Comparative analysis of the sedative effects of mequitazine and other antihistaminic drugs: review of the literature

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Authors' objectives
To compare the adverse sedative effects of mequitazine with those of other antihistamines used in clinical practice.

Searching
MEDLINE and EMBASE were searched from 1975-1999. Additional publications on mequitazine were provided by the manufacturer of the drug.

Study selection
Study designs of evaluations included in the review
All publications of mequitazine and recent comprehensive review articles on nonsedating antihistamine drugs.

Specific interventions included in the review
Mequitazine (5mg once daily, BID or QD) compared to antihistamines (sedating and non-sedating) and/or placebo.

Participants included in the review
Healthy volunteers and patients with allergic disorders, chronic urticaria, dermal disorders, and ear, nose and throat conditions.

Outcomes assessed in the review
Subjective symptom rating of level of sedation, drowsiness and fatigue were the main outcomes considered. Both physician and patient ratings scales were used including visual analogue scales, line analogue scales, alertness rating scale, diary cards and assessments of sedation.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
The authors do not state that they assessed validity.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction. Data were extracted on study population, trial design, drug regimen, subjective symptom rating and relative level of sedation.

Methods of synthesis
How were the studies combined?
A narrative synthesis was presented.

How were differences between studies investigated?
Heterogeneity was not formally investigated.

Results of the review
Four clinical trials comparing mequitazine with sedating antihistamines, two in healthy volunteers (n=32) and two in patients with allergic disorders (n=89). Six clinical trials comparing mequitazine with non-sedating antihistamines, one in healthy volunteers (n=9), one in patients with various dermal disorders and allergic rhinitis (n=115), one in patients with various dermal and ear, nose, and throat conditions (n=48) and four in patients with allergic rhinitis (n=556).

Mequitazine compared to sedating antihistamines (n=4):

Mequitazine produced less drowsiness and fatigue than the sedating antihistamines, both in healthy volunteers and in patients with allergic disorders.

Mequitazine compared to non-sedating antihistamines (n=6):

Patients were found to have few CNS effects. Mequitazine produced levels of drowsiness and fatigue similar to the non-sedating antihistamines and placebo.

Authors' conclusions
The classification of antihistamines based on their chemical structure alone is misleading. Based on our review of all available product literature on mequitazine and recently published reviews of non-sedating antihistaminic drugs, mequitazine demonstrates a clinically proven low-sedation profile, similar to that seen with current antihistamines, which are frequently reported to be non-sedating. Mequitazine has a low propensity to induce drowsiness, comparable to that of cetirizine and loratidine. Thus it differs from truly sedative antihistaminic drugs, such as dexchlorpheniramine, which produce drowsiness and fatigue in patients with atopy to a degree that is measurably different from placebo.

CRD commentary
The review appears to be a reasonable summary of the area, however, insufficient methodological details, such as how inclusion criteria were applied and how data were extracted, are presented. The literature search was adequate however, it is not clear whether unpublished data were included in the review or whether any language restrictions were applied, thus the results may be subject to publication bias. Validity was not formally assessed or discussed and so it is difficult to draw firm conclusions regarding the robustness of the results presented. Study details are presented but actual results are not presented and those reported in the text appear subjective thus it is difficult to tell whether these results may be biased. The authors conclusions appear to follow from the results presented but should be interpreted with caution due to the limitations highlighted above.

Implications of the review for practice and research
The authors did not report any implications for further research or practice.

Bibliographic details

Indexing Status
Subject indexing assigned by CRD

MeSH
Histamine H1 Antagonists /adverse effects; Phenothiazines /adverse effects; Rhinitis, Allergic, Perennial /drug therapy; Urticaria /drug therapy

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.