Research Paper

PAIN®

Reporting of IMMPACT-recommended core outcome domains among trials assessing opioids for chronic non-cancer pain

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Abstract

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) has recommended that trialists evaluating treatments for chronic pain should consider reporting 9 patient-important outcome domains. We examined the extent to which clinical trials evaluating the effect of opioids for chronic non-cancer pain (CNCP) report outcome domains recommended by IMMPACT. We systematically searched electronic databases for English-language studies that randomized patients with CNCP to receive an opioid or a non-opioid control. In duplicate and independently, reviewers established the eligibility of each identified study and recorded all reported outcome domains from eligible trials. We conducted a priori regression analyses to explore factors that may be associated with IMMPACT-recommended outcome domains. Among 156 eligible trials, reporting of IMMPACT-recommended outcome domains was highly variable, ranging from 99% for pain to 7% for interpersonal functioning. Recently published trials were more likely to report the effect of treatment on physical functioning, emotional functioning, role functioning, sleep and fatigue, and participant disposition. Trials for which the corresponding author was from North America were more likely to report treatment effects on physical functioning and participant ratings of improvement and satisfaction with treatment. Trials published in higher impact journals were more likely to report treatment effects on emotional function, but less likely to report participant ratings of improvement and satisfaction with treatment. Most IMMPACT domains showed an increased rate of reporting over time, although many patient-important outcome domains remained unreported by over half of all trials evaluating the effects of opioids for CNCP.

Keywords: Core outcome domains, Clinical trials, IMMPACT, Chronic pain

1. Introduction

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) first convened in 2002 to establish a standard set of patient-important outcome domains to guide the reporting of randomized controlled trials evaluating therapies for chronic pain.[17] In a 2003 article, this group, which includes representatives from the academic, governmental, and pharmaceutical communities, recommended that researchers report the following 6 core outcome domains in chronic pain clinical trials: (1) pain, (2) physical functioning, (3) emotional functioning, (4) participant ratings of global improvement and satisfaction with treatment, (5) symptoms and adverse events, and (6) participation disposition. In a 2008 publication, after conducting focus groups and surveys of individuals with chronic

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.painjournalonline.com).

PAIN 156 (2015) 1615–1619

http://dx.doi.org/10.1097/j.pain.0000000000000241

pain, IMMPACT recommended an additional 3 core outcome domains: (7) role functioning, (8) interpersonal functioning, and (9) sleep and fatigue.[18]

Establishing a standard set of outcome domains among chronic pain clinical trials has several merits. First, it encourages trialists to consider chronic pain as a complex phenomenon that affects patients across multiple dimensions.[2,3,7,11,12,19,20] Second, it protects against selective outcome reporting bias, which is a common issue across the medical literature.[4,5] Third, it facilitates the conduct of systematic reviews and meta-analyses, which allow researchers to generate more precise estimates of treatment effects by pooling common outcome data from individual trials.[10]

Although there have been anecdotal claims of improved outcome reporting following publication of IMMPACT recommendations,[16] there is no empirical evidence to support these assertions. Hence, we explored this issue among clinical trials evaluating the effectiveness of opioids for chronic non-cancer pain (CNCP).

2. Methods

2.1. Literature search

We searched for relevant studies, in any language, by tailored searches of AMED, CINAHL, CENTRAL, EMBASE, HealthSTAR, MEDLINE, and PsychINFO, from the inception of each database through March 2, 2012. An experienced academic librarian collaborated in the development of the search strategy for each electronic database.

2.2. Eligibility criteria

We included English-language studies if they randomly allocated patients with CNCP to opioid therapy or any non-opioid control group.

2.3. Study selection and data abstraction

Teams of reviewers worked independently and in duplicate to determine eligibility status of all identified citations, first by screening the titles and abstracts, then by reviewing the full texts of all potentially eligible articles. Two reviewers (A.M. and L.S.) used a pilot-tested standardized form to extract information, including details on all reported IMMPACT core outcome domains, from each eligible study. We also examined details about the study participants, interventions, and authors to assess whether multiple eligible articles resulted from the same trial. A third reviewer (L.C.L.) independently confirmed data extraction from every 10th article for quality assurance purposes. Reviewers resolved any disagreements by discussion or with the help of an adjudicator (J.W.B.).

