

ODPRN Drug Class Review Proposal Pharmacoepidemiology Unit

Study Title: Epidemiologic analyses of triptan use in Canada

Objectives:

1. To examine national and provincial trends in use of triptans and other migraine therapies (e.g. ergot alkaloids) over the past 5 years
2. To examine the impact(s) of changes in provincial formulary listing status (if any) on triptan utilization and costs among public drug plan beneficiaries
3. To perform cross-provincial comparisons of the characteristics of triptan users among a population of public drug plan beneficiaries
4. To describe current patterns of triptan use in Ontario

Objective 1: National and provincial trends in triptan use

Study Design:

Design: Time series analysis with quarterly time intervals

Study period: January 2008 to December 2012

Population: All provinces and territories

Data Source: *IMS Compuscript*: aggregated data for all prescriptions dispensed at retail pharmacies across Canada

Study Population:	<p>Inclusion Criteria:</p> <ul style="list-style-type: none"> ○ All privately and publically-funded triptan prescriptions dispensed in Canada <ul style="list-style-type: none"> ○ Almotriptan ○ Eletriptan ○ Frovatriptan ○ Naratriptan ○ Rizatriptan ○ Sumatriptan ○ Zolmitriptan ○ All privately and publically-funded prescriptions for other migraine therapies (not including prophylaxis) dispensed in Canada. <ul style="list-style-type: none"> ○ Ergot alkaloids (e.g. migranal, ergodryl, cafergot) ○ Butalbital-containing analgesics (e.g. fiorinal) ○ Butorphanol (e.g. stadol) ○ Adults aged 18+ at time of triptan dispensing
Outcome(s) of Interest:	<p>Measured over entire study period (quarterly):</p> <ul style="list-style-type: none"> • Number and rate of triptan prescriptions dispensed • Number and rate of triptan units dispensed • Total cost of triptan prescriptions <p>Stratify all analyses by:</p> <ul style="list-style-type: none"> • Province • Payer (public, private) • Drug (triptan, ergot alkaloid, butalbital-containing analgesic, butorphanol) • Age (<65 vs. 65+) (<i>pending data availability</i>)
Limitations:	<ul style="list-style-type: none"> • There is no <u>patient-level</u> data available through IMS Compuscript; information is only available at the prescription and unit level.

Objective 2: Cross-provincial changes in listing status of triptans

Study Design: Design: Time series analysis with annual time intervals
Study period: January 2000 to December 2012
Data Sources:

- *National Prescription Drug Utilization Information System Database (NPDUIS):* aggregated data for all publically funded prescriptions dispensed in Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, PEI, and NIHB

Study Population:

- Inclusion Criteria:
 - All publically-funded triptan prescriptions dispensed in Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, PEI, and NIHB
 - Almotriptan
 - Eletriptan
 - Frovatriptan
 - Naratriptan
 - Rizatriptan
 - Sumatriptan
 - Zolmitriptan
 - Adults aged 18+ at time of triptan dispensing

Outcome(s) of Interest: Measured over entire study period (annually):

- Number and rate of triptan users
- Total costs
- Average cost per user

Stratify all analyses by:

- Province
- Triptan (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan)
- Age (<65, 65+)

Limitations:

- Publically-funded, patient-level prescription data for PEI is only available as of 2004. We are therefore unable to determine triptan use prior to that date.
- There is no patient-level data available for publically paid prescriptions in British Columbia, Quebec, Newfoundland & Labrador or the Territories. Therefore, we will be unable to make comparisons between Ontario rates and rates of use in these provinces.

