Comparison of Opioid Doctor Shopping for Tapentadol and Oxycodone: A Cohort Study

M. Soledad Cepeda,* Daniel Fife,* Lien Vo,† Gregory Mastrogiovanni,‡ and Yingli Yuan‡


Abstract: Obtaining opioids from multiple prescribers, known as doctor shopping, is 1 example of opioid abuse and diversion. The dual mechanism of action of tapentadol could make tapentadol less likely to be abused than other opioids. The aim of this retrospective cohort study was to compare the risk of shopping behavior between tapentadol immediate release (IR) and oxycodone IR. Subjects exposed to tapentadol or oxycodone with no recent opioid use were included and followed for 1 year. The primary outcome was the proportion of subjects who developed shopping behavior defined as subjects who had opioid prescriptions written by >1 prescriber with ≥1 day of overlap filled at ≥3 pharmacies. The opioids involved in the shopping episodes were assessed. A total of 112,821 subjects were exposed to oxycodone and 42,940 to tapentadol. Shopping behavior was seen in .8% of the subjects in the oxycodone group and in .2% of the subjects in the tapentadol group, for an adjusted odds ratio of 3.5 (95% confidence interval, 2.8 to 4.4). In the oxycodone group, 28.0% of the shopping events involved exclusively oxycodone, whereas in the tapentadol group, .6% of the shopping events involved exclusively tapentadol. Results suggest that the risk of shopping behavior is substantially lower with tapentadol than with oxycodone.

Perspective: The risk of opioid doctor shopping, ie, obtaining opioid prescriptions from multiple prescribers, is lower with tapentadol than with oxycodone.

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Key words: Tapentadol, shopping behavior, oxycodone.

Pain is a significant public health problem. The 2011 Institute of Medicine report states that chronic pain affects at least 116 million adults in the U.S. and that uncontrolled pain substantially reduces quality of life and productivity. Opioids provide treatment for acute and chronic pain and are increasingly prescribed for these conditions. However, there is growing concern about the risk of opioid abuse, misuse, diversion, and overdose. Diversion through family and friends is now the greatest source of illicit opioids. Obtaining opioid prescriptions from multiple prescribers, known as doctor shopping, is a way in which opioids may be abused and their use diverted.

The mechanism of action of an opioid could influence its abuse potential. Tapentadol is an opioid with 2 mechanisms of action. It activates opioid receptors and inhibits the reuptake of norepinephrine. Tapentadol has 50-fold lower affinity to the mu receptor than morphine. Since the activation of the mu opioid receptor is responsible for the mood alterations and the euphoria associated with opioids, the risk of abuse associated with tapentadol may be expected to be lower than with other strong opioids. Internet monitoring, surveillance of addiction treatment centers, and pharmacovigilance efforts to assess the risk of misuse, abuse, and diversion of tapentadol appear to support this view. The lower rates of abuse observed with tapentadol compared to oxycodone take into consideration drug availability—the number of subjects receiving prescriptions for these drugs.

Shopping behavior has been traditionally assessed by counting the number of prescribers or number of pharmacies a subject visits in a specific time period.
However, even when it is required that the prescriptions written by different prescribers had to overlap, such a definition of shopping behavior does not differentiate between opioids and diuretics in that shopping defined in this way occurs in approximately the same proportion of opioid users and diuretic users. Such a definition of shopping may incorrectly identify patients as shoppers with deleterious consequences for understanding shopping behavior and evaluating interventions aimed at decreasing it.

An alternative definition of shopping behavior to differentiate opioids from diuretics requires not only overlapping prescriptions from more than 1 prescriber but also the filling of those prescriptions at 3 or more pharmacies. In a previous study using this definition, subjects exposed to diuretics exhibited lower frequency of shopping behavior (.03%) than subjects exposed to opioids (.18%).

The aim of this study was to compare the risk of shopping behavior of tapentadol immediate release (IR) with the risk of shopping behavior of oxycodone IR.

Methods

Study Design

This retrospective cohort study used the IMS LRx database.

