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Study Protocol: The Association of Postoperative Opioid Prescribing and Persistent Opioid Use

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ABSTRACT

This retrospective cohort study will investigate the incidence of new persistent opioid use between patients prescribed opioids after surgery versus patients not prescribed opioids after surgery. Patients are included if they underwent one of nine procedural categories between January 1, 2017 and October 31, 2019. The primary exposure of interest is being prescribed an opioid upon hospital discharge. The primary outcome is the incidence of new persistent opioid use between groups, defined as filling at least one opioid prescription between post-discharge days 4-90 and filling at least one opioid prescription between post-discharge days 91-180. Secondary outcomes are the incidence of new persistent opioid use by each procedure, the incidence of new persistent use among patients who received a postoperative opioid prescription by quartiles of total prescription size, and a sensitivity analysis to compare new persistent use among patients who experienced a 30-day clinic event and patients who did not experience a 30-day clinical event. Multivariable logistic regression models will be used to adjust for demographic and clinical differences between study groups.

EXTERNAL LINK

https://michigan-open.org/

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KEYWORDS

Opioids, surgery, new persistent opioid use, perioperative care

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Brief Rationale and Hypothesis

1 Opioid-naive patients who use prescription opioids after surgery are at risk of developing new persistent opioid use, wherein they become long-term opioid users after what is meant to be short-term opioid exposure. The association between being prescribed opioids after surgery and developing persistent opioid use is currently unclear. The purpose of this study is to compare the incidence of new persistent opioid use after surgery between patients who are prescribed opioids postoperatively and patients who are not prescribed opioids postoperatively. We hypothesize that patients who are prescribed opioids will have a higher incidence of persistent opioid use. If true, this knowledge may help inform and improve perioperative prescribing practice to reduce this risk.

Study Design

2 Retrospective cohort study using a clinical registry linked to a prescription drug monitoring program.

Data Sources

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1. **Michigan Surgical Quality Collaborative (MSQC) Clinical Registry**: The MSQC maintains a clinical registry that collects patient demographics, perioperative processes, and 30-day outcomes for patients undergoing surgery in Michigan. Specifically, the MSQC captures whether patients were prescribed opioids at discharge after surgery. Participating hospitals receive funding from Blue Cross Blue Shield of Michigan to fund trained data abstractors that use standardized methods to obtain data for patients. Cases are audited annually for accuracy and reviewed using a sampling algorithm designed to minimize selection bias.
2. **Michigan Automated Prescription System (MAPS)**: The MAPS database is Michigan's prescription drug monitoring program (PDMP) which tracks all controlled substance fills (schedules 2-5) for residents of Michigan. Within this database, all controlled substance prescription fills are uniquely linked to individuals. The purpose of MAPS is to allow prescribers to monitor whether patients have existing controlled substance prescriptions or prescriptions from multiple sources and assess the associated risk prior to providing a new prescription.

Data linkage between MSQC and MAPS is performed by an independent third party data broker who then provides encrypted, de-identified data.

Inclusion Criteria

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1. Adult patients (18 years of age and older) undergoing surgery in the MSQC clinical registry
2. Surgical procedure categories: laparoscopic appendectomy, laparoscopic cholecystectomy, colon and small bowel procedures, inguinal/femoral hernia repair, ventral/incisional hernia repair, laparoscopic hysterectomy, vaginal hysterectomy, total abdominal hysterectomy, and thyroidectomy
3. Date range: patients undergoing surgery between January 1, 2017 to October 31, 2019

Exclusion Criteria

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1. Patients who have more than one match in MAPS
2. Non-Michigan residents (out of state controlled substance fills are not captured by MAPS)
3. Patients who have an opioid prescription fill in MAPS between preoperative days -365 to -1
4. Patients who have had another surgery recorded in MSQC within 180 days of discharge from the index operation or have a re-operation recorded within 30 days of their index operation
5. Patients who die within 30 days of surgery

Explanatory Variables

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1. **Key explanatory variable (i.e., study groups)**: being prescribed (opioid prescription recorded in MSQC) vs. not being prescribed (no opioid prescription in MSQC) a postoperative opioid prescription at the time of discharge as recorded in the MSQC clinical registry
2. Demographics: age, sex, race/ethnicity, insurance type
3. Patient characteristics: American Society of Anesthesiologists (ASA) classification, obesity, cancer, tobacco use in the year prior to surgery, diabetes, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), hypertension (HTN), chronic steroid use, dialysis, functional status (independent vs. non-independent)
4. Clinical characteristics: admission status (inpatient vs. outpatient), surgical priority (elective vs. urgent/emergent), surgical approach (open vs. minimally invasive), procedure type
5. 30-day clinical events: complication (anastomotic leak, postoperative cardiac arrest, postoperative *Clostridium*

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difficile infection, surgical site infection (superficial incisional, deep incisional, or organ space), deep venous thrombosis, myocardial infarction, pneumonia, pulmonary embolism, sepsis, septic shock, severe sepsis, stroke, urinary tract infection (catheter-associated or spontaneous)), emergency department visit, readmission, length of stay > 14 days, discharge not to home

Primary Outcome

7 Incidence of new persistent opioid use in both study groups defined as both (1) at least one opioid fill in MAPS between post-discharge days 4-90, and (2) at least one opioid fill in MAPS between post-discharge days 91-180.

Secondary Outcomes

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1. Incidence of new persistent opioid use in both study groups *by procedure*
2. Incidence of new persistent opioid use in patients who received an opioid prescription *by quartiles of total postoperative opioid prescription size* as recorded in MSQC discharge prescription
3. Sensitivity Analysis: incidence of new persistent use in both study groups among patients *without* 30-day clinical events and among patients *with* 30-day clinical events

Statistical Analysis

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1. Descriptive analysis of patients who receive a prescription vs. patients who do not receive a prescription
2. Multivariable logistic regression of new persistent use with all explanatory variables, which will be used to estimate the predicted probability of new persistent opioid use between the two study groups overall and the predicted probability of new persistent opioid use between the two study groups by procedure
3. Multivariable logistic regression of new persistent opioid use in patients who received an opioid prescription, with quartile of total postoperative opioid prescription size (as recorded in MSQC discharge prescription) being the covariate of interest
4. Sensitivity analysis: multivariable logistic regression of new persistent use only for patients *without* 30-day clinical events and repeated again only for patients *with* 30-day clinical events

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