

PublisherInfo		
PublisherName	:	BioMed Central
PublisherLocation	:	London
PublisherImprintName	:	BioMed Central

GI toxicity of rofecoxib compared to naproxen

ArticleInfo		
ArticleID	:	121
ArticleDOI	:	10.1186/ar-2001-66873
ArticleCitationID	:	66873
ArticleSequenceNumber	:	78
ArticleCategory	:	Paper Report
ArticleFirstPage	:	1
ArticleLastPage	:	3
ArticleHistory	:	RegistrationDate : 2001-1-8 OnlineDate : 2001-1-8
ArticleCopyright	:	Biomed Central Ltd2001
ArticleGrants	:	
ArticleContext	:	130753311

Keywords

Coxibs, GI toxicity, NSAID, rofecoxib

Context

The hypothesis that selective inhibitors of cyclo-oxygenase (COX)-2 (coxibs) would have less serious upper gastrointestinal (GI) toxicity than traditional non-selective nonsteroidal anti-inflammatory drugs (NSAIDs) has recently been affirmed for celecoxib (see Additional information). This study tests the hypothesis for rofecoxib in rheumatoid arthritis (RA).

Significant findings

Confirmed GI events were less with rofecoxib than naproxen (2.1 versus 4.5 per 100 patient-years, relative risk 0.5), as were the rates of complicated events (0.6 versus 1.4 per 100 patient-years, relative risk 0.4). The incidence of myocardial infarction (MI) was higher with rofecoxib than naproxen (0.4% versus 0.1%, relative risk 0.2).

Comments

This study confirms the hypothesis that selective inhibition of COX-2 in the treatment of RA is associated with significantly less GI toxicity than NSAIDs. However, treatment with neither celecoxib (see Additional information) nor rofecoxib completely eliminates serious GI toxicity in RA or osteoarthritis patients. The increased incidence of MI in the rofecoxib-treated patients occurred primarily in patients for whom low-dose aspirin would have been appropriate, but not allowed by the trial.

Methods

Prospective, randomized controlled trial with active comparator

Additional information

Silverstein FE, Faich G, Goldstein JL, Simon LS, Pincus T, Whelton A, Makuch R, Eisen G, Agrawal NM, Stenson WF, Burr AM, Zhao WW, Kent JD, Lefkowitz JB, Verburg KM, Geis GS: **Gastrointestinal toxicity with celecoxib vs nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis: the CLASS study: A randomized controlled trial. Celecoxib Long-term Arthritis Safety Study.** *JAMA* 2000, 284:1247-1255 ([PaperReport](#)).

References

1. Bombardier C, Laine L, Reicin A, Shapiro D, Burgos-Vargas R, Davis B, Day R, Ferraz MB, Hawkey CJ, Hochberg MC, Kvien RK, Weaver A, Schnitzer TJ: Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis. *N Engl J Med.* 2001, 343: 1521-1528.