Study Setting

The longitudinal database covers 65% of all retail dispensing in the United States and includes all types of pharmacies—chains, food stores, mass merchandisers, and independent stores. From each of the pharmacies in the panel, the database captures all prescriptions that were dispensed, regardless of payment type. Therefore, the LRx database includes prescriptions filled for patients with any insurance type (commercial, Medicare, Medicaid) or patients who pay cash. Dispensing records are collected directly from pharmacies, which provide encrypted patient identifiers compliant with Health Insurance Portability and Accountability Act (HIPAA) privacy regulations.

The LRx database includes data on the de-identified subject, the pharmacy, and the prescriber. To uniquely identify a subject who filled prescriptions at multiple pharmacies, a probabilistic match is performed using a proprietary algorithm based on encrypted, nonidentifiable data elements including gender, date of birth, last name, first name, address, city, state, zip code, and payer identification.

Unlike statewide prescription monitoring programs (statewide electronic databases that collect data on controlled substances dispensed in the state) or electronic health care databases, LRx is not constrained by state lines, captures filling of prescriptions paid in cash, and includes information on both the prescriber and the pharmacy. It is unusual for health care databases to include information on both prescriber and pharmacy, and it is important to capture information on cash transactions because approximately 45% of subjects exhibiting shopping behavior pay in cash.

Participants and Interventions

We included subjects exposed to tapentadol IR or oxycodone IR from July 2009 to December 2010 who had not received an opioid of any type in the 3 months before the index date. The index date was the date of the first prescription for tapentadol IR or oxycodone IR after June 30, 2009. Each subject was followed for 1 year from the index date.

Oxycodone IR, as a single drug, not in combination, was selected as a comparator because it is a strong opioid, is widely used, is available as IR formulation, and was the opioid that served as an active comparator in tapentadol’s efficacy trials. The only formulation of tapentadol available on the market during the present study was IR. A 1-year follow-up was deemed sufficient because in a previous study with a longer follow-up the mean time to the first shopping episode in subjects newly exposed to opioids was 9 months.

We excluded subjects who filled a prescription for an opioid other than tapentadol IR or oxycodone IR on the index date or in the next 3 days. This exclusion was made to ensure that subjects did not have the outcome of interest before the study started, and to isolate the exposure to the indexed opioid; ie, to decrease the likelihood of introducing bias to the association of the indexed opioid and shopping behavior.

The study was powered to detect a 50% reduction in the risk of shopping behavior with 80% power and 5% alpha error, assuming the risk of shopping behavior during the follow-up period with oxycodone IR was 67/100,000, which is the risk observed in subjects exposed to opioids at 1 year of follow-up in a previous study that assessed shopping behavior. Because fewer subjects were exposed to tapentadol IR than to oxycodone IR, we matched up to 4 oxycodone subjects, if available, to each tapentadol subject. The choice of matching variables allowed us to control for several potentially important potential confounders in the design rather than in the analysis.

Each tapentadol IR-exposed subject was matched to up to 4 randomly selected oxycodone IR-exposed subjects by: calendar quarter and year of initial exposure (index date); first 3 digits of the zip code of the pharmacy dispensing the opioid at the index date; age ±5 years; and specialty of prescriber. The specialties of the prescribers were categorized as 1) “Primary care,” for specialties such as family practice, internal medicine, nurse practitioner, physician assistant, pediatrics, general practice, obstetrics, and gynecology; 2) “Orthopedic surgery or general surgery,” for orthopedic surgery, general surgery, or orthopedic surgery of the spine; 3) “Pain medicine,” for pain medicine, pain management, physical medicine and rehabilitation, and rheumatology; 4) “Dentistry,” for dentistry; 5) “Emergency medicine,” for emergency medicine; 6) “Addiction medicine,” for addiction medicine; and 7) “Other,” for cardiology, nephrology, plastic surgery,
etc. This classification differentiates specialties that are associated with low and high risk of having subjects with opioid shopping behavior.4

A matching ratio of 1:4 was chosen because there is little gain in power going beyond a ratio of 4 or 5 controls to cases.14 The matching variables were selected because they are potential confounders or potential sources of bias in observational studies. There is an association between the amount and type of opioids available in a geographic area and abuse in that area.2 Subjects between 19 and 64 years of age are at increased risk of developing opioid shopping behavior compared to older subjects.6 Certain specialties have in their practices more opioid shoppers than others, likely due to channeling of high-risk subjects to specific specialties,4 and matching on calendar time will control for time trends in prescriber practices or shopping risk.

