surgery:_____

Otamixaban Dose_____ Time stopped, days before surgery:_____

Letaxaban Dose_____ Time stopped, days before surgery:_____

Eribaxaban Dose_____ Time stopped, days before surgery:_____

Ticagrelor Dose_____ Time stopped, days before surgery:_____

Clopidogrel Dose_____ Time stopped, days before surgery:_____

Prasugrel Dose_____ Time stopped, days before surgery:_____

Ticagrelor Dose_____ Time stopped, days before surgery:_____

Cangrelor Dose_____ Time stopped, days before surgery:_____

Elinogrel Dose_____ Time stopped, days before surgery:_____

Ticlopidine Dose_____ Time stopped, days before surgery:_____

Abciximab Dose_____ Time stopped, days before surgery:_____

Eptifibatide Dose_____ Time stopped, days before surgery:_____

Tirofiban Dose_____ Time stopped, days before surgery:_____

Roxifiban Dose_____ Time stopped, days before surgery:_____

Orbofiban Dose_____ Time stopped, days before surgery:_____

(6) Spinal hematoma - Description of lesion:

Date and time of first symptom: _____ /_____ /_____ (dd/mm/yy) _____(0 to 24:00)

Date and time of first neurological symptom (sensory/motor): _____ /_____ /_____

(dd/mm/yy) _____(0 to 24:00)

Date and time of imaging study: _____ /_____ /_____ (dd/mm/yy) _____ (0 to 24:00)

Date and time of laminectomy incision: ____ /____ /____(dd/mm/yy)_____(0 to 24:00)

How did the lesion present (please note location, deficit, and laterality): _____

Symptoms (pain, weakness, etc.): _____

Neuro deficits: _____

Laterally: Rt._____, Lt. _____, Bilateral _____

Lesion: Epidural hematoma _____, Subdural hematoma _____, Subarachnoid hematoma

_____, intraspinal hematoma, hematoma in paraspinal muscles_____.

Did lesion present before or after catheter removal: _____

Neurological outcome: Complete recovery ___, Major residual deficit ___, Mild residual

deficit ____

Description of deficit: _____

_____

Please comment on any other details that may be pertinent to the case:

_____

_____