Safety and Efficacy of Glibenclamide on Cerebral Edema Following Aneurysmal Subarachnoid Hemorrhage: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

Methods

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Procedures

For the baseline assessment, we collected demographic information, past medical history (including hypertension, diabetes mellitus, coronary artery disease, cerebral infarction, and subarachnoid hemorrhage), clinical scores upon admission (Hunt - Hess grade, World Federation of Neurological Surgeons (WFNS) grade, modified Rankin Scale (mRS)), radiological scores resulted from CT scanning (modified Fisher scale, SEBES), location of the aneurysm, and documented vascular embolization and any other treatments administered for cerebral edema (including time and dose of osmotic therapy, lumbar puncture, cerebrospinal fluid shunt, decompressive craniectomy). Laboratory tests, clinical scores and radiological scores were repeated on days 7, 10, and at the time of discharge. Throughout the hospitalization period, we diligently recorded concomitant treatments and any adverse events experienced by the patients. At 3 months and 6 months after enrollment, telephone follow-up assessments were conducted to evaluate the mRS.

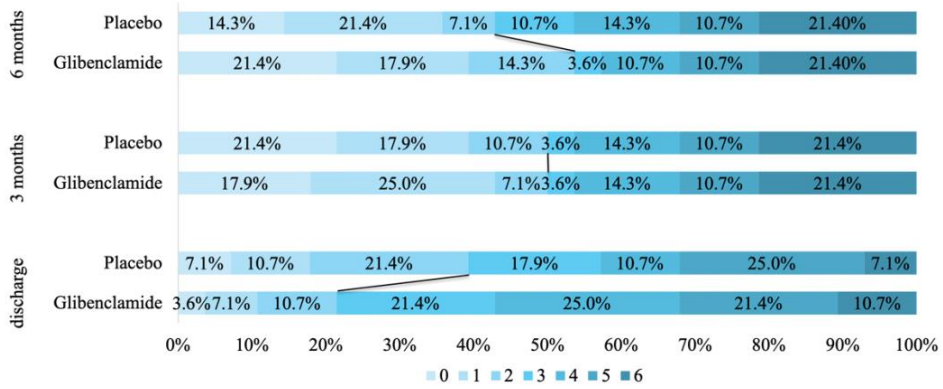
Patient safety

Both patient groups underwent blood glucose monitoring every 2 hours for the initial

48 hours of medication, followed by monitoring every 4 hours thereafter. The following response options were employed: 1) If the blood glucose level exceeded 11.0 mmol/L, glibenclamide 5 mg three times daily could be administered for glycemic control. If blood glucose remained elevated, it could be combined with insulin. 2) If blood glucose levels remained above 6.0 mmol/L after drug usage, insulin and other hypoglycemic drugs was prohibited. In the event of a declining trend, discretionary recommendations included supplementation with 5% glucose. 3) If continuous monitoring indicated blood glucose levels in the range of 4.0-6.0 mmol/L, 10% glucose supplementation was prescribed. 4) For blood glucose levels below 3.9 mmol/L, supplementation with 50% glucose was recommended. 5) If blood glucose levels remained below 3.1 mmol/L despite continuous glucose supplementation for over 24 hours, the trial was to be halted. If maintaining adequate blood glucose levels remained a challenge after 50% glucose supplementation, glibenclamide dosage was tapered to 2.5 mg three times daily. Blood glucose levels below 3.9 mmol/L were defined as adverse events indicative of hypoglycemia.

Supplementary materials

- Figure S1. The Modified Rankin Scale score at vary times.



Data are presented percentag of patients (%).