

## PAIN

# Pain after orthopaedic surgery: differences in patient reported outcomes in the United States vs internationally. An observational study from the PAIN OUT dataset

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## Abstract

**Background:** A previous PAIN OUT study found that American orthopaedic-surgical patients rated 'worst pain' higher than did similar European patients. This study aims to confirm these findings in a larger, international patient sample, explore whether risk factors for greater postoperative pain exist disproportionately in the American population, and confirm the findings for one procedure.

**Methods:** Surveyors collected patient reported outcomes (PROs) and perioperative pain management practices using PAIN OUT methodology. Most PROs used 11-point numerical rating scales (0=null, 10=worst possible). Risk factors included: female gender, younger age, high BMI, chronic pain, and opioid use before surgery. Initial analysis used a mixed patient cohort. A secondary analysis used only patients undergoing total knee replacement (TKR). Inference was based primarily on effect size using Cohen's d.

**Results:** 13,770 patients in 13 European and non-European countries (international) and 564 patients from the United States (US) contributed data on the 1st postoperative day. Three of 11 PROs differed between the cohorts: 'worst pain' [US 7.5 (2.5) vs international 5.6 (2.8); d=0.66 [confidence interval (CI) 0.58–0.75]]; proportion 'receiving information about treatment options' [US 0.86 vs international 0.66; d=0.53 (CI 0.39–0.66)]; reporting adverse effects and their severity [US 0.87 vs international 0.73; d=0.52 (CI 0.38–0.66)]. Risk factors did not differ between the two cohorts. PROs and management patterns in TKR patients were similar to the mixed cohort.

**Conclusions:** Three PROs differed between international and US patients, with higher 'worst pain' for US patients. Neither risk factors, nor patient mix accounted for the observed differences for 'worst pain'.

**Clinical trial registration:** NCT 02083835.

**Keywords:** observational study; pain; postoperative; patient reported outcome measures

**Editor's key points**

- PAIN OUT is an international network, using standardised data collection, aiming to improve perioperative pain control.
- Previous analyses of orthopaedic procedures found worse pain in the US compared with other countries.
- Neither surgery type nor known perioperative pain risk factors accounted for the worse pain scores.
- US patients had a higher chronic pain incidence and had a higher opioid load overall.

Perioperative pain management is an important public health concern because approximately 240 million patients undergo major surgery annually, worldwide.<sup>1</sup> Surveys conducted over the past 50 yrs in the United States (US) and Europe demonstrate that management of these patients' pain is generally suboptimal, as indicated by poor patient reported outcomes (PROs) in a high proportion of patients and the large variability in patient care.<sup>2</sup> Poorly managed perioperative pain causes suffering, interferes with recovery, reduces quality of life, and is a major predictor of chronic pain.<sup>3,4</sup>

The PAIN OUT ([www.pain-out.eu](http://www.pain-out.eu)) quality improvement network set out to address this deficiency by offering clinicians web-based tools to evaluate perioperative pain management practices in their centres and to compare their findings with similar patients in other hospitals. Participation is open to clinicians internationally. Patients fill in the International Pain Outcomes Questionnaire<sup>5</sup> (IPO-Q) in their native language. The repository holds more than 60 000 records from patients in Europe, the Americas, Africa, and South East Asia, offering a unique opportunity to compare PROs and pain management practices, internationally.

Routine pain assessment is a cornerstone for providing safe, effective, and individualised pain management.<sup>6</sup> Using PAIN OUT methodology, Chapman and colleagues<sup>7</sup> tested the hypothesis that pain-related PROs of orthopaedic patients in the US, where pain is assessed routinely and is a criterion for hospital accreditation, would be lower compared with those reported by patients in seven countries in Europe, where assessment is not routine nor, generally, a criterion for accreditation. Findings revealed that some PROs of American patients were significantly worse, particularly 'worst pain', despite a higher proportion of patients receiving treatment. As these findings are counterintuitive, this study sought to gain further understanding of the differences by carrying the following analyses comparing US patients to a large sample of international patients in order to: (1) contrast PROs and perioperative pain management practices; (2) explore whether known risk factors associated with greater pain after surgery, such as female gender or younger age, were present in the US population in a disproportionate number, and so could account for the findings; and (3) restrict the analyses to patients undergoing a single procedure, to determine whether a similar pattern of responses existed, independent of surgery type.

**Methods****Study design and hospitals contributing data**

This was a cross-sectional study. The network contributing data comprised hospitals participating in PAIN OUT that had submitted 30 or more records to the repository. All

collaborators obtained approval for collecting non-identified patient data from their local ethics committees. The primary publications describe the methodology used in PAIN OUT.<sup>5,8</sup>

**Patients**

Inclusion criteria required that the patient: (1) underwent any type of in-patient orthopaedic surgery; (2) was of consenting age (18 yr in most countries or 16 yr in the UK) or older; (3) was on the 1st postoperative day (POD1) and back on the ward from the recovery room for at least 6 h; and (4) agreed to participate in the survey. Consent could be oral or written, depending on requirements of the local ethics committee.

**Questionnaires**

Data collection for each patient involved two questionnaires.

- (1) *Patient characteristics and clinical data* comprised variables such as gender, age (yr of birth), weight and height, administration of opioids before admission and analgesics perioperatively, type of surgery and anaesthesia, and whether there was a record of assessing pain at least once since surgery. A surveyor obtained this information from the medical record.
- (2) *IPO-Q<sup>5</sup>* evaluating the following domains: severity of pain and relief from treatments; interference of pain with function in and out of bed; negative effect because of pain, specifically anxiety and helplessness; adverse effects (AEs), specifically nausea, fatigue, dizziness, itch; and perception of care, specifically wish for more pain treatment, satisfaction with pain treatment, participation in decisions about pain treatment, and receipt of information about pain treatment options. Patients also reported existence and severity of chronic pain before admission to hospital. Most items were scored using an 11-point numerical rating scale (0=null, 10=worst possible); two items were scored using a percentage scale ranging from 0 to 100% and two items used a dichotomous yes/no scale. The questionnaire's psychometric properties have been assessed and validated in eight languages. Translations are available in an additional 10 languages. Patients related all questions to the time since surgery. To reduce interviewer bias, patients completed the questionnaire independently with no assistance from family or staff. If a patient requested help, the surveyor could assist.

**Data collection, management and storage**

Surveyors were students, nurses, or medical residents and they underwent training for approaching patients, collecting data, and entering the data into a web-based password secure, portal. As far as possible, surveyors did not have clinical duties on wards from which they collected data. The principal investigator in each hospital determined whether surveyors were paid or worked on a voluntary basis. The Institute for Medical Informatics, Statistics and Epidemiology at the University of Leipzig, Germany, hosts and maintains the database.

**Plan for the evaluation**

- (1) Compare PROs in a mixed patient sample of US and international patients.

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