European Review for Medical and Pharmacological Sciences 2021; 25: 7211-7217

Effects of postoperative atorvastatin use in elderly patients with chronic subdural hematoma

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Abstract. – OBJECTIVE: Atorvastatin has been suggested to reduce hematoma volume and improve neurological outcomes in patients with chronic subdural hematoma (CSDH). However, the benefits and harms of atorvastatin use after surgery in elderly patients are not well studied.

PATIENTS AND METHODS: We conducted a retrospective trial to analyze older people (> 60 years) with CSDH, those who were treated with surgical intervention. Patients were assigned to study group if they received oral atorvastatin after surgery at least 1 week, and patients without atorvastatin medication postoperatively were assigned to control group. The primary outcome was the overall rate of recurrence at 1 month after surgery. The main secondary endpoints were the scores on the modified Rankin Scale (mRS), hematoma volume, mortality, and complications after surgery.

RESULTS: A total of 49 eligible patients were included — 21 in the study group and 28 in the control group. The baseline characteristics were similar between the 2 groups. At 1 month, recurrence of subdual hematoma requiring repeat surgery was reported in 4 of 21 patients (19.0%) in the study group and in 5 of 28 patients (17.9%) in the control group (p=0.915). The hematoma volume was similar between the 2 groups (p=0.979). A favorable outcome (a score of 2 or less on the mRS) occurred in 90.5% of patients in the study group and in 96.4% of those in the control group (p=0.390).

CONCLUSIONS: In older people with CSDH, postoperative atorvastatin use barely reduces the incidence of recurrence and hematoma volume.

Key Words:
Chronic subdural hematoma, Surgery, Atorvastatin, Recurrence, Safety.

Introduction

Chronic subdural hematoma (CSDH) is a common neurosurgical disease and especially prevalent among older people[1]. It had been reported that the overall incidence of CSDH was around 0.0581‰ per year among the elderly populations (>65 years), with a rising trend on the incidence rate ascribing to the demographic shift toward to aging population, as well as the widely use of antithrombotic and anticoagulative drugs[2,3]. As a result, the overall incidence rate has doubled while the incidence rate of older people aged 80 years or older has almost tripled since 1990 according to a more recent study[4].

Head trauma remains the most common cause to develop CSDH[5]. Current evidence has suggested that inflammatory cascade reaction after traumatic event involving in the formation of membrane and fragile neovessels was contributed to the occurrence and expansion of subdural hematoma[6]. The progression of subdural hematoma could compress the brain parenchyma leading to intracranial hypertension and brain hernia. Therefore, symptomatic patients with symptoms or signs related to the intracranial pressure elevation and compression of brain parenchyma, or radiological evidence on the subdural hematoma, generally receive surgical intervention for surgical evacuation of the subdural hematoma, such as burr hole craniostomy and open craniotomy[7-9]. However, the surgical outcomes are not as expected. 10-20% of patients after surgical evacuation were estimated to receive reoperation owing to hematoma recurrence[10]. In contrast, conservative treatments with pharmaceuticals and regular follow-up were usually utilized for asymptomatic patients.

Several drugs have been routinely utilized to treat CSDH in clinical practice, including steroids, tranexamic acid, and statin[1,11-14]. Among these drugs, atorvastatin is a more recent agent and has been suggested to reduce hematoma

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volume and improve neurological outcomes with a low risk of adverse events in nonoperative patients (≥ 18 and < 90 years) CSDH in a multi-center, randomized controlled trial[13]. However, the benefits and harms of postoperative atorvastatin use in elderly patients are not well studied. The aim of this study is to determine the effects of postoperative atorvastatin use in older people with CSDH.

Patients and Methods

Study Design

To determine whether the atorvastatin use after surgical treatments improves the outcomes in older people with CSDH, we conducted a retrospective trial at West China Shangjin Hospital to analyze older people (> 60 years) with CSDH, those who were treated with surgical intervention from Jan 2019 through June 2020. This trial was conducted based on the Guidelines for Good Clinical Practice and the Declaration of Helsinki (2002). All patients had been fully informed and signed the informed consents before participating in this trial.

