Automating peer review for research articles

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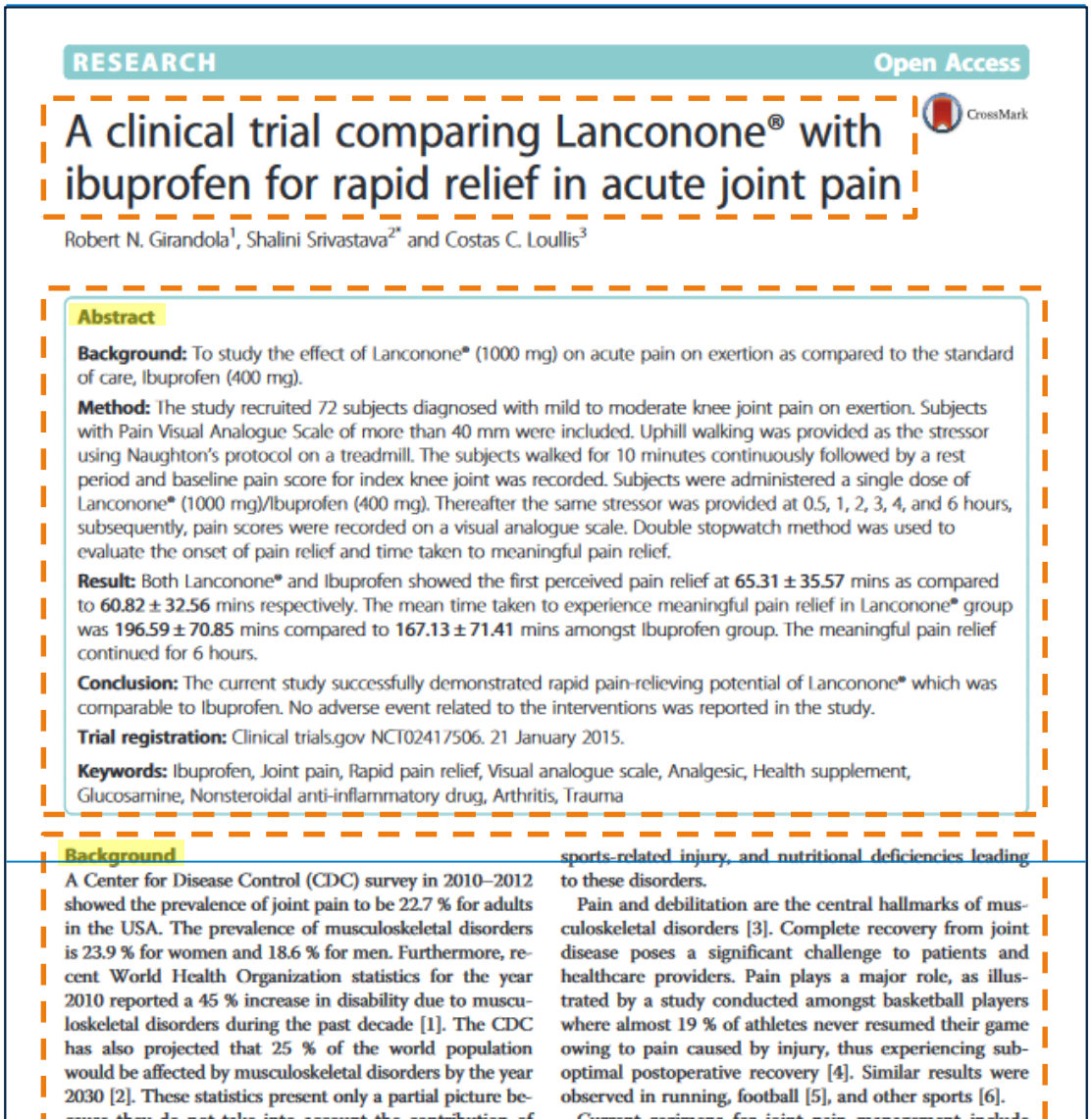
Automated statistical and methodological review

We are working with Associate Professor Timothy Houle (Wake Forest School of Medicine) and Chad Devoss (Next Digital Publishing) to investigate if it is feasible to automate the statistical and methodological review of research.

The programme, StatReviewer uses iterative algorithms to “look for” for critical elements in the manuscript, including CONSORT statement content and appropriate use and reporting of p-values.

It makes no judgement call as to the quality of validity of the science, only regarding the reporting of the study.

The StatReviewer process



RESEARCH Open Access

A clinical trial comparing Lanconone® with ibuprofen for rapid relief in acute joint pain

Robert N. Girandola[1], Shalini Srivastava[2*] and Costas C. Loullis[3]

Abstract

Background: To study the effect of Lanconone® (1000 mg) on acute pain on exertion as compared to the standard of care, Ibuprofen (400 mg).

Method: The study recruited 72 subjects diagnosed with mild to moderate knee joint pain on exertion. Subjects with Pain Visual Analogue Scale of more than 40 mm were included. Uphill walking was provided as the stressor using Naughton's protocol on a treadmill. The subjects walked for 10 minutes continuously followed by a rest period and baseline pain score for index knee joint was recorded. Subjects were administered a single dose of Lanconone® (1000 mg)/Ibuprofen (400 mg). Thereafter the same stressor was provided at 0.5, 1, 2, 3, 4, and 6 hours, subsequently, pain scores were recorded on a visual analogue scale. Double stopwatch method was used to evaluate the onset of pain relief and time taken to meaningful pain relief.

