Safety of chewable tablets for children

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Authors' objectives
To assess the safety of chewable tablets in young children.

Searching

Further information was also obtained from the Physicians Desk Reference, the IMS Health National Prescription Audit Plus 7 and the IMS Health National Disease and Therapeutic Index (1997 to November 1998), and by purchasing the products from a local drugs store. Specific manufacturers were also contacted.

Study selection
Study designs of evaluations included in the review
Single case reports were included if they mentioned chewable tablets. Case series of patients who had aspirated a foreign body were included if more than 10 patients were reported, if children were included, and if the type of foreign body aspirated was specified. Reviews of the management of aspiration were excluded. The studies included in the review were case series, case reports and randomised controlled trials (RCTs).

Specific interventions included in the review
Studies of chewable tablets were eligible for inclusion.

Participants included in the review
Studies of patients of any age, including children, who had aspirated a foreign body were included. Reports that only included people who had aspirated a metal or plastic foreign body were excluded. The patients in the included studies were aged from one to 78 years.

Outcomes assessed in the review
The inclusion criteria were not explicitly defined in terms of the outcomes. The review assessed safety, principally aspiration.

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

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

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

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

How were differences between studies investigated?
Differences between the studies were not discussed.

Results of the review
Twenty-nine retrospective case series of foreign body injuries were included (greater than 10,000 participants). Two RCTs and two single case reports were also included. One RCT was on lozenge dissolution time, while the other was on the effectiveness of chewable tablets in curing hookworms (the number of children was not stated for either RCT).

Sixty-eight different formulations of drugs were available for use in children in the USA.

The approved age range was specified for 39 of the chewable tablets. Thirty-one of these were approved for use in children down to 2 years of age. None of the 59 products with a product circular or bottle label mentioned the risk of choking or aspiration. Approximately two million prescriptions were written for chewable tablets for children aged five years or younger, in the USA, in the past two years.

Only two case series mentioned children who had aspirated tablets. The first of these (234 children aged less than 16 years old who had tracheobronchial foreign bodies removed) included one case of medicine tablet, but provided no details of the type of tablet or the patient’s age. The second (1,130 cases of non food foreign body aspiration or ingestion in children aged 0 to 3 years reported to the National Surveillance System between 1988 and 1990) found that 12% of the 41 deaths due to aspiration were due to medication such as pills. The average age at death was 14.8 months. No details of the individual cases, or the types of pills aspirated, were presented.

One case report was of a 13-month-old baby who died following the aspiration of baby aspirin. Another case report was of three infants (aged 9 months to 2.5 years) who also aspirated baby aspirin; two suffered severe neurological deficits and one died.

One small RCT found that none of the children studied (aged 3 to 5 years) aspirated fluoride lozenges of 10.0 or 13.5 mm in diameter.

One RCT found that, in children aged 8 to 13 years, chewed or crushed tablets of pyrantel pamoate increased hookworm cure rates compared with chewable tablets swallowed whole.

Two single case reports identified one child aged 4 years with chemical burns due to chewable aspirin, and one adult with dental erosion as a result of long-term use of chewable vitamin C tablets.

Authors’ conclusions
Chewable tablets offer a safe, easily administered and well-tolerated means of giving drugs to children aged two years or older.

CRD commentary
The review question was clear in terms of the study design, intervention and participants, but the inclusion criteria were not explicitly stated in terms of the outcomes. Several relevant sources were searched and the search terms were stated. Some relevant studies may have been omitted by limiting the included studies to those in English. The methods used to select the studies, assess validity and extract the data were not described; hence, the adequacy of the methods used cannot be judged. Given the nature of the review and the evidence, a narrative review was appropriate.

The evidence in the review appears to state that the risk of children aspirating chewable tablets is low. The authors’ conclusion goes further and states that chewable tablets are easily administered. Adequate support for this would require a systematic search aimed at identifying studies that assess the tolerability and ease of administration of chewable tablets in children.
Implications of the review for practice and research
Practice: The authors stated that chewable tablets have many advantages over other drug formulations for use in children.

Research: The authors did not state any implications for further research.

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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.