2.4. Statistical analyses

We measured agreement at the stage of full-text review and interpreted the chance-independent agreement (Φ) for selection of eligible studies.[8] Values of 0 to 0.20 represented slight agreement, 0.21 to 0.40 represented fair agreement, 0.41 to 0.60 represented moderate agreement, 0.61 to 0.80 represented substantial agreement, and greater than 0.80 represented almost perfect agreement.[13] We summarized the data using mean and SD for continuous variables that were normally distributed, median and interquartile range (IQR) for continuous variables that were not normally distributed, and proportions for categorical variables.

We conducted adjusted logistic regression analyses and hypothesized, a priori, the following associations with higher rates of reporting IMMPACT-recommended core outcome domains: (1) more recently published trials, (2) trials published by corresponding authors from North America, (3) trials published in higher impact journals,[1] and (4) trials that began recruiting participants $\geq$1 year after publication of IMMPACT outcome recommendations. We estimated the date when patient recruitment began for trials that did not report this information by calculating the median duration from the beginning of the recruitment period to the date of publication among trials that did report this information, then subtracting this value from the date of publication among trials that required imputation.

We fit one model per IMMPACT domain that showed sufficient variability in reporting; specifically, we did not consider domains that were reported less than 10% of the time or greater than 90% of the time. We tested for multicollinearity to examine whether any predictors were correlated. Specifically, we calculated the variance inflation factors associated with each independent variable in each regression model and considered values $\geq$5 to indicate the presence of multicollinearity. If we detected multicollinearity between 2 or more variables, we removed the variable(s) that we deemed of lower importance. For all analyses, we calculated odds ratios (ORs) and the associated 95% confidence intervals (CIs) and set the level of significance at $P \leq 0.05$.

Our secondary objective was to explore the extent to which trials reporting IMMPACT core domains used patient-reported outcome measures, or otherwise, ie, clinician-reported, proxy-reported, or a combination.

We conducted all statistical analyses using IBM SPSS Statistics software (version 20).

3. Results

3.1. Study characteristics

Our searches yielded 23,156 unique citations, of which we deemed 156 English-language studies eligible. No 2 articles resulted from the same trial. The chance-independent agreement was 0.77, representing substantial agreement. **Table 1** summarizes the characteristics of these trials, and eTable 1 provides details regarding the clinical population under study, the intervention, and most commonly reported adverse events (available online as Supplemental Digital Content at http://links.lww.com/PAIN/A106). Typical studies originated from the United States (42.3%), reported a funding source (57.1%), which was usually an industry sponsor (66.3%), and did not report registering their protocol (91.0%). Of the 14 trials with a registered protocol, authors of 12 trials (85.7%) reported at least 1 more outcome domain in the eventual publication than was reported in their protocol, and 1 (7%) failed to report an outcome specified in their protocol (eTable 2, available online as Supplemental Digital Content at http://links.lww.com/PAIN/A107). The median impact factor of the journals (n = 147) in which the trials were published was 2.8 (IQR: 2.2-5.6). The median sample size used for the primary analyses in the trials was 61 participants (IQR: 31-210). Of the trials published after 2004, 95.2% did not refer to the 2003 IMMPACT consensus statement. The median duration from start of participant recruitment to publication, among the 43 trials that reported this information, was 1402 days (IQR: 1005-2160).

3.2. Overall reporting

Trials most commonly reported pain (98.7%) and symptoms and adverse events (93.6%), whereas they least reported

Table 1

Study characteristics.

Country of study (n = 156), n (%)	
United States	66 (42.3)
United Kingdom	18 (11.5)
Canada	16 (10.3)
France	8 (5.1)
Germany	8 (5.1)
Sweden	8 (5.1)
Australia	5 (3.2)
Italy	4 (2.5)
Belgium	3 (1.9)
Norway	3 (1.9)
Denmark	2 (1.3)
Other*	15 (9.5)
Impact factor (n = 147),† median (IQR)	2.8 (2.2-5.6)
Funding (n = 156), n (%)	
Not reported	67 (42.9)
Exclusively industry-funded	59 (37.8)
Partially industry-funded	7 (4.5)
Funded by nonindustry	22 (14.1)
Not funded	1 (0.6)
Protocol registration (n = 156), n (%)	
Not registered	142 (91.0)
Registered	14 (9.0)
Sample size for analysis (n = 156), median (IQR)	61 (31-210)
Reference to IMMPACT recommendations among RCTs published from 2004 onwards (n = 63), n (%)	3 (4.8%)

* 2 studies each from Korea, Switzerland, and Turkey; 1 study each from Austria, Brazil, China, Czech Republic, the Netherlands, Pakistan, Scotland, South Africa, and Venezuela.

