adverse effects profile of the medication. The most support was registered for the optimal scenario (halt disease progression, no adverse effects).

empirical evidence. The objective of this study was to evaluate whether there were differences in adverse event reporting for propoxyphene by age group using a large post-marketing safety surveillance database. METHODS: Analysis was conducted using the 2003–2008 Adverse Event Reporting System (AERS) data in the US, which was developed to support the FDA’s post-marketing safety surveillance program. AERS is an approved product. Adverse events reported with propoxyphene as primary, secondary, or interacting drug were categorized into central nervous system (CNS) and gastrointestinal (GI) adverse events (AEs). Logistic regressions were used to assess the risk of CNS and GI adverse events (AEs) among the elderly (age ≥ 65) and younger patients (age < 65) controlling for gender and those reporting the AEs. Proportional reporting ratios (PRR) for the propoxyphene-AE combination were also computed for the elderly and younger patients. RESULTS: In the period 2003–2008, a total of 2497 propoxyphene-AE combinations were reported, 261 were CNS related, and 17 were GI related. In multivariate analysis, controlling for gender and those reporting the AEs, no significant differences were observed in the risk of CNS-related AEs (Odds ratio: 0.827; 95% CI: 0.619–1.050; p = 0.199) or GI-related AEs (Odds ratio: 1.216; 95% CI: 0.832–1.778; p = 0.313) among elderly versus young patients. Among the elderly, the PRR for propoxyphene-CNS AEs was 0.795 and the PRR for propoxyphene-GI AEs was 0.596. These were similar to the PRRs among younger patients, which were 0.700 and 0.439, respectively. CONCLUSIONS: Using a voluntary post-marketing surveillance database, the study found no differences in the extent of CNS AEs and GI AEs reported with propoxyphene among elderly patients versus younger patients.

CONCLUSIONS: Differences in patient population and demographic characteristics may influence adverse event reporting. Adverse event reporting in the elderly population needs to be a focus of post-marketing surveillance 

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**SYSTEMIC DISORDERS/CONDITIONS – Clinical Outcomes Studies**

**PSY1**

**SYSTEMATIC REVIEW OF THE EFFICACY AND SAFETY OF PHARMACOTHERAPIES USED IN CHRONIC LOW BACK PAIN**

**OBJECTIVES:** Chronic low back pain (CLBP) is a major cause of disability, affecting mainly working-age adults and imposing a large economic burden on society. Since no consensus exists regarding standard of care for this condition, the objective of this study was to systematically review the efficacy and safety of pharmacotherapies used for CLBP.

**METHODS:** A systematic literature review was conducted through July 2008, searching MEDLINE, EMBASE, and bibliographic details of relevant studies. Prospective trials and observational studies were included if they assessed pharmacotherapies used for CLBP and were generally in agreement with two other South African studies, although differences were observed. A lower prescribing rate for triptans has been observed. Qualitative studies on migraine are needed in South Africa and the cognitive issues associated with CLBP are relevant. Observational studies, where the drug is used in the real world and categorized as appropriate, are needed. Qualitative studies on migraine are needed in South Africa and the cognitive issues associated with CLBP are relevant. Observational studies, where the drug is used in the real world and categorized as appropriate, are needed.

**RESULTS:** 2005–2008 Adverse Event Reporting System (AERS) data in the US, which was developed to support the FDA’s post-marketing safety surveillance program. AERS is an approved product. Adverse events reported with propoxyphene as primary, secondary, or interacting drug were categorized into central nervous system (CNS) and gastrointestinal (GI) adverse events (AEs). Logistic regressions were used to assess the risk of CNS and GI adverse events (AEs) among the elderly (age ≥ 65) and younger patients (age < 65) controlling for gender and those reporting the AEs. Proportional reporting ratios (PRR) for the propoxyphene-AE combination were also computed for the elderly and younger patients. RESULTS: In the period 2003–2008, a total of 2497 propoxyphene-AE combinations were reported, 261 were CNS related, and 17 were GI related. In multivariate analysis, controlling for gender and those reporting the AEs, no significant differences were observed in the risk of CNS-related AEs (Odds ratio: 0.827; 95% CI: 0.619–1.050; p = 0.199) or GI-related AEs (Odds ratio: 1.216; 95% CI: 0.832–1.778; p = 0.313) among elderly versus young patients. Among the elderly, the PRR for propoxyphene-CNS AEs was 0.795 and the PRR for propoxyphene-GI AEs was 0.596. These were similar to the PRRs among younger patients, which were 0.700 and 0.439, respectively. CONCLUSIONS: Using a voluntary post-marketing surveillance database, the study found no differences in the extent of CNS AEs and GI AEs reported with propoxyphene among elderly patients versus younger patients.

**CONCLUSIONS:** Using a voluntary post-marketing surveillance database, the study found no differences in the extent of CNS AEs and GI AEs reported with propoxyphene among elderly patients versus younger patients.

**CHALLENGES IN USING THE LITERATURE TO ESTIMATE THE OUTCOMES OF CURRENT RISK STRATIFICATION METHODS IN ADULT PATIENTS WITH PRIMARY ACUTE MYELOID LEUKEMIA**

**OBJECTIVES:** Treatment of patients with acute myeloid leukemia (AML) is based upon stratification into risk (prognosis) groups. New diagnostic methods are in development to improve this stratification. Economic evaluations of these methods require knowledge of what happens when the current stratification methods are used. We examined whether the literature can provide valid estimates for the outcomes of complete remission rates for patients with primary AML aged 16–60 years. METHODS: A systematic literature review was performed using PubMed and Embase. Inclusion criteria were: 109 AML patients and detailed outcomes per risk group (favorable, intermediate, unfavorable). Excluded were: Phase II studies, studies not containing any patients aged 16–60 years or with primary AML. We compared various study characteristics such as patient population, treatment given, risk group definitions and complete remission (CR) rates as outcome. A chi-square test for homogeneity of CR rates was performed. RESULTS: Twelve studies fulfilled the eligibility criteria. Great variation was found between study populations. While treatment varied between the studies, all patients received cytarabine and an anthracycline. Definition of risk groups varied greatly except for the favorable risk group. There was no homogeneity in our CR rate (range: 52–87%). Exclusion of a single study lowered CR rates significantly and decreased the number of patients other than the target population, heterogeneity between the remaining studies decreased (N = 7, p = 0.083). CR rates were homogeneous in the favorable group (p = 0.223), but heterogeneous in the intermediate and unfavorable groups (p = 0.044 and p = 0.096 respectively). CONCLUSIONS: Differences in patient population and