Patients

Two investigators screened the patients for eligibility through the database of West China Shangjin Hospital. Patients with CSDH were included in this study if they were 60 years or older and received surgical intervention from Jan 2019 through June 2020. Patients under 60 years, receiving atorvastatin medication before surgery, receiving atorvastatin shorter than 1 week, receiving antithrombotic, antiplatelet, or anticoagulative drugs on a regular basis before surgery, had prior history of hematoma evacuation, were lost to follow-up, or without known cause, were excluded. All patients were fully informed to the potential benefits, harms and responsibilities during the trial, and they signed the informed consent before participating in this trial. Eligible patients were assigned to study group if they received oral atorvastatin after surgery, and patients without atorvastatin medication postoperatively were assigned to control group. The baseline information including age, sex, comorbidities, etiology, Glasgow Coma Scale (GCS), modified Rankin Scale (mRS), clinical manifestations, duration of symptoms, radiological features, surgical methods, and length of stay at the time of admission were collected.

Outcomes

The primary outcome was the overall rate of recurrence at 1 month after surgery. According to previous studies, the recurrence of hematoma was defined as the recurrence of ipsilateral subdural hematoma that required repeat surgery[1]. The decision to perform reoperation was made by the attending neurosurgeons in combination with the patient according to the clinical symptoms related to subdural hematoma and hematoma volume.

The main secondary endpoints were the scores on the mRS, hematoma volume, mortality, length of stay, and any adverse events at discharge from hospital and at 1 month after surgery. A score of 2 or less on the mRS (higher is worse) was defined as favorable outcome. The hematoma volume was calculated by 2 independent evaluators through axial head CT. In brief, we first outlined the hematoma of each slice and calculated the volume of corresponding area by multiplying with slice thickness. The volume of each slice was summed to get the total volume of the subdural hematoma. Re-evaluation was performed by a third reviewer if there was significant difference between these 2 evaluators. The hematoma evacuation rate (HER) was calculated as follows:

$$\mathrm{HER} = \frac{(Volume_{preoperation} - Volume_{postoperation})}{Volume_{preoperation}} \times 100\%$$

Statistical Analysis

All data were analyzed using the statistical software program SPSS version 19 (IBM, Armonk, NY, USA). As refers to the quantitative data, Kolmogorov-Smirnov test was first used to determine the normality. Quantitative data that followed normal distribution were described as mean ± standard deviation (SD) and compared between the 2 groups using independent sample *t*-test. Quantitative data that did not follow normal distribution were described as median (range) and compared between the 2 groups using Wilcoxon rank sum test. Categorical data were described as number (percentage) and compared between the 2 groups using Chi-quarter test (Fisher's exact test was used if appropriate). *p*-value (2-side) < 0.05 was considered to have statistical difference.

Results

Patients

From Jan 2019 through June 2020, a total of 91 operative patients diagnosed as CSDH was

screened for eligibility. 26 patients under 60 years, 1 patient with atorvastatin medication before surgery, 1 patient with atorvastatin shorter than 1 week, 6 patients with regularly antithrombotic, antiplatelet and anticoagulative drugs before surgery, and 8 patients with unknown cause, were excluded. Thus, 49 patients were included in the trial — 21 in the study group (oral atorvastatin after surgery) and 28 in the control group. Patients in the study group were administered atorvastatin at 20 mg per day for at least 1 week after surgery. Table I showed the baseline characteristics of total patients.

Among the 49 eligible patients, 45 (91.8%) underwent burr hole craniostomy and 4 (8.2%) underwent open craniotomy for evacuation of the subdural hematoma. The mean age of the patients was 74.5 years, and 73.5% were male. 25 patients (51.0%) and 17 patients (34.7%) had history of hypertension and diabetes mellitus, respectively. The median GCS and mRS were 15 and 2, respectively. Headache (81.6%) and gait impairment (42.9%) were the most common symptoms while other symptoms including hemiparesis, confusion, vomiting, and speech arrest were also observed in patients. All patients had known head trauma. The hematoma volume before surgery was similar in the 2 groups (60±23 *vs.* 57±24, p=0.662). Unilateral hematoma was observed in 43 of 49 patients (87.8%).

