

Commentary on Assessment of Burr-Hole Craniostomy for Chronic Subdural Hematoma: A Randomized Unblinded Comparative Trial of Burr-Hole Craniostomies and Drainage with or without Irrigation for Newly Progressed Chronic Subdural Hematoma

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STUDY DESCRIPTION

Background and purpose

Chronic subdural hematoma (CSDH) is one of the most common clinical entities in neurosurgical practice. Although the therapeutic management is well established with burr-hole craniostomy and drainage, patients with CSDH still suffer from recurrence up to 33% [1-3]. Recently reported randomized controlled studies revealed that drainage is the most effective treatment in controlling recurrence [4,5]. As far as we know, there is no reported trials revealing whether simple drainage without irrigation (simple drainage) or with irrigation (irrigation drainage) could treat CSDH with less recurrence rate compared to the other. The purpose of this study is to analyze the postoperative recurrence rate and complications between drainage with and without irrigation. The present trial is permitted by Institutional Review Board of Kyoto Okamoto Memorial Hospital (No. 2020-18).

Methods

We enroll newly diagnosed CSDH patients visiting our institute, from June 2020 on, collect clinical data including patients' age, gender, comorbidities (hypertension, diabetes, dyslipidemia, any stroke, ischemic heart diseases, malignancies, maintenance dialysis), condition of antithrombotic therapy, past history of any trauma, head surgery, ventriculo-peritoneal (VP) shunt, lumbar arachnoid space-peritoneal (LP) shunt, and ventriculo-atrial (VA) shunt, hematoma thickness, homogeneity on computed tomography (CT) imaging of hematoma, presence of niveau, and brain midline shift. We exclude patients who underwent any surgery for ipsilateral CSDH within three months, any patients who have undergone interventional embolization for ipsilateral hematoma capsule, VP, LP, or VA shunt. We also exclude patients under twenty-year-old. We divide finally enrolled patients, expected a hundred and twenty patients, into two groups, simple drainage and irrigation drainage groups at

random, observe them for any complications and recurrence for three months. We define recurrence as regrowth of ipsilateral CSDH which needs reoperation within three months after the initial surgery. We use normal saline for irrigation of the hematoma. The patients who are on antithrombotic therapy are treated on continuous medication besides on the operation day. The patients are required for bed rest before the subdural drain is removed on the next day of surgery subsequently to reference for the CT imaging. Age at the time of presentation will be compared using Student's t-test. Sex distribution and frequencies of patients' comorbidities, past histories, niveau formation, homogeneity of hematoma, and brain midline shift will be compared using Fisher's exact test. The difference in recurrence rate between the two groups are tested by log-rank test.

The mean thickness of the hematomas in two groups will be assessed by using Student's t-test. We will analyze the data using SPSS (Statistical Package for Social Science) Statistics 24.0 (IBM), with significance as $p < 0.05$.

We hypothesize that simple drainage is as safe and effective as irrigation drainage, which means irrigation might not be necessary against recurrence. If we could elucidate simple drainage might give the same performance as irrigation drainage, we will have to validate it by multicenter prospective study design. Saving irrigation could result in shorter operation time, less invasive to the patients, and more cost effective, which might be preferable to daily practice. If we could not indicate our hypothesis, we definitely stop the present trial immediately, subsequently, we might be able to consider the cause and arrange the study design. The optimal surgical therapeutic management is expected to be elucidated by the present study.

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