

# Goreisan for chronic subdural hematoma

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Most asymptomatic patients with [chronic subdural hematoma](#) (CSDH) are followed conservatively but can require surgical treatment if the hematoma expands. Nakao et al. conducted a retrospective evaluation of the effect of Gorei-san on CSDH. This study included patients treated between April 2013 and March 2015. In total, 289 patients were diagnosed with CSDH and 110 patients received conservative management. Finally, 39 patients who met the requirements were registered. We retrospectively examined the age, gender, medical history, hematoma thickness, clarity of sulci below hematomas, and midline shift of the patients. The primary outcome was the median surgery-free interval, and the secondary results were the rate of CSDH shrinkage and surgery avoidance. A comparison of patient characteristics between the Gorei-san (G) and non-Gorei-san (NG) groups found no significant differences in the percentage of men, average ages, past history, the thickness of CSDH ( $15.0 \pm 3.1$  mm vs.  $15.3 \pm 2.6$  mm,  $p = 0.801$ ), or midline shift ( $2.0 \pm 2.7$  mm vs.  $4.0 \pm 5.0$  mm,  $p = 0.230$ ). The median surgery-free interval was significantly different between the G and NG groups [n. r. vs. 41 days (95% CI: 5-79), log-rank  $p = 0.047$ ]. The CSDH avoidance rate was not significantly different between the two groups (70.0% vs. 34.4%,  $p = 0.071$ ). Additionally, the CSDH shrinkage rate was significantly different between the two groups (60.0% vs. 10.3%,  $p = 0.004$ ). This retrospective study demonstrated that CSDH treatment with Gorei-san reduces hematoma significantly more than treatment that does not include Gorei-san <sup>1)</sup>

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prospectively prescribed KBG 7.5 g/day for 12 CSDH patients after burr-hole surgery. As a control cohort, we retrospectively collected 48 patients treated by GRS 7.5 g/day. The recurrence within 1 month and the hematoma thickness after 1 month were evaluated.

Results: The median age was 84 years old. All the patients' symptoms improved after surgery. The median preoperative midline shift and mean hematoma thicknesses were 6.0 mm and 23.75 mm. Those at 1 month were 2.0 mm and 11.43 mm. The recurrence rate was not significantly different between the KBG cohort (1 of 12) and the GRS cohort (4 of 48) ( $P = 0.999$ ). The KBG's noninferiority to GRS regarding the hematoma thickness at 1 month was statistically proven; KBG (12.26 mm) and GRS (11.20 mm).

The recurrence rate at 1 month was not different between the KBG and GRS cohorts. The hematoma thickness at 1 month in the KBG cohort was not statistically inferior to that in the GRS cohort <sup>2)</sup>

Dexamethasone (RR: 0.46, 95% CrI: 0.23-0.91) was more effective in reducing recurrence requiring surgery than goreisan. Additionally, atorvastatin reduced the hematoma volume to a greater extent than placebo (MD: -7.44, 95% CrI: -9.49 to -5.43) or goreisan (MD: -14.09, 95% CrI: -23.35 to -4.82). Moreover, tranexamic acid (MD: -12.07, 95% CrI: -21.68 to -2.29) reduced the hematoma volume to a greater extent than goreisan. These findings suggest that dexamethasone is the best treatment to reduce recurrence and atorvastatin is the best treatment to reduce hematoma volume in patients with CSDH. However, clinicians should pay close attention to the elevated risk of all-cause mortality and potential adverse events caused by dexamethasone. Future well-designed RCTs with more participants are needed to verify these findings. Clinical Trial Registration: <http://osf.io/u9hqp><sup>3)</sup>.

## Prospective randomized studies

A prospective randomized study to investigate whether Goreisan treatment decreases the recurrence rate of CSDH. Between March 2013 and December 2018, a total of 224 patients who underwent initial burr hole surgery for CSDH were randomly assigned to receive Goreisan for 3 months (Group G) or no medication (Group N). The primary endpoint was symptomatic recurrence within 3 months postoperatively, and the secondary endpoint was complications, including the adverse effects of Goreisan. Of 224 randomized patients, 208 were included in the final analysis (104 in Group G and 104 in Group N). The overall recurrence rate was 9.1% (19/208). The recurrence rate of Group G was lower than that of Group N (5.8% vs 12.5%,  $P = 0.09$ ), but the difference was not statistically significant. However, a significant preventive effect of Goreisan was found in 145 patients with high-risk computed tomography (CT) features, namely, homogeneous and separated types (5.6% vs 17.6%,  $P = 0.04$ ). Although the present study did not prove the beneficial effect of Goreisan treatment, it suggested the importance of selecting patients with an increased risk of recurrence. A subset of patients whose hematoma showed homogeneous and separated patterns on CT image might benefit from Goreisan treatment<sup>4)</sup>.