Except that more female patients were included in the study group, the baseline characteristics were similar in the two groups in most aspects, including age (p=0.906), comorbidities (hypertension: p=0. 0.322; diabetes mellitus: p=0. 665), GCS (p=0.584), mRS (p=0.137), and hematoma location (p=0.706), which were demonstrated to be associated with surgical outcomes in some studies.

Outcomes

At 1 month, recurrence of subdual hematoma requiring repeat surgery was reported in 4 of 21 patients (19.0%) in the study group and in 5 of 28 patients (17.9%) in the control group (p=0.915). Among the 9 patients with recurrence, 8 patients underwent reoperation while 1 patient in the control group refused surgery.

As shown in Figure 1, the hematoma volume was similar in the 2 groups at discharge from hospitalization (20±11 *vs.* 18±9, p=0.450), as well as at 1 month after surgery (6±7 *vs.* 6±6, p=0.979). The results on the HER, corresponding to the degree of hematoma reduction, were calculated and shown in Table II. No statistical difference

Table I. The baseline characteristics.

	Total (n = 49)	Study group (n = 21)	Control group (n = 28)	*p*-value
Age	74.5 ± 7.2	74.3 ± 7.3	74.6 ± 7.4	0.906
Sex				0.004*
Male	36 (73.5%)	11 (22.4%)	25 (51.0%)	
Female	13 (26.5%)	10 (20.4%)	3 (6.1%)	
Comorbidities				
Hypertension	25 (51.0%)	9 (18.4%)	16 (32.7%)	0.322
Diabetes mellitus	17 (34.7%)	8 (16.3%)	9 (18.4%)	0.665
GCS	15 (12-15)	15 (12-15)	15 (13-15)	0.584
mRS	2 (1-4)	1 (1-4)	3 (1-4)	0.137
Symptoms				
Headache	40 (81.6%)	19 (38.8%)	21 (42.9%)	0.166
Hemiparesis	12 (24.5%)	5 (10.2%)	7 (14.3%)	0.924
Gait impairment	21 (42.9%)	8 (16.3%)	13 (26.5%)	0.560
Confusion	10 (20.4%)	4 (8.2%)	6 (12.2%)	0.838
Vomiting	11 (22.4%)	6 (12.2%)	5 (10.2%)	0.374
Speech arrest	8 (16.3%)	5 (10.2%)	3 (6.1%)	0.220
Hematoma volume, mL	59 ± 23	60±23	57 ± 24	0.662
Hematoma location				0.706
Unilateral	43 (87.8%)	18 (36.7%)	25 (51.0%)	
Bilateral	6 (12.2%)	3 (6.1%)	3 (6.1%)	
Surgical treatments				0.763
Burr-hole craniostomy	45 (91.8%)	19 (38.8%)	26 (53.1%)	
Open craniotomy	4 (8.2%)	2 (4.1%)	2 (4.1%)	

GCS, Glasgow Coma Scale; mRS, modified Rankin Scale.

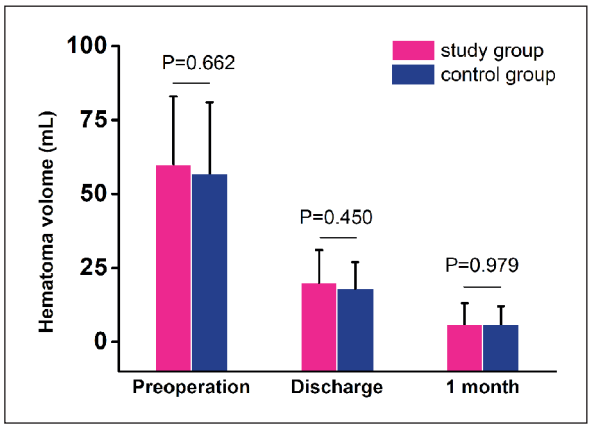

Figure 1. The hematoma volume at discharge and at 1 month.

