

Clinical observation of Danhong Injection (herbal TCM product from *Radix Salviae miltiorrhizae* and *Flos Carthami tinctorii*) in the treatment of traumatic intracranial hematoma

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Abstract

Danhong Injection (DHI), a Chinese Materia Medica standardized product extracted from *Radix Salviae Miltiorrhizae* and *Flos Carthami tinctorii*, has the actions of promoting blood circulation and resolving stasis to promote regeneration. The clinical therapeutic effects of DHI on traumatic intracranial hematoma (TICH) were observed. Eighty patients with TICH were randomly assigned to trial group and a control group (40 patients per group), and all were administered with routine medication. Additionally, DIH was administered intravenously to patients in the trial group. Pre and post-treatment GCS was observed in the two groups, along with GOS after therapy. The intracranial hematoma absorption, hemorheological changes, and changes in coagulation indexes pre- and post-treatment were evaluated. The results indicated that GCS and GOS after therapy for the trial group were superior to those for the control group ($p < 0.05$). There was a significant post-treatment difference in the intracranial hematoma absorption between the two groups ($p < 0.01$). Each hemorheological index in the trial group improved significantly as compared with that of the control group ($p < 0.05$ or $p < 0.01$). The plasma levels of fibrinogen and D-dimer in the trial group were significantly decreased after therapy ($p < 0.01$). These results suggest that DHI is conducive to the recovery of patients with TICH.

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Keywords: Danhong injection (*Salvia miltiorrhiza*; *Carthamus tinctorius*); Traumatic intracranial hematoma; Clinical observation; Hemorheology; Coagulation function

Introduction

Traumatic intracranial hematoma (TICH) is a common severe encephalopathy secondary to brain injury.

Its incidence has increased along with the increased use of motor vehicles, along with higher fatality and deformity rates (Holm et al. 2005). Brain tissue injury and intracranial hematoma after brain injury may induce brain edema and increased intracranial pressure. Cerebral blood flow may decrease, resulting in the contraction of vessels all over the body, contraction of local cerebral vessels and disorders of cerebral blood

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circulation, including cerebral capillary spasm, increased vasopermeability, hemorheological changes (Daniel et al. 1997). These factors may further accelerate cerebral ischemia and hypoxia, thus further aggravating the edema of injured brain tissue. Cerebral edema is the most significant secondary pathological lesion after brain injury. Therefore, reducing cerebral edema and improving cerebral microcirculation disturbance are of great significance for the treatment of brain injury (Cao et al. 2002).

The diagnosis rate of TICH has improved greatly with the use of computed tomography (CT) and Magnetic resonance imaging (MRI). These also provide reliable scientific evidence for clinical tracing, observation, and absorption judgment of small and moderate-sized hematomas in nonsurgical treatment. Symptomatic treatments such as dehydration therapy to reduce cranial pressure, pain relief, and so on are often adopted in neurosurgery for those having small and moderate-sized, non-life-threatening hematomas. The therapeutic course is rather longer, but the clinical results obtained are not satisfactory (Li et al. 2003). However, TICH treated with additional Chinese materia medica in the early phase may result in satisfactory therapeutic effects with improved safety (Liu et al. 2007; Chen and Shao 2005).

Danhong Injection (DHI), a Chinese materia medica standardized product extracted from the herbal *Radix Salviae Miltiorrhizae* and *Flos Carthami*, promotes blood circulation and resolves stasis, and removes stasis to promote regeneration. Its main components include tanshinone, tanshinol acid, safflor yellow, etc. Pharmacological studies show that *Radix Salviae miltiorrhizae* extract dilates cerebral arteries, lowers vascular resistance and blood viscosity, and enhances erythrocyte deformability; it also can clear oxygen free radicals, antagonize the inflow of calcium ions, and improve the activities of adenosine triphosphatase. Meanwhile, it may also improve the anti-hypoxia capacities of brain tissue and exhibit protection of brain tissue (Tai et al. 2005). The flavanoid Safflor yellow is one of the main compounds in *Flos Carthami*, with pharmacological activities including vasodilation, antioxidation, protecting cardiac muscle and brain from injury, decreasing blood pressure, and suppressing immune function. *Flos Carthami* extract *in vivo* and *in vitro* clearly inhibits platelet aggregation, shows certain inhibition of the activation of the intrinsic coagulation system, and plays a role in increasing the blood flow of cerebral arteries and nourishing brain cells (Xin et al. 2004). DHI has shown significant therapeutic effect when applied extensively to the treatment of TICH in the authors' hospital. Therefore, the aim of this clinical study was to observe the short- and long-term therapeutic effects of DHI in the treatment of acute TICH, and to explore its possible mechanisms using hemorheological indexes.

Materials and methods

Subjects

Eighty patients with TICH at the Second Hospital affiliated to Zhejiang University from Dec 2005 to Mar 2008 participated in the study. The causes for TICH ranged from traffic accident injury to falling from higher places, to being hit. The patients were randomly assigned to the two groups upon admission to the hospital. The patients met the diagnostic criteria of mild and moderate TICH (Wang 2005), as follows: those who were admitted within 24 hours after a cerebral injury confirmed by CT; with an intracranial hemorrhage volume between 10 and 40 ml; with no continuously enlarged hematoma after consecutive head CT examinations within 3 days, but not scheduled for surgery; aged between 16 and 65 years; and all with Glasgow coma score (GCS) greater than 8 (Teasdale and Jennett 1974). Exclusion criteria were: severe cardio-/cerebral vascular diseases; liver or renal diseases; diabetes mellitus; other severe organ injuries; coagulation disorders; obviously enlarged hematoma confirmed by head CT and/or aggravated symptoms indicating a need for surgery. Written informed consent was obtained from each subject after the nature, purpose and potential risks of the study had been explained.

Preparation of Danhong Injection

DHI is manufactured by Shandong Buchang Pharmacy Co. Ltd. The raw materials of danshen root and safflower were from a standard medicinal herbs resource base established by Buchang Pharmacy. The two core technologies adopted were ultra-high speed centrifugal separation and membrane separation in the manufacturing technology. Quantities of 750 g danshen root and 250 g safflower were boiled twice with 1000 ml water added, for 1 h each time. The decoction was combined, filtered, clarified after cold storage, and then filtered. A suitable amount of gelatin was added to the filtrate, and the filtrate was cold stored and filtered. The filtrate was concentrated to the relative density of 1.10–1.20, and alcohol was added to the raise alcohol content to more than 80%. The filtrate was then cold stored and filtered, with the pH value readjusted. Following cold storage, the alcohol was recovered from the filtrate till it had no alcohol taste, water was added to achieve a volume of 1000 ml, then the filtrate was cold stored. The filtrate was filtered once more, with water added to the ruled volume, subpackaged and sterilized. Thus the DHI was obtained. HPLC fingerprint analysis (Fig. 1) shows that the total amount of danshensu sodium and Protocatechuic Aldehyde was 1.5 mg/ml, containing 11 mg/ml safflor yellow.

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