Annotation

Neonatal BCG immunisation

Since its introduction in 1921 the efficacy of bacille Calmette-Guérin (BCG) has been extensively debated, yet it remains one of the most widely used of all vaccines today. BCG is compulsory in 64 countries and is officially recommended in a further 118. Schedules differ widely, a testimony to the lack of consensus regarding timing of immunisation. There is growing evidence that neonatal BCG immunisation significantly reduces the risk of clinical tuberculosis.

The controversy
In 10 randomised controlled trials conducted throughout the world since the 1930s, the protective efficacy of BCG vaccination (percentage reduction in risk attributable to vaccination) ranged from 0–80%. The largest and most widely publicised trial from southern India, which reported no protection, only investigated spatum positive disease and did not include neonates. Only two out of these 10 trials evaluated neonatal BCG vaccination. Both were performed in North America and vaccine efficacy was estimated to be 75–80%. An alternative form of assessing the vaccine is the case-control study in which identified cases of infection have been matched with up to four controls. Those studies which have specifically addressed neonatal BCG vaccination have reported protection rates greater than 80%.

Several factors may explain the widely divergent results of the major trials. These include vaccine potency, study design, age at vaccination, regional differences in Mycobacterium tuberculosis strains, nutritional or genetic differences in the trial population, and interaction of vaccines with different mycobacteria which may reduce vaccine efficacy. The answer defies a simple explanation and it is probable that multiple variables are operational.

Although tuberculin sensitivity is the clinical marker of an immunological response to BCG, a positive tuberculin test does not always imply protection to the disease. In a Birmingham study, which demonstrated a protective effect of BCG, there were 108 children with tuberculosis of whom 62 had received the vaccine. Of these 36 had postvaccination testing (three months later) and 31 were found to be tuberculin positive. Approximately 90% of children have been found to be tuberculin positive four to five years after neonatal BCG.

Complications of neonatal BCG
Ulceration at the site of inoculation and osteitis are said to be more common in the newborn. An incidence of BCG osteitis of 29/100 000 prompted Sweden to abandon their neonatal BCG programme in 1975. This particularly high incidence may have been related to the strain of vaccine used.
**Tuberculosis in the UK**

There were 5432 cases of tuberculosis notified to the Office of Population and Census and Surveys in 1989. Ten per cent of cases occurred in children. Tuberculous meningitis accounted for less than 1% of the total cases but 30% of these occurred in children. In a survey in 1983 of all notifications of tuberculosis in children the highest rates occurred in children of Indian subcontinent ethnic origin: 32/100 000 for the Indian and 52/100 000 for the Pakistani and Bangladeshi groups. The rate for white children was 2.4/100 000. Nevertheless white children accounted for 48% of the total number of cases. Altogether 75% of cases of tuberculous meningitis occurred in children under 5 years and were thus in the age group that could have been protected by neonatal BCG vaccination.

**Current practice in the UK**

The Department of Health and the British Paediatric Association recommend a selective policy of neonatal BCG vaccination. They advise that the following groups should receive the vaccine at birth: (i) babies of Asian and other immigrant families with high tuberculosis rates, (ii) infants who reside in or travel to areas where the risk of contracting tuberculosis is thought to be high, (iii) those in contact with active respiratory tuberculosis, and (iv) infants with a family history of tuberculosis in the preceding five years. In a recent yet unpublished survey carried out by the Public Health Laboratory Service (PHLS), Communicable Disease Surveillance Centre, 31 out of 174 district health authorities in England and Wales did not offer BCG immunisation to the newborn (John Watson, PHLS, personal communication). In addition to the high risk groups referred to above there may be areas where other children are at risk. The rate of tuberculosis in white inner city Leeds children at 5.5/100 000 was similar to that of children whose parents originated from the Indian subcontinent (6.2/100 000).

**Conclusion**

Neonatal BCG offers almost complete protection to meningitis and other disseminated forms of tuberculosis in childhood. It is less effective against respiratory disease protecting some 65% of children exposed to infection. Although the incidence of tuberculosis in the UK declined in the early 1980s there has been a recent increase, possibly related to the HIV epidemic, but increases in notifications have been seen in districts with high proportions of residents of Indian subcontinent ethnic origin. Paediatricians should ensure that children at high risk of tuberculosis are protected from this disease.
Neonatal BCG immunisation.

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