during the last month of treatment. RESULTS: Of 167 patients (20 men, 147 women; mean age 43.5 years) included in the analysis, 72% responded to tegaserod. At baseline, SF-36 scores from IBS-C patients were lower than those from the general population, but increased in all dimensions with treatment (p = 0.0068 for General Health), reaching values similar to those of the general population. An increase in all SF-36 dimensions was observed in responders (R), whereas a decrease occurred in non-responders (NR, General Health dimension p = 0.004). IBS-QOL scores (from baseline to treatment) significantly increased in all dimensions (p < 0.0001 for overall assessment). The mean increment in IBS-QOL was greater for R than NR (Overall dimension, p < 0.05). Upon treatment withdrawal, some dimensions of SF-36 and IBS-QOL scores decreased but did not return to pretreatment levels. CONCLUSIONS: QoL is impaired in IBS-C patients. Treatment with tegaserod 6 mg b.i.d. improves QoL in patients with IBS-C to a level almost equivalent to that of the general population, and deterioration in QoL occurs upon treatment discontinuation.

METHODS & CONCEPTS

USE OF_THRESHOLDS FOR SAFETY REPORTING IN CLINICAL TRIALS

Frame D, Fahrbach K, Reynolds MW, Ross SD
MetaWorks Inc, Medford, MA, USA

OBJECTIVE: To assess completeness of safety reporting in published clinical trials, including use of incidence, severity, and relationship to drug to determine which AE thresholds would be listed in published reports, while 71% of migraine studies with a threshold used incidence (e.g. only AEs occurring in more than 5% of patients were listed). The severity threshold (reporting of only serious AEs or only grade 3–4 AEs) was the least common in all three clinical areas examined. No consistent relationship was found between complete AE reporting and study sponsorship (industry vs. non-industry/not reported) or year published (pre vs. post 1995). Smaller studies (<100 patients) were more likely to contain complete AE reporting, perhaps due to the difficulty of providing a comprehensive listing of all events in larger studies. CONCLUSIONS: Incidence and relationship to drug remain common thresholds for AE reporting in published clinical trials. Early detection of rare or anticipated events by meta-analysis of published trial data is thus made more challenging.