Result: Both Lanconone® and Ibuprofen showed the first perceived pain relief at **65.31 ± 35.57** mins as compared to **60.82 ± 32.56** mins respectively. The mean time taken to experience meaningful pain relief in Lanconone® group was **196.59 ± 70.85** mins compared to **167.13 ± 71.41** mins amongst Ibuprofen group. The meaningful pain relief continued for 6 hours.

Conclusion: The current study successfully demonstrated rapid pain-relieving potential of Lanconone® which was comparable to Ibuprofen. No adverse event related to the interventions was reported in the study.

Trial registration: Clinical trials.gov NCT02417506. 21 January 2015.

Keywords: Ibuprofen, Joint pain, Rapid pain relief, Visual analogue scale, Analgesic, Health supplement, Glucosamine, Nonsteroidal anti-inflammatory drug, Arthritis, Trauma

Background

A Center for Disease Control (CDC) survey in 2010–2012 showed the prevalence of joint pain to be 22.7 % for adults in the USA. The prevalence of musculoskeletal disorders is 23.9 % for women and 18.6 % for men. Furthermore, recent World Health Organization statistics for the year 2010 reported a 45 % increase in disability due to musculoskeletal disorders during the past decade [1]. The CDC has also projected that 25 % of the world population would be affected by musculoskeletal disorders by the year 2030 [2]. These statistics present only a partial picture because they do not take into account the contribution of sports-related injury, and nutritional deficiencies leading to these disorders.

Pain and debilitation are the central hallmarks of musculoskeletal disorders [3]. Complete recovery from joint disease poses a significant challenge to patients and healthcare providers. Pain plays a major role, as illustrated by a study conducted amongst basketball players where almost 19 % of athletes never resumed their game owing to pain caused by injury, thus experiencing suboptimal postoperative recovery [4]. Similar results were observed in running, football [5], and other sports [6].

Title

Abstract

Introduction

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Methods

Subjects

The trial was conducted at the outpatient clinics of two orthopedic surgeons having a regular inflow of subjects with knee pain. Knee joint pain is an appropriate model to study pain relief, as the structural changes here are representative of a stable condition to study acute pain. A total of 72 males and females between 40 and 60 years of age with mild to moderate degenerative changes of the knee joint were randomized in the study.

Subject inclusion criteria

1. History of moderate to severe knee pain on minimal exertion but no pain at rest.
2. A score ≥40 mm on the pain visual analog scale (VAS) after walking briskly at a pace of 4 ± 0.5 mph on a treadmill without elevation for 10 minutes continuously.
3. Grade II and III joint functionality assessed clinically as per American Rheumatology Association (ARA) classification [12] and radiologically as per Kellgren Lawrence (KL) classification [13].
4. Physician and subject global assessment of joint pain as "poor" or "very poor" after walking briskly at a pace of 4 ± 0.5 mph on a treadmill without elevation for 10 minutes.

Subject exclusion criteria

1. Any other form of arthritis except OA.
2. Neurological origin of pain, limb deformity, or any other systemic illness that might interfere with the outcome of the study.
3. Subjects taking intra-articular or oral steroids/hyaluronic acid/parenteral NSAIDS for a considerable period.
4. Subject with signs of local lower limb(s) injury.

All subjects provided their well-informed written consent for participation in the study which was recorded audio-visually. The study was conducted in compliance with International Conference on Harmonisation - Good Clinical Practice (ICH-GCP) guidelines. Approval for the study was granted by Independent Ethics Committee (IEC-Aditya registered with the Office for Human Research Protections in the US Department of Health and Human Services under registration number IRB00006475). The trial was registered at clinical trials.gov under registration number NCT02417506.

Study design

This study was a prospective noninferiority, randomized, double-blind, comparator-controlled, parallel group, multicenter clinical trial designed to assess the effects of Lanconone® in acute pain. The subjects were randomized to one of the two treatment groups, with appropriate blinding maintained for the subjects, the study coordinators, as well as the investigators. Figure 1 shows the flow of participants in the study.

Section/Topic	Item No	Checklist item
Title and abstract		
	1a	Identification as a randomised trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts [21, 31])
Introduction		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomisation:		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

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Reviewer's report

Did you make any changes to your methods after the trial began (for example, to the eligibility criteria)? Why were these changed?

Were there any unplanned changes to your study outcomes after the study began? Why were these changed?

Please explain how your sample size was determined, including any calculations.

The pilot

- StatReviewer is being used as an adjunct to the normal peer review process for four journals:
    - *Trials*, *Critical Care*, *BMC Medicine*, *Arthritis Research & Therapy*
- Relevant manuscripts (clinical trials) will be identified on submission and included on an opt-out basis;
- Peer review of these manuscripts will follow the journal's normal policy, with the manuscript also sent to StatReviewer for an additional review;
- All reports will be returned to the author, although the StatReviewer report will be flagged as such in the comments;
- StatReviewer will only be used for new submissions, not resubmitted manuscripts to prevent confounding issues.

Outcomes

The primary aim of the pilot is to evaluate the feasibility and acceptability of an automated review in our workflows for these journals.

- **Main outcome** will be the percentage completeness of the reporting of the manuscripts before and after review
- **Secondary outcomes** will include comparisons between the StatReviewer report and the normal peer reviewer reports (on an opt-in basis); and a comparison of authors' response to the StatReviewer reports compared with 'human' reviews.

Thank you

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