To ascertain the duration of follow-up in the database, we searched prescriptions for any medication during the year of follow-up.

### Main Outcome Measurements

The primary outcome was prespecified as the proportion of subjects who developed shopping behavior at any time during the 1 year of follow-up. Shopping behavior was defined as >1 prescription by ≥2 different prescribers within 1 day of overlap and filled at ≥3 pharmacies. All of these conditions had to be met.

Secondary outcomes, also prespecified, were the number of shopping episodes during the year of follow-up, time to first shopping episode, and whether the dispensing in the shopping episodes were for the same opioid or not. To count shopping episodes, each time a new prescription was observed the rule for shopping behavior was checked, and if the criteria for shopping behavior were met a new episode was counted. The shopping episodes were classified as 1) episodes in which all the prescriptions were for the indexed opioid; 2) episodes in which none of the prescriptions were for the indexed opioid; and 3) episodes in which some of the prescriptions were for the indexed opioid.

As a post hoc analysis, the risk of developing “heavy” shopping behavior was compared between the subjects exposed to tapentadol IR and the subjects exposed to oxycodone IR. A subject was considered a heavy shopper if he or she had ≥5 shopping episodes in 1 year. This definition of heavy shoppers has been used previously.5,6

### Additional Potential Confounders

In addition to the matching variables (time of the exposure, geographic area, specialty of the prescriber, and age), we considered gender, any exposure to benzodiazepines during the 3 months before the index date, and type of payment at the index date as potential confounders. Men endorse nonmedical use of opioid prescriptions more frequently than women,1 and subjects on opioids and concomitant benzodiazepines have a higher risk of having diagnoses of drug dependence.15 How the subjects paid for the opioid at the index date is an indicator of access to health care and a proxy for socioeconomic status. Socioeconomic status has been linked to the risk of drug abuse.13 The types of payments were cash, Medicaid, and third party, which includes commercial insurance and Medicare. These variables were not included in the matching as it would have substantially increased the difficulty of finding matches. The effect of these variables was controlled for in the analysis.

### Statistical Analysis

To compare the characteristics of the 2 treatment groups, mean and standard deviation (SD) were calculated for continuous variables and proportions were calculated for categorical variables.

Matched analyses were used to compare the risk of shopping and heavy shopping behavior between tapentadol IR and oxycodone IR. We built conditional logistic regression models. The grouping variable was the variable that identified the matches. The outcome was shopping behavior or heavy shopping behavior, and covariates in the logistic models were the treatment group, gender, type of payment, and prior use of benzodiazepines. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. Subjects with missing data for any of the matching variables were excluded from matching. The gender was unknown in less than 1% of subjects (125) and such a category was created and included in the logistic regression models.

Kruskal-Wallis, a nonparametric test, as well as t-tests and 95% CIs, were used to compare number of shopping episodes and time to event between tapentadol IR and oxycodone IR. A chi-square test was used to compare the type of shopping episodes (ie, percentage of events in which all the prescriptions were for the indexed opioid).

All analyses were conducted in STATA v.10.1 (StataCorp LP, College Station, TX). Because this study used completely anonymized data and did not involve patient contact, institutional review board approval was not required.

### Results

A total of 42,940 eligible subjects exposed to tapentadol were matched to 112,821 eligible subjects exposed to oxycodone; 13,937 eligible subjects exposed to tapentadol could not be matched to any eligible subject exposed to oxycodone. Fig 1 depicts the flow of subjects in the study.

The tapentadol and oxycodone groups were similar in age, specialties of the prescribers at the index date, calendar quarter and year of exposure, and duration of follow-up. In both groups, primary care prescribers were the most common prescribers. The tapentadol group had fewer males, fewer subjects exposed to benzodiazepines, higher number of subjects with commercial insurance, and longer follow-up time (Table 1).

Shopping behavior was observed in .8% of the subjects in the oxycodone group and in .2% of the subjects in the tapentadol group (Table 2). Heavy shopping behavior...
was also higher in the oxycodone group (.07%) than in the tapentadol group (.01%) (Table 2). The risk of shopping behavior in the unmatched subjects exposed to tapentadol was .26%.

