Poster # 110

Treating Osteoarthritis Pain: Effectiveness of Immediate- and Extended-Release Acetaminophen Products

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Background

- Acetaminophen became available as an over the counter (OTC) analgesic in 1959.
- The FDA approved acetaminophen 650 mg extended-release (ER) for the treatment of mild to moderate pain related to osteoarthritis (OA) in 1994.
- Data from 5 Johnson & Johnson Consumer Inc (JJCI) sponsored home-use clinical trials, 2 previously unpublished (Trials 1, 2) and 3 published (Trials 3, 4, 5),[1-3] which assessed effectiveness and safety of acetaminophen among 856 individuals with radiographically confirmed hip or knee OA are compared.
- These trials contain clinical data that inform healthcare professionals of the evidence supporting effectiveness and safety of currently available drugs.

Goals

- Compare participant-reported outcomes from 5 company-sponsored clinical trials following 1, 2 and 4 weeks of treatment with acetaminophen immediate release (IR) 4000 mg (n=429) or acetaminophen ER 3900 mg (n=427) to examine effectiveness and safety of acetaminophen.

Study Details

- JJCI databases were searched for OA clinical trials with ≥1 oral, acetaminophen-only treatment arm.
- All trials were randomized, double blind, active-controlled, multiple-dose, parallel, multicenter, home-use clinical trials with dosing ≥4 weeks.
  - Trial 1 (IR) was conducted between Feb 1994 and Jun 1995; Trial 2 (IR) between Dec 1993 and Nov 1995; Trial 3 (IR) between May 2000 and June 2003; Trial 4 (ER) between April 2002 and March 2003; Trial 5 (ER) between January and November 2004.
- In each trial, participants were ≥40 years of age; had radiographically confirmed hip or knee OA with secondary pain requiring use of NSAID, acetaminophen, or other analgesic on a regular basis for ≥3 months and positive response to ≥1 agent; pain ≥ moderate intensity on 5-point verbal scale for ≥6 months; able to walk without assistive devices; no history or evidence of other types of arthritis or collagen vascular disease.
- Acetaminophen efficacy data collected during the initial 4 weeks of treatment were used in these analyses. Participant-reported outcomes included level of OA pain, physical function and assessment of acetaminophen as an analgesic.
- Adverse events (AEs) were collected for all participants at each visit and reported by the participants in a daily diary. Pooled adverse events of acetaminophen IR 4000 mg/d and acetaminophen ER 3900 mg/d from these trials are presented.

Figure 1: % Reduction in pain at rest and pain on walking vs baseline

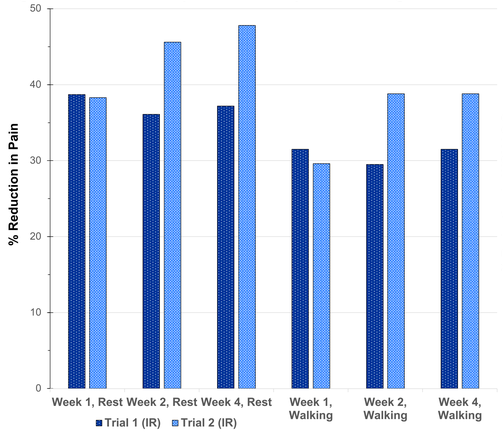


Figure 2: % Reduction in WOMAC pain and stiffness scores vs baseline

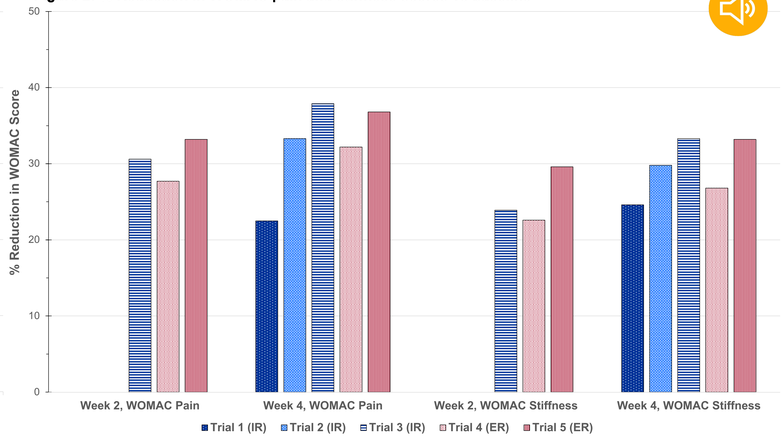
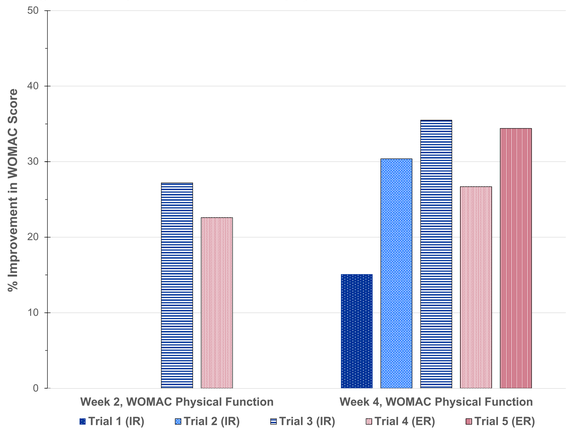


Figure 3: % Improvement in WOMAC physical function score vs baseline



Conclusions

Participant-reported responses throughout the 4 weeks of acetaminophen IR 4000 mg/d or acetaminophen ER 3900 mg/d use confirm

- Decreased pain at rest and on walking
- Decreased WOMAC pain and stiffness scores
- Improved WOMAC physical function scores

Demographics of Study Population

	Trial 1 (IR)	Trial 2 (IR)	Trial 3 (IR)	Trial 4 (ER)	Trial 5 (ER)
# OA Patients	46	96	287	160	267
Mean age (y)	52	56	59	62	62
Female	57%	71%	67%	71%	78%
Moderate-moderately severe baseline pain	89%	a	91%	100%	100%

a: Mean score = 2.4 on 5-point scale: none (0), mild (1), moderate (2), moderately severe (3), and severe (4)

Results

Participant response data from 5 home-use clinical trials

- Confirms the analgesic effectiveness and safety of acetaminophen in the management of moderate to moderately severe pain related to hip and knee OA.
- Confirms reductions in pain beginning at the first assessment, 1 week after starting acetaminophen IR 4000 mg/d to manage their OA pain and continuing throughout 4 weeks. (Fig 1, 2, 3)
- Confirms sustained reductions throughout 4 weeks in pain and stiffness and improvements in physical function on the WOMAC OA Index among those taking acetaminophen ER 3900 mg/d. (Fig 2, 3)
- Headache (5.6% - 21.7%), abdominal pain (1.3% - 30.4%), dyspepsia (1.3% - 21.9%), diarrhea (5.2% – 21.7%), nausea (1.3% - 9.4%) and infection (0% - 12.7%) were the most commonly reported adverse events.

References

1. Temple AR, et al. Clin Ther. 2006;28(2):222-235. 2. Altman RD, et al. Osteoarthritis Cartilage. 2007;15:454-461. 3. Prior MJ, et al. CMRO. 2014;30:11, 2377-2387.

Disclosures

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