† 7 journals, representing 9 publications, did not have impact factors recorded in the Web of Science's Science Citation Index.

IQR, interquartile range; RCT, randomized controlled trial.

interpersonal functioning (7.1%) (**Table 2**). With the exception of pain, symptoms and adverse events, and participant disposition, fewer than half of all trials reported any of the other 6 IMMPACT-recommended core outcome domains.

3.3. Source of outcome information

Pain (79.9%) and physical functioning (59.2%) were most frequently reported by patients only (**Table 3**). In over half of eligible trials, both patients and clinicians provided information on participants' impressions of improvement and satisfaction with treatment. The source of outcome information was often unclear.

Table 2

Reporting of IMMPACT-recommended core outcome domains.

Outcome domain	Number of trials (n = 156), n (%)
Pain	154 (98.7)
Symptoms and adverse events	146 (93.6)
Participant disposition	118 (75.6)
Physical functioning	71 (45.5)
Participant ratings of improvement and satisfaction with treatment	67 (42.9)
Sleep and fatigue	49 (31.0)
Emotional functioning	44 (28.2)
Role functioning	29 (18.6)
Interpersonal functioning	11 (7.1)

3.4. Factors associated with adherence to individual core outcome domains

After fitting the data using multiple linear regression models, we found that the associated variance inflation factors for all the independent variables were less than 2. Pain relief and symptoms and adverse events were reported in over 90% of trials and interpersonal functioning in fewer than 10%; as such, we did not fit models with these 3 domains.

Recently published trials were more likely to report the following outcome domains than older trials: physical functioning (OR: 2.3; 95% CI: 1.1-4.8; $P = 0.03$), emotional functioning (OR: 2.9; 95% CI: 1.5-5.7; $P < 0.01$), role functioning (OR: 2.5; 95% CI: 1.3-4.8; $P < 0.01$), sleep and fatigue (OR: 3.1; 95% CI: 1.8-5.4; $P < 0.01$), and participant disposition (OR: 2.4; 95% CI: 1.5-3.7; $P < 0.01$).

Trials published by corresponding authors from North America were more likely to report the following outcome domains than trials originating elsewhere: physical functioning (OR: 2.5; 95% CI: 1.2-4.8; $P < 0.01$) and participant ratings of improvement and satisfaction with treatment (OR: 2.4; 95% CI: 1.2-5.0; $P = 0.02$).

Compared with trials published in journals with lower impact factors, trials published in journals with higher impact factors were more likely to report treatment effects on emotional function (OR: 1.3; 95% CI: 1.1-1.6; $P < 0.01$), but less likely to report participant ratings of improvement and satisfaction with treatment (OR: 0.8; 95% CI: 0.7-0.9; $P < 0.01$).

Among trials that began recruiting participants after December 2004, ie, 1 year after publication of the original 6 IMMPACT recommendations, we did not find any statistically significant associations between publication of the IMMPACT recommendations and outcome reporting (Appendix, available online as Supplemental Digital Content at http://links.lww.com/PAIN/A105). As no eligible trials began recruiting participants after July 2009, ie, 1 year after publication of the later 3 IMMPACT recommendations, we could not explore for associations between publication of the latter IMMPACT recommendations and outcome reporting.

4. Discussion

4.1. Findings

Almost all trials evaluating the use of opioids for CNCP reported effects on pain and symptoms and adverse events. However, fewer than half of eligible trials evaluated treatment effects across 6 of the 9 IMMPACT-recommended core outcome domains: physical functioning, participant ratings of improvement and satisfaction with treatment, sleep and fatigue, emotional functioning, role functioning, and interpersonal functioning. With the exception of participant ratings of global improvement, pain, and adverse events, which we could not explore because of insufficient variability, our adjusted analyses found that all IMMPACT domains showed an increased rate of reporting over time. Publication of IMMPACT recommendations was not associated with more complete reporting of IMMPACT core domains.

4.2. Strengths and limitation

The strengths of our study include systematic searches of several electronic databases. Teams of reviewers conducted all subjective processes, including determining trial eligibility and data collection, independently and in duplicate. To guard against spurious associations, we specified independent variables for regression models a priori, including the anticipated direction of association.

Table 3

Source of information for IMMPACT-recommended core outcome domains.