After adjusting for gender and benzodiazepine use while respecting the matches, the risk of shopping behavior in the oxycodone IR group was 3.5 times (95% CI, 2.8 to 4.4) the risk in the tapentadol group. The adjusted risk of heavy shopping was also much higher in the oxycodone group than in the tapentadol group with OR = 6.9 (95% CI, 2.5 to 19.3) (Table 2).

The number of shopping events during the year was higher in the oxycodone group than in the tapentadol group. The first shopping episode was observed earlier in the oxycodone group than in the tapentadol group (Table 3). In terms of the type of opioid involved in the shopping episodes, in the oxycodone group, 28.0% of the shopping events involved exclusively oxycodone, whereas in the tapentadol group, .6% of the shopping events involved exclusively tapentadol. In the oxycodone group, 11.1% of the shopping events did not include oxycodone, whereas in the tapentadol group, 69.1% of the shopping events did not include tapentadol.

Discussion

The risk of shopping behavior was substantially lower with tapentadol IR than with oxycodone IR. Subjects exposed to tapentadol were less likely to shop, and they also developed shopping behavior later and had fewer shopping episodes than the oxycodone subjects. The lower risk of shopping behavior of tapentadol may be due to its dual mechanism of action and relatively low affinity for the mu receptor.

Subjects in the tapentadol group rarely shopped for tapentadol, in contrast to oxycodone subjects who often shopped for oxycodone. Although this finding could suggest that subjects found oxycodone more desirable than tapentadol, it could also reflect the market—oxycodone is more commonly prescribed than tapentadol and subject to lower copays than tapentadol.

The definition of shopping behavior used in this study required the overlapping of prescriptions written by different prescribers. One concern is that the overlap could be as small as 1 day. To address this, we conducted a post hoc analysis in which only subjects who had 5 or more shopping episodes were considered shoppers. The findings were even more striking; the risk of shopping behavior in the tapentadol group was even lower relative to that in the oxycodone group.

We used a definition of shopping behavior that minimizes the inappropriate flagging of individuals with legitimate use of opioids (false positive results) and has been validated using LRx. This database allows capturing information across states and cash transactions. Because it is the largest pharmacy database in the U.S., it permitted us to evaluate a very large number of subjects exposed to tapentadol IR or oxycodone IR. Such a sample size would be very difficult to obtain in any other setting.

In this study, subjects were followed for a year, meaning that all pharmacy transactions for tapentadol IR or oxycodone IR within that year were assessed. However, since this is a retrospective database study, not all the subjects remained in the database for a year (eg, some could have changed to a pharmacy that is not among

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**Table 1. Baseline Characteristics of the Subjects in the Tapentadol and Oxycodone Groups**