Objective 3: Cross-provincial comparisons of triptan users

Study Design:

Design: Cross-sectional analysis

Study period: January 2012 to December 2012

Data Sources:

- *National Prescription Drug Utilization Information System Database (NPDUIS)*: aggregated data for all publically funded prescriptions dispensed in Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, PEI, and NIHB
- *Ontario Drug Benefit Database (ODB)*: individual level data for all publically funded prescriptions dispensed in Ontario. This dataset contains additional variables (long-term care residence, public drug plan coverage) that is not available through NPDUIS

Study Population:

- Inclusion Criteria:
 - All publically-funded beneficiaries of Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, PEI, and NIHB
 - Adults aged 18+ at time of triptan dispensing

Outcome(s) of Interest:

For each province, report:

- Number of patients eligible for public drug coverage
- Number and rate of triptan users (overall and by triptan)
- Number and rate of ergot alkaloid therapy users
- Number and rate of butalbital-containing analgesic therapy users
- Number and rate of butorphanol therapy users
- Number and rate of triptan prescriptions dispensed (overall, and by triptan)
- Number and rate of triptan units dispensed (overall, by triptan, and by triptan formulation)
- Number of triptan units dispensed per person (Mean, SD)
- Age at time of prescription (Mean, SD)
- Proportion of prescriptions dispensed to males (N, %)
- Proportion of prescriptions dispensed to urban and rural residents (N, %)
- Proportion of prescriptions dispensed by socioeconomic status (measured using income quintiles)
- Proportion of prescriptions dispensed, by dose (standard dose, above standard dose, and below standard dose (N, %))
 - *Note: Standard dose to be determined by systematic review*

In Ontario only (where more detailed data is available):

- Proportion of prescriptions dispensed to LTC residents (N, %)
- Proportion of prescriptions dispensed by plan (Seniors, Ontario Disability Support Program, Ontario Works, Long-Term Care, Homes for Special Care, Trillium, Home Care, Special Drugs Program, Other (N, %))

Stratify the above analysis by age (overall, <65, 65+)

Limitations:

- There is no patient-level data available for publically paid prescriptions in British Columbia, Quebec, Newfoundland & Labrador or the Territories. Therefore, we will be unable to make comparisons between Ontario rates and rates of prescribing in these provinces.

Objective 4: Patterns of Triptan Use in Ontario

Study Design:	<p><u>Design:</u> Cross-sectional analysis</p> <p><u>Study period:</u> January 2008 to December 2012</p> <p><u>Data Sources:</u></p> <ul style="list-style-type: none"> • <i>Ontario Drug Benefit Database (ODB)</i>: individual level data for all publically funded prescriptions dispensed in Ontario.
Study Population:	<ul style="list-style-type: none"> • Inclusion Criteria: <ul style="list-style-type: none"> ○ All publically-funded beneficiaries of Ontario who initiate triptan therapy (defined as no prescription for a triptan in the past 365 days) ○ Adults aged 66+ at time of triptan dispensing
Outcome(s) of interest:	<ul style="list-style-type: none"> • <u>Duration of Triptan Therapy:</u> <ul style="list-style-type: none"> ○ Define ongoing use of triptan therapy according to receipt of a subsequent prescription within 180 days of the prior prescription. • <u>Report the following:</u> <ul style="list-style-type: none"> ○ Total number of new triptan users (overall, and stratified by triptan type) ○ Median duration of therapy ○ Number of different triptan drugs prescribed over the period of triptan use ○ Prevalence of concomitant use of other acute pharmacologic migraine treatment options (NSAIDs, ASA, acetaminophen, opioids, ergots, antiemetics) ○ Among those who fill ≤ 5 prescriptions prior to discontinuation (e.g. "early discontinuers"), the number of different triptan drugs prescribed (<i>to assess whether patients are being tried on multiple options before discontinuing triptan therapy</i>)
Limitations:	<ul style="list-style-type: none"> • Certain acute pharmacologic treatment options (e.g. ASA, acetaminophen) are available over the counter, and therefore we will underestimate the true prevalence of concomitant use. • Due to issues with incomplete data and unavailability of eligibility information, this analysis is restricted to patients aged 66 and older. Therefore, these findings may not be generalizable to the younger population.

General Limitations:

- We cannot isolate migraines vs. cluster headaches through any of the data holdings (ODB, NPDUIS, IMS).
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