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Concern about addiction is associated with lower quality of life in patients with osteoarthritis: an observational data analysis

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BACKGROUND

- Osteoarthritis (OA) pain is one of the most common and economically burdensome conditions in the United States, affecting approximately 20% of adults and resulting in substantial healthcare costs and lost work productivity.
- Clinical guidelines recommend a multimodal approach to treating OA, combining physical therapies with pharmacological intervention.
- According to a prior US treatment preference study of a hypothetical pharmacological treatment that would prevent OA from worsening, patients with OA would be willing to accept some degree of risk for adverse events¹.
- In a more recent study of OA patient preferences, Turk et al. (2020)² showed that control of OA pain and symptoms and reduced treatment-related risk of physical dependency would be the two most important attributes of a new medicine for adult patients with moderate to severe OA and inadequate response to pain treatment.
- Several different measurement instruments could be helpful in weighing these impacts on patient quality of life (QoL). One of the most widely used disease-specific measures of OA symptoms is the Western Ontario and McMaster Universities of Osteoarthritis Index (WOMAC)®.
- While the WOMAC is commonly used in clinical studies, it is not suitable for direct use in conventional economic evaluation because WOMAC scores provide neither a cardinal nor a preference-based index scale.
- Therefore, economic evaluations sometimes rely on a mapping from WOMAC to predict the EQ-5D. Several studies, including Cappelleri et al. (2016)³, have shown consistent statistical relationship between the two with demonstrated goodness of fit.

OBJECTIVE

- In the current research, we aim to evaluate the relationship between self-reported concerns about becoming addicted to a medicine (for this condition, opioids) and individual patient QoL measured alternatively by (a) the EQ-5D-5L Index score (EQ-5D) and (b) the EQ-5D Visual Analogue Scale (VAS) in patients with OA.

METHODS

- This unique, observational study used patient-level cross-sectional survey data collected from February-May 2017 from the US Adelphi Disease Specific Programme (DSP)[™],⁴
- The Adelphi DSP for OA selected 153 physicians (primary care, rheumatology, and orthopedic surgeons) identified from publicly available lists of healthcare professionals.
- Physicians completed an online survey and an electronic patient record form collecting de-identified data on their next 9 adults (≥18 years) patients with OA.
- Each patient was invited to complete a self-completion survey relevant to the disease area.
- The question of interest was about "concerns of medication addiction" as reflected in the Likert-scale question:
 - Completely agree (1) to completely disagree (5) with the statement "I am concerned about becoming addicted to my medicine".

METHODS (CONT.)

- A set of ordinary least squares (OLS) regressions using QoL measures (EQ-5D Index score and EQ-5D VAS) as outcomes and Concern about addiction (CAA) as a continuous predictor were estimated, including models with CAA as a categorical predictor as a sensitivity analysis.
- The relationship between EQ-5D Index score as a predictor and EQ-5D VAS as the outcome was also studied.
- Treating the EQ-5D VAS as the more general indicator of QoL, an OLS regression with the EQ-5D VAS as an outcome and with the EQ-5D-5L Index score and the CAA as two independent continuous predictors was estimated in this sample.
- Correlations between the measures were also assessed.

RESULTS

- A total of 866 OA patients completed the survey with the majority being female (61.2%), white (77.7%) and with mean age of 64.2 years (SD 11.7).
 - 835 patients completed the single item: 'I am concerned about becoming addicted to my medicine' (CAA)
- The CAA responses were well distributed with sizable representation for each category: about one-third of the patients responded that they "agree" (18%) or "completely agree" (11%), while 27% responded "completely disagree" and 20% "disagree" (Figure 1).
- The relationship between CAA as a continuous predictor and the EQ-5D Index score revealed that a one-category increase in CAA score is associated with a 0.029 reduction in the EQ-5D Index score, equivalent to 0.14 in terms of the standardized effect sizes (ES), which can be interpreted "trivial-to-small" effect (Figure 2).
- The difference in means between the lowest category ("Completely disagree") and the highest category ("Completely agree") corresponds to value of 0.11 ($p < 0.0001$) in the EQ-5D Index score (a "median" 0.57 ES). Correlation between CAA and the EQ-5D Index score is 0.19 (p -value <0.0001).
- The relationship between CAA and EQ-5D VAS showed that one-category increase in CAA score was associated with a 2.6 point reduction in the EQ-5D VAS (0.15 ES). The difference in means between the lowest and the highest category is 10.5 ($p < 0.0001$) representing "medium" ES of 0.59. Correlation between CAA and the EQ-5D VAS is 0.20 (p -value <0.0001) (Figure 3). Using CAA as a categorical predictor indicated that a linear approximation is appropriate in both models.
- A significant and robust relationship between EQ-5D VAS as an outcome and EQ-5D Index score as a predictor was observed (slope: 60.7; p value <0.0001). Correlation between EQ-5D Index score and the EQ-5D VAS is substantial 0.69 (p -value <0.0001) (Figure 4). Using EQ-5D Index score as a categorical predictor indicated that a linear approximation is appropriate.
- When both EQ-5D Index score and CAA scores were used simultaneously as predictors of EQ-5D VAS, the effect of CAA (after adjusting for EQ-5D Index) was still significant (slope: -0.97, $p=0.0071$) (Table 1).
- In this case, the difference between the CAA lowest and highest categories is 3.89 and the associated ES is 0.22, which would be regarded as "small". This is equivalent to -0.039 on a utility scale of 0-1.0, which would be regarded as significant in utility and economic terms.