<table>
<thead>
<tr>
<th></th>
<th>OXycodone IR</th>
<th>TAPENTADOL IR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants, n</td>
<td>112,821</td>
<td>42,940</td>
</tr>
<tr>
<td>Age in years, mean (SD)</td>
<td>51.5 (14.9)</td>
<td>50.1 (14.9)</td>
</tr>
<tr>
<td>Men, n (%)</td>
<td>54,450 (48.3)</td>
<td>16,002 (37.3)</td>
</tr>
<tr>
<td>History of benzodiazepine use, n (%)</td>
<td>19,324 (17.1)</td>
<td>5,171 (12.0)</td>
</tr>
<tr>
<td>Prescriber specialty, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Addiction medicine</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Dentistry</td>
<td>72 (0.6)</td>
<td>47 (1.1)</td>
</tr>
<tr>
<td>Emergency medicine</td>
<td>2,478 (2.2)</td>
<td>946 (2.2)</td>
</tr>
<tr>
<td>Surgery</td>
<td>17,559 (15.6)</td>
<td>8,203 (19.1)</td>
</tr>
<tr>
<td>Pain medicine</td>
<td>6,406 (5.7)</td>
<td>3,363 (7.8)</td>
</tr>
<tr>
<td>Primary care medicine</td>
<td>44,769 (39.7)</td>
<td>15,052 (35.0)</td>
</tr>
<tr>
<td>Other</td>
<td>41,537 (36.8)</td>
<td>15,329 (35.7)</td>
</tr>
<tr>
<td>Calendar year and quarter of first exposure, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009 Q3</td>
<td>10,006 (8.9)</td>
<td>3,461 (8.1)</td>
</tr>
<tr>
<td>2009 Q4</td>
<td>12,964 (11.5)</td>
<td>4,670 (10.9)</td>
</tr>
<tr>
<td>2010 Q1</td>
<td>14,393 (12.8)</td>
<td>5,276 (12.3)</td>
</tr>
<tr>
<td>2010 Q2</td>
<td>19,906 (17.6)</td>
<td>7,532 (17.5)</td>
</tr>
<tr>
<td>2010 Q3</td>
<td>24,648 (21.8)</td>
<td>9,422 (21.9)</td>
</tr>
<tr>
<td>2010 Q4</td>
<td>30,904 (27.4)</td>
<td>12,579 (29.3)</td>
</tr>
<tr>
<td>Active in database, days (SD)</td>
<td>252.5 (135.0)</td>
<td>270.6 (127.2)</td>
</tr>
<tr>
<td>Type of payment, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash</td>
<td>16,532 (14.6)</td>
<td>3,332 (7.8)</td>
</tr>
<tr>
<td>Medicaid</td>
<td>7,259 (6.4)</td>
<td>1,046 (2.4)</td>
</tr>
<tr>
<td>Third party</td>
<td>89,030 (78.9)</td>
<td>38,562 (89.8)</td>
</tr>
</tbody>
</table>
the 65% of U.S. pharmacies covered by this database). The follow-up was similar in the tapentadol group, so differential follow-up cannot explain the lower risk of shopping behavior observed in the tapentadol group.

This study illustrates the advantage of using a very specific definition of shopping behavior for research purposes to avoid misclassification of the outcome and to increase the likelihood of detecting a true difference in shopping behavior between opioid medications. However, 1 consequence of adopting a strict definition of shopping behavior is that the absolute risk of shopping study is likely to be underestimated.

Shopping behavior is of interest in its own right. Some readers may see it as being of greater interest as a surrogate marker for abuse or diversion of prescribed opioids. To the extent that shopping behavior is viewed in this way, we should point out that abuse and diversion of prescribed opioids is likely to be more common than is shopping behavior as defined in this study because they can occur without shopping. In addition, though some definitions of doctor shopping have been explicitly linked to opioid abuse, the definition used in the current study has not been explicitly linked to abuse.

The LRx database does not contain information on medical conditions, so we could not control for pain diagnosis or any other medical conditions that might confound the results. However, we did control for the type of prescriber and use of benzodiazepines. The type of prescriber was considered a proxy for the type and duration of pain. For example, dentists often serve subjects with acute pain and pain specialists often serve subjects with chronic pain. The use of benzodiazepines was considered a proxy for the presence of comorbidities associated with higher risk of abuse. For example, subjects with posttraumatic stress disorder often are exposed to benzodiazepines.

More subjects in the tapentadol group had insurance and fewer had Medicaid. This suggests that they had different socioeconomic status, and socioeconomic status has been linked to the risk of drug abuse. However, rates of shopping behavior remained lower among tapentadol users than oxycodone users after adjustment for type of payment. Subjects were matched on the geographic area of the pharmacy that dispensed the opioid at the index date as well. Matching on zip code allowed us to control for the effect of opioid availability, which has been found as an impactor risk factor, and at least partially adjust for socioeconomic status as well. We excluded subjects with an opioid prescription 3 months before the index date. By focusing the study on subjects without recent exposure to opioids, we avoided having an imbalance of subjects with recent history of opioid abuse. Nonetheless, this is an observational study and the groups could have had dissimilar distributions of unmeasured confounders. In view of the size of the observed OR, a confounder would need to be very strongly associated with both the exposure and the outcome to explain the results of the present study.

