



## **Fibrinogen and LDL apheresis in treatment of sudden hearing loss: a randomised multicentre trial**

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**Background:** Sudden sensorineural hearing loss (SSHL) is thought to have many different origins, including disturbances of microcirculation, autoimmune pathology, and viral infection. We aimed to determine whether acute reduction of plasma fibrinogen and serum LDL is effective for treatment of SSHL of suspected vascular origin.

**Methods:** Between January, 2000, and June, 2001, we recruited 201 patients with sudden hearing loss from our four otorhinolaryngology clinics in Germany. Patients were randomly allocated to single fibrinogen/LDL apheresis or standard treatment (250 mg prednisolone reduced by 25 mg per day, 500 ml 6% hydroxyethyl starch, 400 mg pentoxifylline per day). The primary outcome was recovery of hearing as measured by pure-tone audiometry 48 h after the start of treatment. Secondary outcomes were recovery of hearing 6 weeks after treatment, improvement of speech audiometry, tinnitus, and frequency of side effects. Analysis was done per protocol.

**Results:** Overall improvement of pure-tone thresholds was slightly better in patients given apheresis than those given standard treatment (difference 7.7, 95% CI -8.2 to 23.6). However, the mean sound level at which 50% of recorded digits were recognised was significantly lower after 48 h in the apheresis group (21.6 dB, SD 20.8) than in the standard group (29.3 dB, 29.4;  $p=0.034$ ). After 6 weeks, the mean 50% speech perception was at 13.6 dB (SD 14.3) in the apheresis group and at 20.8 dB (25.4) in those on standard treatment ( $p=0.059$ ). At 48 h, in patients with plasma fibrinogen concentrations of more than 295 mg/dL, speech perception was improved much more in those on apheresis (15.3 dB, 17.3) than in those on standard treatment (6.1 dB, 10.4;  $p=0.005$ ). A single fibrinogen/LDL apheresis lasting for 2 h could therefore be used as an alternative to conventional infusion treatment and prednisolone for 10 days. Patients with a plasma fibrinogen of more than 8.68  $\mu\text{mol/L}$  improve much better when treated with apheresis, especially if serum LDL concentrations are also raised.

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