PROSAIKA: A prospective multicenter registry with the first programmable gravitational device for hydrocephalus shunting


Abstract:
OBJECTIVE: Cerebrospinal fluid (CSF) overdrainage is a major problem in shunt therapy for hydrocephalus. The adjustable gravitational valve proSA allows for the first time a targeted compensation for overdrainage in the upright position without interfering with the differential pressure valve. To evaluate benefit, safety and reliability, the multicenter prospective registry PROSAIKA was conducted in 10 German neurosurgical centers. METHODS: Between March 2009 and July 2010, 120 hydrocephalic patients undergoing first time shunt implantation or shunt revision using proSA entered the study. 93 patients completed the 12 months follow-up. RESULTS: Hydrocephalus symptoms were improved in 86%, unchanged in 9% and deteriorated in 3%. In 51%, the proSA opening pressure was readjusted one or several times to treat suspected suboptimal shunt function, this resulted in clinical improvement in 55%, no change in 25%, and deterioration in 20% of these patients. The 1 year censored proSA shunt survival rate was 89%. Device related shunt failure was seen in two cases. CONCLUSIONS: This is the first clinical report on the implantation of the adjustable gravitational valve proSA with a follow-up of 12 months in a substantial number of patients. Irrespective of different hydrocephalus etiologies and indications for shunt surgery, the overall results after 12 months were very satisfying. The high frequency of valve readjustments underlines the fact that preoperative selection of the appropriate valve opening pressure is difficult. The low number of revisions and complications compared to other valves proves that proSA implantation adds no further risk; this valve is reliable, helpful and safe.