Tapentadol IR was launched in June of 2009 and has been on the U.S. market for much less time than oxycodone IR. A case could be made that forces in place for fostering the nonmedical use of oxycodone are stronger than the ones in place for fostering the nonmedical use of tapentadol. For instance, there might have not been enough time for abusers to experiment with tapentadol. Data from the Researched Abuse, Diversion and Addiction-Related Surveillance, a surveillance system that monitors the abuse, misuse, and diversion of prescription opioids, suggest that abuse can be seen very soon after a new opioid is marketed. Similarly, it could be argued that differences in the street price between tapentadol and oxycodone would make oxycodone more likely to be diverted. The street price of tapentadol is much lower than the street price of oxycodone, about 10 cents per milligram of tapentadol versus 1 dollar per milligram of oxycodone. On the

### Table 2. Risk of Shopping and Heavy Shopping Behavior

<table>
<thead>
<tr>
<th></th>
<th>OXYCODONE IR</th>
<th>TAPENTADOL IR</th>
<th>MATCHED BUT NOT OTHERWISE ADJUSTED OR (95% CI)</th>
<th>*MATCHED AND ADJUSTED OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects</td>
<td>112,821</td>
<td>42,940</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Number of subjects who exhibited shopping behavior (%)</td>
<td>967 (.86, .80–.91)</td>
<td>88 (.20, .16–.25)</td>
<td>3.9 (3.1 to 4.9)</td>
<td>3.5 (2.8–4.4)</td>
</tr>
<tr>
<td>Number of subjects who exhibited heavy shopping behavior (%)</td>
<td>80 (.07, .06–.09)</td>
<td>4 (.01, .0025–.02)</td>
<td>7.4 (2.7–20.4)</td>
<td>6.9 (2.5–19.3)</td>
</tr>
</tbody>
</table>

*Taking matching into account and controlling for gender, benzodiazepine use, and type of payment at the first opioid exposure using a conditional logistic regression.

### Table 3. Characteristics of the Shopping Events in the Oxycodone and Tapentadol Groups

<table>
<thead>
<tr>
<th></th>
<th>OXYCODONE IR</th>
<th>TAPENTADOL IR</th>
<th>DIFFERENCE (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean number of shopping events per subject ± SD</td>
<td>0.2 ± .3</td>
<td>0.004 ± .1</td>
<td>.015 (.01–.02)</td>
</tr>
<tr>
<td>Mean number of shopping events per subject who exhibited shopping behavior ± SD</td>
<td>2.1 ± 2.6</td>
<td>1.8 ± 1.9</td>
<td>.30 (–2.2–8)</td>
</tr>
<tr>
<td>Time to event* (mean days [SD])</td>
<td>156.1 ± 100.9</td>
<td>180.4 ± 104.6</td>
<td>–24 (–46.4 to –2.2)</td>
</tr>
<tr>
<td>Episodes (%) in which all prescriptions in the events were for the index drug</td>
<td>582 (28.0)</td>
<td>1 (6)</td>
<td>P &lt; .001</td>
</tr>
<tr>
<td>Episodes (%) in which none of prescriptions in the events were for the index drug</td>
<td>231 (11.1)</td>
<td>112 (69.1)</td>
<td></td>
</tr>
<tr>
<td>Episodes (%) in which at least 1 prescription was for the index drug</td>
<td>1,266 (60.9)</td>
<td>49 (30.2)</td>
<td></td>
</tr>
</tbody>
</table>

*Using Kruskal-Wallis, P = .04.
other hand, the lower street price of tapentadol could reflect a lower desirability and demand for tapentadol among abuser populations.11 Definitive proof for the lower abuse potential of tapentadol will need to await longer experience with tapentadol, because the desirability of an opioid can change over time.11 It could be also argued that the lower frequency of shopping behavior observed with tapentadol is due to inadequate pain relief or poor tolerability. Randomized controlled trials for acute and chronic pain conditions have shown that at equianalgesic doses tapentadol IR and oxycodone IR have comparable efficacy, with tapentadol having superior gastrointestinal tolerability.12 Moreover, lack of analgesia or lack of tolerability with tapentadol will likely place those subjects at a higher risk of being considered shoppers because they would more likely have more office visits and more than 1 prescriber.

In summary, this observational study found that subjects exposed to tapentadol IR had a lower risk of shopping behavior than subjects exposed to oxycodone IR. Its findings are subject to the limitations of observational studies.

Acknowledgment

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