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Michael Veronin
The University of Texas at Tyler, mveronin@uttyler.edu

Robert P. Schumaker
University of Texas at Tyler, rschumaker@uttyler.edu

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Michael A. Veronin, Robert P. Schumaker
The University of Texas at Tyler, Tyler, Texas U.S.A.
mveronin@uttyler.edu, rschumaker@uttyler.edu

INTRODUCTION

Opioid analgesics continue to be the mainstay of pharmacologic treatment of moderate to severe pain. An adjunct is a drug that in its pharmacological characteristic is not identified primarily as an analgesic, but that has been found in clinical practice to have either an independent analgesic effect or additive analgesic properties when used with opioids. By using an adjunct to maximize the level of analgesia, the required opioid dosage may be reduced, together with concomitant adverse effects.

BACKGROUND

Real World Data (RWD) refers to data that describe observations in normal clinical practice obtained by any non-interventional methodology, such as Randomized Controlled Trials (RCTs). The U.S. Food and Drug Administration (FDA) maintains one of the largest government databases in the country, the FDA Adverse Event Reporting System (FAERS). It is comprised of adverse event reports submitted to the FDA through the "MedWatch" reporting program and contains a plethora of Real World Data: thousands of case reports on opioids and adjunct drugs, comprised of unstructured textual data. The *objective* of this study is to identify the therapeutic effectiveness of adjunct drugs with opioids by examination of narrative text in MedWatch cases.

METHODS

This project follows the traditional approach of knowledge discovery in databases, comprised of five steps: 1) Data selection, 2) Pre-processing, 3) Transformation, 4) Data mining and 5) Interpretation. The strategy employed will transform the narrative text data into an organized and

concise summary of key endpoints. An appropriate sample (500 to 1,000 relevant patient cases) that describe opioids and adjunct drugs will be included in the case report data set**.**

Key task 1: Data selection and pre-processing (Steps 1,2). MedWatch narratives of patient cases that describe the types of opioid and adjunct drug combinations used in real-life clinical settings will be obtained from the FAERS database. *Key task 2*: Data transformation and mining (Steps 3,4). Cases will be organized in a Structured Query Language (SQL) database. A lexicon of words and terms clinically or theoretically related to opioid and adjunct drug therapy will be developed, which will serve as a reference for analysis of the text. Using Natural Language Processing (NLP) techniques, textual data will be transformed into n-grams using a MySQL n-gram parser. N-gram extraction will identify notes containing n-grams matching terms from the theory-and expert-derived lexicon. Categories will be formed from the most frequently identified n-grams and their total frequency.

RESULTS (PROJECTED)

Key task 3: Evaluate and interpret results (Step 5) and compile the information into a useful format for healthcare providers. The most commonly extracted n-grams will be identified by category, then frequency, and displayed in tabular format. N-gram analysis of the corpus of case reports reveals the frequency with which and adjunct drug was used with an opioid, and indicate impact on analgesic effect. Completion of key tasks provides evidence on the associated outcomes of treatment; whether the adjunct drug therapy indicates treatment success or failure.

CONCLUSION

Findings of this project will add to the existing body of knowledge on opioid adjunct therapy for analgesia and may corroborate or refute other existing evidence for adjunct drug therapeutic effectiveness derived from case reports or clinical trials.