## Prospective studies

A prospective study investigated whether [tranexamic acid](#) and Goreisan effectively prevent recurrence after burr hole surgery for a chronic subdural hematoma.

A total of 297 patients with chronic subdural hematoma underwent initial burr hole surgery at our hospital from April 2014 to March 2018. Of these, 206 patients (250 hematomas) consented to participate in this study. Patients were randomly divided into the nonadministration, tranexamic acid, and Goreisan groups based on age. The oral administration intervention was implemented from the day after surgery, after which there was a 3-month follow-up. Recurrence rates were measured, and head computed tomography scan was used to measure the volume of residual hematoma 1 day, 1 week, and 1, 2, and 3 months after surgery.

A total of 193 patients (232 hematomas) were followed-up for 3 months (82 hematomas in the nonadministration group, 72 hematomas in the tranexamic acid group, and 78 hematomas in the Goreisan group). There were no significant between-group differences in demographic characteristics, current drug treatment, comorbidities, hematoma, operation side (bilateral or unilateral),

preoperative hematoma volume, and recurrence rates. At 1, 2, and 3 months, the residual hematoma volume was significantly smaller in the tranexamic acid group than in the other 2 groups.

Oral administration of tranexamic acid or Goreisan does not minimize recurrence after chronic subdural hematoma burr hole surgery; however, tranexamic acid can reduce the hematoma volume<sup>5)</sup>.

## Case series

A retrospective, single-center, cohort study was conducted at the Tokyo Metropolitan Hiroo Hospital. After applying the inclusion/exclusion criteria, data from 107 patients (70 men and 37 women; mean age,  $77.1 \pm 10.9$  years), admitted for CSDH from January 2013 to December 2018, were included in the Goreisan group, whereas those of 122 patients (84 men and 38 women; mean age,  $73.9 \pm 13.3$  years), admitted for CSDH from January 2007 to December 2012, were included in the control group. This corresponded to 114 lesions, with 14 reoperation lesions, in the Goreisan group and 108 lesions, with 16 reoperation lesions, in the control group. Lesions were categorized as homogeneous, laminar, separated, or trabecular type, and patients with homogeneous type lesions in the Goreisan group were approximately 50% less likely to undergo reoperation compared with those in the control group (7.3% versus 14%; odds ratio = 0.51; 95% confidence interval = 0.12-2.11). Thus, the homogeneous type CSDH was the most responsive to Goreisan, whereas the separated type was the least responsive. Therefore, selecting treatment strategies for preventing CSDH recurrence on CSDH type may contribute toward reducing reoperation rates<sup>6)</sup>.

1)

Nakao J, Marushima A, Fujita K, Fujimori H, Mashiko R, Kamezaki T, Sato N, Shibata Y, Takano S, Ishikawa E. Conservative Treatment of Chronic Subdural Hematoma with Gorei-san. *Neurol Med Chir (Tokyo)*. 2023 Jan 15;63(1):31-36. doi: 10.2176/jns-nmc.2022-0229. Epub 2022 Oct 25. PMID: 36288975; PMCID: PMC9894621.

2)

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3)

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4)

Fujisawa N, Oya S, Yoshida S, Tsuchiya T, Nakamura T, Indo M, Matsui T. A Prospective Randomized Study on the Preventive Effect of Japanese Herbal Kampo Medicine Goreisan for Recurrence of Chronic Subdural Hematoma. *Neurol Med Chir (Tokyo)*. 2021 Jan 15;61(1):12-20. doi: 10.2176/nmc.oa.2020-0287. Epub 2020 Nov 19. PMID: 33208583; PMCID: PMC7812313.

5)

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Harada Y, Yoshida K, Nojiri S, Kurihara Y, Kobayashi H, Arai H. Identification of chronic subdural hematoma types most responsive to Goreisan, Kampo medicine: A retrospective study. *J Clin Neurosci*. 2020 Aug;78:198-202. doi: 10.1016/j.jocn.2020.04.063. Epub 2020 Apr 23. PMID: 32336630.

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