on the HER was observed at discharge from hospitalization (p=0.872), or at 1 month after surgery (p=0.853). In brief, at discharge from hospital, percentage of 80% or more, 60% to 80%, 40% to 60%, and 40% or less on the HER were respectively reported in 14.3%, 52.3%, 28.6%, and 4.8% of patients in the study group. Percentage of 80% or more, 60% to 80%, 40% to 60%, and 40% or less on the HER were respectively reported in 17.9%, 60.7%, 14.3%, and 7.1% of patients in the control group. At 1 month, an 80% or more reduction in hematoma volume occurred in 76.1% of patients in the study group and in 71.4% of those in the control group. The hematoma volume of 14.3% and 9.5% of patients in the study group reduced by 60% to 80% and 40% to 60% while that of 25.0% and 3.6% of patients in the control group reduced by 60% to 80% and less than 40%.

Figure 2 showed the cumulative proportions of results on the mRS, corresponding to the percentage of all scores that are lower than the given score. According to the Figure 2, a favorable outcome (a score of 2 or less on the mRS) occurred in 71.4% of patients in the study group and in 57.1% of those in the control group at discharge from hospital (p=0.305). At 1 month, a favorable outcome occurred in 90.5% of patients in the study group and in 96.4% of those in the control group (p=0.390). Besides, the median scores on the mRS were similar in the 2 groups at both evaluation point (At discharge: p=0.374; At 1 month: p=0.382). Additionally, the median length of stay was also similar (p=0.872). No patients died within 1 month after surgery. Only 1 patient in the study group had mild liver abnormalities that was related to the atorvastatin medication according to the laboratory examinations.

Discussion

In this study involving elderly patients with CSDH treated by surgical intervention, we found that the incidence rates of patients who underwent hematoma recurrence were similar between the patients those who received oral atorvastatin after surgery and patients those who did not. We hypothesized that postoperative atorvastatin use could reduce hematoma volume and improve neurological outcomes in older people with CSDH. Contrary to our hypothesis, the hematoma volume and the percentage of patients who obtained a favorable outcome (a score of 2 or less on the mRS) following surgical evacuation were similar between the 2 groups. As a result, our study suggested that postoperative atorvastatin use barely reduce the risk of recurrence and hematoma volume and was unable to improve the neurological function after surgical evacuation in elderly patients with CSDH occurring secondary to head trauma.

Table II. The baseline characteristics.

	Study group	Control group	*p*-value
HER at discharge, no. (%)			0.872
80-100%,	3 (14.3)	5 (17.9)	
60-80%	11 (52.3)	17 (60.7)	
40-60%	6 (28.6)	4 (14.3)	
< 40%	1 (4.8)	2 (7.1)	
HER at 1 mo, no. (%)			0.853
80-100%,	16 (76.1)	20 (71.4)	
60-80%	3 (14.3)	7 (25.0)	
40-60%	2 (9.5)	0 (0)	
< 40%	0 (0)	1 (3.6)	

HER, hematoma evacuation rate.