FIGURE 1: Distribution of Response

Response Category	Percent of Patients
Completely Disagree	27%
Disagree	20%
Neither Disagree nor agree	23%
Agree	18%
Completely agree	11%

Figure 1. Distribution of the responses to the question/item "I am concerned about becoming addicted to my medicine"

FIGURE 2: Relationship between EQ-5D Index Score and CAA Score

Figure 2 shows the relationship between EQ-5D Index score and CAA score. This graph indicates that the linearity assumption, after allowing for natural sampling variation, for the relationship between EQ-5D Index score and CAA is appropriate

TABLE 1: Predicting EQ-5D VAS with EQ-5D Index Score and CAA

Effect	Estimate	Standard Error	P Value
Intercept	33.5593	2.2028	<.0001
EQ-5D Index	58.4143	2.3753	<.0001
CAA	- 0.9734	0.3603	0.0071

Table 1 shows that effect of the CAA is still significant (slope: -0.9734; p -value=0.0071)

CONCLUSIONS

- Patients with a diagnosis of OA who have concerns about medication addiction have significantly and meaningfully different EQ-5D Index and EQ-5D VAS scores compared with patients who do not have this concern.
- Concern about addiction has an additional negative impact – of potential clinical and economic importance – that is not fully captured in EQ-5D Index.
- Health technology assessment authorities who rely on the EQ-5D Index score may underestimate the value of products that reduce concerns about opioid addiction.
- It would be worthwhile to consider a "bolt-on" question for inclusion, after successful psychometric validation, about these concerns in an assessment of the impact of new interventions on OA patients⁵.

DISCLOSURES

Research funding provided by Pfizer, Inc and Eli Lilly and Company. LPG: received consulting fees associated with this study. PS, MD, LT, JC, AB: employees and stockholders of Pfizer. RLR, JH: employee of Eli Lilly and Company and own stocks. JJ and MB: employees of Adelphi Real World.

FIGURE 3: Relationship between EQ-5D VAS Score and CAA Score

Figure 3 depicts the relationship between EQ-5D VAS score and CAA score. This graph indicates that the linearity assumption, after allowing for natural sampling variation, for the relationship between EQ-5D VAS score and CAA is appropriate.

FIGURE 4: Relationship between EQ-5D VAS vs EQ-5D Index Score

Figure 4 shows the relationship between EQ-5D VAS and EQ-5D Index score. This graph indicates that the linearity assumption, after allowing for natural sampling variation, for the relationship between EQ-5D VAS and EQ-5D Index score is appropriate.

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REFERENCES

- Fraenkel L, Suter L, Cunningham CE, Gillian H. Understanding Preferences for Disease Modifying Drugs in Osteoarthritis. Arthritis Care Research. 2014; 66(8): 1186-1192; 2. Turk DC, Boeri M, Abraham L, Atkinson J, Bushmakin A, Cappelleri JC, Hauber B, Klein K, Russo L, Viktrup L, Walsh DA. Patient preferences for osteoarthritis pain and chronic low back pain treatments in the United States: A discrete choice experiment. Osteoarthritis and Cartilage. In press; 3. Cappelleri JC, Bushmakin AG, Whipple S, Hlavacek P, Sadosky A, Wilkie RJ. Mapping the Western Ontario and McMaster Universities Arthritis Index (WOMAC) to the EQ-5D. Value in Health 2016; 19:A235-A236; 4. Anderson P et al. Curr Med Op 2008; 24:3063-72; 5. Longworth L, Yang Y, Young T, Mulhern B, Hernández Alava M, Mukuria C, Rowen D, Tosh J, Tsuchiya A, Evans P, Devianee Keetharuth A, Brazier J. Use of generic and condition-specific measures of health-related quality of life in NICE decision-making: a systematic review, statistical modelling and survey. Health Technol Assess. 2014 Feb;18(9):1-224. * © 1996 Nicholas Bellamy. WOMAC® is a registered trademark of Nicholas Bellamy (CDN, EU, USA).

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