Franklin GM, Stover BD, et al. Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries The Disability Risk Identification Study Cohort. Spine 2008;33:199–204

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Design: Prospective cohort study

Purpose of study: In workers with back injuries, to examine the association between early opioid prescription and the development of later disability

Population/sample size/setting:

- 1843 (68% male, mean age 39.4) workers with lost time claims for back injuries in Washington State Workers Compensation between July 2002 and April 2004

- Eligibility was based upon having an accepted back injury claim with Washington State WC state fund with 4 or more days of lost time from work, age over 18, receiving at least 1 day of wage replacement in the first year of the claim, not being hospitalized in the acute period after injury, and completion of a baseline telephone interview after enrollment in the study
- Workers who were not part of the state fund (covered by one of 450 self-insured companies) were excluded because of lack of sufficient data from the self-insureds
- A total of 4354 claimants would have been eligible for the study, but only 1843 were contacted and provided complete information for analysis

Assessment of exposure:

- Trained interviewers contacted all back injury claimants within 2 weeks of claim receipt by the Department of Labor and Industries administrative database for baseline data:
    - Age group (18-29, 30-44, 45-54, and over 54)
    - Race/ethnicity
    - Education (less than high school, finished high school, some college, and college degree)
    - Tobacco use (never, occasionally or frequently, daily)
    - Alcohol use in past year
    - Average pain in the previous week on a scale of 0 to 10
        - Low was 0-3
        - Moderate was 4-6
        - High was 7-10
    - Roland-Morris Disability, categorized into levels 0-6, 7-13, 14-18, and 19-24
- Injury severity rating was based on a review of the initial report of injury and early chart notes of the attending physician, analyzed as minor strain/sprain with little

evidence of immobility, major sprain/strain with substantial immobility, and clear evidence of radiculopathy

- Worker expectation of recovery on a 10 point scale, based on their certainty that they would be working again within six months, where 0 is “not at all certain” and 10 is “extremely certain”, categorized 0-5, 6-9, 10
- Fear-avoidance beliefs questionnaire categorized ad very low 0-3, moderate 3.1 to 4.9, high 5-6
- Opioid exposure was ascertained from the medical billing database of the Washington WC payment system, for all opioid prescriptions within 6 weeks of the first medical visit that were submitted to the state fund and were paid, and categorized as to dose and abuse risk:
    - DEA Schedule II, III, or IV
    - Drug strength, number of pills, days supply
    - Doses were converted into morphine-equivalent doses in mg/day

Ascertainment of outcome:

- Primary outcome was receipt of wage replacement benefits for temporary total disability 365 days after claim receipt
- A secondary outcome was the number of work disability days in the first year of the claim
- Work status at one year (disability) was also an outcome

Analysis of exposure/outcome association:

- 254 of the 1843 claimants (14%) were disabled at one year
- The median number of work disability days in the first year for the whole population was 17, but the mean number of work disability days was 83
- Radiculopathy was present in 25% of the cohort at baseline
- Mean pain intensity at the time of telephone interview was 6.8 and the mean Roland-Morris Disability score was 12.9
- 34% of the cohort received (n=630) at least one opioid prescription during the first six weeks, and about half of these (n=319) were received at the first medical visit
    - In the six week period, the mean number of days of opioid was 12.1, the mean number of opioid prescriptions was 2.2, the mean dose was 47.9 mg/day
    - 337 workers (53%) of the 630 workers who had opioids received them for more than 7 days, and about 10% (65 of 630) received them for 18 days or more during the six weeks
- Logistic regression models were developed in order to characterize the association between opioid exposure and disability at one year, where opioid prescription was the main independent variable and the covariates were age, gender, race, education,

injury severity rating, pain intensity at the time of baseline telephone interview, and Roland-Morris disability at baseline interview
    - Relative to having no opioid prescription in the first 6 weeks, receipt of opioids for more than 7 days had an adjusted odds ratio of 2.2 for work disability at one year (95% confidence interval 1.5-3.1)
    - Relative to no opioid prescription, receipt of 2 opioid prescriptions almost doubled the risk of disability at one year (95% CI 1.1-3.0)
    - Schedule II or III opioids for less than 7 days was not associated with work disability at one year
    - Schedule II drugs for more than 7 days were not associated with work disability at one year, but Schedule III drugs for more than 7 days had an odds ratio of 2.7
- In the regression models, the relationship between opioid prescriptions and disability were not altered by the other factors such as work expectation and fear-avoidance as ascertained by the baseline interviews
- In an additional analysis, the total morphine equivalents prescribed in the first six weeks were associated with disability duration, and an increase of 100 mg morphine equivalents in 6 weeks was associated with an additional 1.5 disability days

Authors' conclusions:

- In a cohort of injured workers with lost-time claims for back injuries, opioid prescriptions were associated with subsequent work disability at one year; receipt of an opioid prescription for more than 7 days in the first 6 weeks doubled the risk of work disability when compared to no opioid prescription in the first 6 weeks
- The baseline measures of work and back function during the telephone interviews may not reflect the levels which occurred at the time when the opioid prescriptions were written
- There are limitations in this study: the effects of unmeasured variables cannot be ascertained, the opioid prescriptions in the database may not reflect the amounts of opioid actually taken, and the relationships of opioid potency (Schedule II or III) to work disability were not clear

Comments:

- The strengths of the study were reflected in having had interviews with individual patients and with having access to initial physician notes, which would not be possible with having only a large administrative database for ascertainment of exposure

- The credibility of the multivariable logistic model is underscored by the difference in Table 2 between the crude and adjusted odds ratios for opioid prescription measures with work disability status: for opioid prescription over 7 days, the crude odds ratio of 4.5, and the adjusted odds ratio is 2.2, indicating that even though the crude odds ratio was subject to confounding by the injury severity variables, there remained a significant association between early opioid prescriptions and eventual work disability
- The study was also large enough to allow the authors to develop regression models with reasonably stable coefficients for the opioid prescriptions as independent variables
- As is always the case with observational studies, there is a possibility that there is residual confounding not captured in the baseline data; this could include individual patient factors associated with how pain is reported, whether a preference for opioids is expressed, and which also are predictive of prolonged disability from a back injury
- It is unclear, as the authors note, why there would be an association between more than 7 days of Schedule III drugs and later disability, but not an association with Schedule II drugs
    - When a large number of associations are explored in regression models, some spurious and non-reproducible associations may arise from time to time

Assessment: High quality prospective cohort study supporting good evidence that in the setting of common low back injuries, when baseline pain and injury severity are taken into account, a prescription for more than seven days of opioids in the first six weeks is associated with an approximate doubling of disability one year after the injury.