

# ADVERSE REACTIONS TO BCG

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## SUMMARY

In the post-war period the following BCG vaccines were successively in use for preventive vaccination in the Czech territory: (a) Copenhagen BCG, 1947-1950, (b) Prague BCG 725, 1951-1980, (c) Moscow BCG, 1981-1993, and (d) Behring BCG, from 1994 onwards. These BCG substrains can be now identified by modern methods of molecular genetics. Introducing the Moscow BCG brought about an elevated incidence of iatrogenic local and regional lymph node adverse reactions compared with the previous Prague BCG product and, as a new phenomenon, bone and joint involvements in children vaccinated at birth. The aim of this study was to analyze the incidence of postvaccination adverse reactions reported in the period from 1981 to 1993 as related to the Moscow BCG vaccine and, to demonstrate the effect of lower vaccination dosage on their frequency.

The concentration of the Moscow BCG varied from  $11$  to  $22.6 \times 10^6$  (average  $16.2$ ) CFU per  $1$  mg. In the period when full dose of BCG ( $0.05$  mg per  $0.1$  ml) was applied to newborns  $437$  local and  $195$  regional lymph node complications were recorded, i.e.  $0.08\%$  of vaccinated were affected, demanding antituberculosis chemotherapy in  $6.5\%$  and surgical interventions in  $24\%$ . When the lowered vaccination dose ( $0.025$  mg per  $0.1$  ml) was inoculated to newborns the local adverse reactions rose paradoxically affecting  $0.1\%$  of vaccinated but the regional lymph node reactions fell considerably to reach  $0.01\%$ ; the demand for chemotherapy and surgery also fell down to  $3.1$  and  $4.8\%$  respectively. Bone and joint adverse involvements were recorded in  $28$  cases, i.e. in  $3.7$  per  $10^5$  of those vaccinated with the full dose. After reduction of the vaccination dosage other  $18$  osteitis cases were recorded, i.e. the complication rate was reduced to  $2.05$  per  $10^5$  vaccinated.

The authors conclude that this excessive incidence of adverse post-vaccination reactions causes a considerable burden to afflicted children and their families, needing an exacting and costly medical treatment. To continue to use vaccines inducing an excessive number and severe forms of postvaccination reactions is not justified within any preventive policy.

*Key words:* *Mycobacterium bovis* BCG, BCG vaccination, postvaccination complication, adverse reactions to vaccination

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