Treatment of Calmette-Guerin bacillus adenitis: a metaanalysis

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Authors' objectives
The aim of the study was to assess the efficacy of various therapeutic interventions in the management of Calmette-Guerin bacillus (BCG) adenitis. In particular, the more specific question of whether drug treatment reduces the frequency of suppuration in BCG was addressed.

Searching
MEDLINE was searched for relevant articles published in English, but the search dates were not provided. In addition, the bibliographies of retrieved articles and relevant textbooks were examined for further articles, and major indexed paediatric journals were handsearched (1985 to 1999).

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were included in the review.

Specific interventions included in the review
Any treatment for BCG adenitis was eligible for inclusion.

The specific interventions examined were: isoniazid at a dose of 10 mg/kg per day; isoniazid and rifampin at a dose of 10 mg/kg per day, with both these regimes administered for 2 months; erythromycin at doses ranging from 30 to 50 mg/kg per day for 1 month; and a single streptomycin instillation. The control groups received placebo or no treatment.

Participants included in the review
All of the participants were infants at the time of presentation with ipsilateral lymph node enlargement after BCG vaccination.

Outcomes assessed in the review
The outcome measures examined differed according to the type of adenitis. The primary outcome measure for nonsuppurative BCG adenitis was the frequency of the development of suppuration among treatment and control participants. For suppurative BCG adenitis, the frequency of spontaneous drainage and the time taken to heal were considered the primary outcome measures.

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 articles identified were assessed according to the following criteria: allocation concealment, blinding of the outcome assessment, and blinding to other patient (age of presentation) and disease characteristics (size of lymph nodes). The amount of variation in the therapeutic interventions and outcome measures was also assessed. Two authors assessed the papers independently. There were no further details of how the validity assessment was conducted, or how any disagreements between the authors were resolved.

Data extraction
Two authors extracted the data independently and any discrepancies were resolved by discussion. Data were extracted on the authors, year, country, samples size, interventions, outcomes and results.
Methods of synthesis
How were the studies combined?
A random-effects model was used to calculate summary estimates of the relative risks (RRs) and 95% confidence intervals (CIs). No details of how the studies were weighted, or whether publication bias was assessed, were given.

How were differences between studies investigated?
A subgroup analysis was performed for erythromycin and isoniazid.

Results of the review
Five RCTs were included. Two trials examined only nonsuppurative BCG, one trial only suppurative BCG, and the remaining two trials both types of BCG. The authors did not provide any further details of the outcomes for participants with suppurative BCG. In the four trials examining nonsuppurative BCG (360 participants in total), 107 patients received isoniazid, 21 received isoniazid and rifampin, 116 received erythromycin and 15 participants received streptomycin.

The pooled RR was 1.10 (95% CI: 0.88, 1.38). From the subgroup analysis by type of intervention, the RR was 1.04 (95% CI: 0.79, 1.37) for erythromycin and 1.35 (95% CI: 0.84, 2.18) for isoniazid.

Authors’ conclusions
The results of the RCTs indicated that treating BCG adenitis with drugs does not reduce the frequency of suppuration. Moreover, the authors stated that this is true for both antibiotics (e.g. oral erythromycin) and antituberculous drugs like isoniazid.

CRD commentary
This was a relatively poorly reported review in which it was difficult to assess the methods used to conduct the review. The review question addressed the type of interventions and study designs that were to be included, but did not state the specific type of outcome measures or the populations to be examined. This means that the results of the review may well be limited to the specific populations included.

The literature search was adequate, but only one database was searched and the studies were restricted to those published in English. It is therefore quite likely that other studies may have been missed. The authors undertook a validity assessment, but did not provide any further details as to how this was undertaken. Errors in the validity assessment process may, therefore, have been made. No details on the individual studies were provided, so it is impossible to assess whether the results of the review were consistent with the included studies. The statistical analysis was poorly reported and no test for heterogeneity was undertaken. In addition, the authors did not present any results for the suppurative adenitis treatments.

Overall, due to the reporting of this review, it is difficult to assess whether the authors’ conclusions are consistent with the evidence base reviewed.

Implications of the review for practice and research
Practice: The authors stated that the treatment of BCG adenitis with oral erythromycin or antituberculous drugs does not reduce the frequency of suppuration. Therefore, no therapy can be recommended for its treatment.

Research: The authors stated that the efficacy of potential therapeutic regimens for the treatment of BCG adenitis must be assessed in well-designed RCTs.

Bibliographic details
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.