Outcome domain (number of trials)	Patient-reported, n (%)	Clinician-reported, n (%)	Patient- and clinician-reported, n (%)	Not clear, n (%)
Pain (n = 154)	123 (79.9)	1 (0.6)	6 (3.9)	24 (15.6)
Physical functioning (n = 71)	42 (59.2)	2 (2.8)	1 (1.4)	26 (36.6)
Emotional functioning (n = 44)	21 (47.7)	0	0	23 (52.3)
Participant ratings of improvement and satisfaction with treatment (n = 67)	24 (35.8)	8 (11.9)	33 (49.3)	2 (3.0)
Symptoms and adverse events (n = 146)	61 (41.8)	8 (5.5)	74 (50.7)	3 (2.1)
Role functioning (n = 29)	13 (44.8)	0	1 (3.4)	15 (51.7)
Interpersonal functioning (n = 11)	5 (45.5)	0	1 (9.1)	5 (45.5)
Sleep and fatigue (n = 49)	39 (79.6)	0	0	10 (20.4)

As we only looked at trials of opioids for CNCP, a limitation of our study is that our findings may not be generalizable to other chronic pain clinical trials.

4.3. Implications

Our study is the first to systematically evaluate adherence to IMMPACT-recommended outcome domains. We found that, although most IMMPACT domains showed an increased rate of reporting over time, most domains remained unreported by over half of all trials evaluating the effects of opioids for CNCP. Publication of IMMPACT recommendations was not associated with increased reporting of IMMPACT-recommended core outcome domains, which is contrary to the belief held by some observers.[16]

Without consistent and more complete reporting of patient-important outcomes in randomized controlled trials for chronic pain, trialists will be unable to fully convey the effects of a given treatment. Some may argue that reporting effects on pain relief and symptoms and adverse events provides sufficient information about a treatment's merits and risks. While there is empirical evidence that suggests a relationship between pain and other patient-important outcomes,[14,15,21] differences in the magnitude and direction of treatment effects between outcome domains remain plausible. For instance, a previous systematic review of clinical trials of opioids for CNCP showed that, when compared with placebo, the effects of opioids on pain relief are more than twice as great as their effects on functional gains.[6] Furthermore, in evaluating the effectiveness of treatments for their pain, patients have identified aspects of their daily lives that go beyond pain and symptoms and adverse events.[18]

However, the reporting of large numbers of subjective outcomes is not without its problems. Comprehensive measurement of 9 different domains may threaten the feasibility of a trial. Patients, for instance, may experience the requirement to complete these measures as an onerous burden; this may lead to a considerable amount of missing data, including for outcomes that are most important to patients. Furthermore, trialists may think it is unlikely for a treatment to have important effects on multiple outcome domains, especially within studies that follow patients for short periods, ie, less than 2 weeks. In addition, trialists (and systematic reviewers) may find sifting through large amounts of outcome information and synthesizing treatment effects in a succinct and easily digestible manner an overwhelming task. In recognition of this issue, the Grading of Recommendations Assessment, Development and Evaluation Working Group has recommended that systematic reviewers present no more than 7 outcomes in Summary of Findings tables.[9] Such considerations, and a corresponding desire to focus on the outcomes that patients consider most important, may underlie investigators' decisions not to measure all IMMPACT-recommended domains.

Exploration of reasons why chronic pain clinical trialists do not include comprehensive measurement of all domains and improved guidance from IMMPACT to address potential feasibility concerns warrant attention.

Conflict of interest statement

The authors have no conflicts of interest to declare.

This is a substudy of a systematic review funded by the Canadian Institutes of Health Research (CIHR). S. M. Mulla is supported by an Ontario Graduate Scholarship. S. Ebrahim is supported by a MITACS Elevate Fellowship Award and a SickKids Restracomp Postdoctoral Fellowship Award. G. H. Guyatt is supported by a CIHR Health Researcher of the Year Prize.

Acknowledgements

The authors thank Samantha Craigie for her assistance in coordinating this research study and Rachel Couban for developing the search strategy and conducting the literature searches.

Appendix A. Supplemental Digital Content

Supplemental Digital Content associated with this article can be found online at http://links.lww.com/PAIN/A105, http://links.lww.com/PAIN/A106, http://links.lww.com/PAIN/A107.

Article history:
Received 19 December 2014
Received in revised form 6 April 2015
Accepted 19 May 2015
Available online 26 May 2015

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