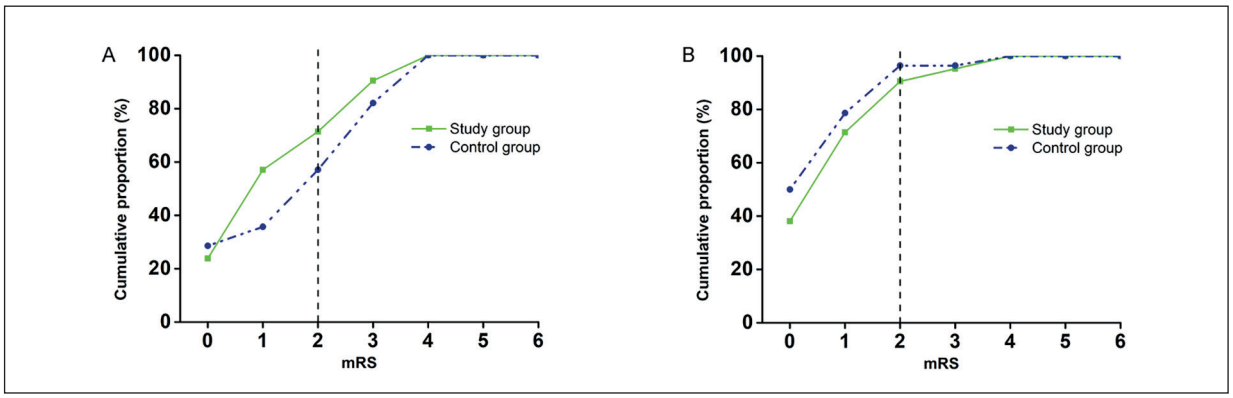

Figure 2. The cumulative proportions of results on the modified Rankin's Scale (mRS). **A,** At discharge from hospital. **B,** At 1 month after surgery. A score of 2 or less on the mRS (higher is worse) was defined as favorable outcome.

Our findings differ from those of some retrospective studies. Tang et al[15] analyzed the adult patients with CSDH aged 18 to 89 years and found that the percentage of patients who underwent recurrence following burr hole craniostomy was lower among those who were administered atorvastatin perioperatively than among those who were not. In line with the work by Min et al[16], we also demonstrated perioperative atorvastatin use was associated with favorable outcome including lower hematoma volume and better neurological status in patients with CSDH aged 16 years or older compared with non-atorvastatin treatments.

One possible explanation is that the increased age is closely contributed to the surgical outcomes. It has long been known that increased age is an important predictor of increased morbidity or mortality[17-21]. More importantly, the brain compliance, which are involved in hematoma evacuation after surgery, are poor with the age[21,22]. We did include older patients (>60 years) and exclude the young patients in this study. In this regard, atorvastatin use after surgery is unlikely to prevent elderly patients from recurrence and reduce the hematoma volume. Another possible explanation for the different outcomes concerns the preoperative atorvastatin use. Patients in our study were not administered atorvastatin before surgery. Previous study has also indicated that fewer patients with atorvastatin were switched to surgery than patients with placebo, suggesting that atorvastatin may be effective in avoiding surgery[13]. It was only concluded that taking atorvastatin that began after surgical intervention was not associated with favorable outcome. However, whether atorvastatin use in elderly patients with CSDH could reduce the possibility of surgery is not clear and needs to be addressed in the future studies.

Our findings could provide evidence and guidance on the postoperative management of patients with CSDH. In this light, it was not recommended to take atorvastatin after surgery in elderly patients with CSDH if they did not use before surgery based on our results because of the potential impairments of liver and kidney function. According to the comparison of baseline, more female patients were included in the study group. To strengthen the results, we calculated the relative risk (RR) and its 95% CI. The RR of female was 1.385 (0.040-4.748), suggesting the gender difference was not associated with the outcomes.

Although there is no association between postoperative atorvastatin use and surgical outcomes, the surgical intervention has been demonstrated to be effective in removing the subdural hematoma. The percentage of patients with a 60% or more reduction on the hematoma volume was 73.5% at discharge from hospital, and the percentage increased to 93.9% at 1 month after surgery. Besides, hematoma recurrence occurred in 9 of 49 patients (18.4%), a rate that is similar to previous studies. Some limitations of our study should be noted. This trial is retrospective in the presence bias. We will conduct a prospective trial to further demonstrated the benefits of atorvastatin use in addition to surgery.

Conclusions

In elderly patients with CSDH receiving surgical intervention, postoperative atorvastatin use barely reduces recurrence rates and hematoma volume, and barely improves the neurological function.

Conflict of Interest
The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Funding
This work was supported by the West China Hospital, Sichuan University (No. 141191462).

Institutional Review Board Statement
The ethical review and approval were waived for this study since this study was retrospective.

Informed Consent Statement
Informed consent was obtained from all subjects involved in the study.

Authors' Contribution
Conceptualization: Tong Sun, Junwen Guan; Formal analysis: Yikai Yuan; Methodology: Tong Sun, Junwen Guan, Chao You; Software: Ke Wu; Investigation: Ke Wu; Funding acquisition: Junwen Guan; Project administration: Junwen Guan; Writing – original draft: Tong Sun, Yikai Yuan; Writing – review & editing: Junwen Guan, Chao You. All authors have agreed to be listed and have seen and approved the manuscript.

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