



Treatment of Carotid Atherosclerotic Plaque Dengzhan Shengmai Capsule Versus Aspirin

Background For the treatment of carotid atherosclerosis, aspirin is a highly efficient antiplatelet drug [1]. However, the drug's significant risk of bleeding incidents necessitates the search for a safer substitute with as much or more efficacy as aspirin [2]. Dengzhan Shengmai pills have been used extensively to treat carotid atherosclerosis, and if they are found to be non-inferior to aspirin, they may be preferred over that drug due to its many benefits [3]. In order to determine if DZSM is noninferior to aspirin for the treatment of carotid atherosclerotic plaques, we performed a randomised experiment [4]. **Methods** We conducted a prospective, open-label, randomised non-inferiority study in a single centre [5]. Randomly allocated patients with carotid atherosclerotic plaques were recruited and given either DZSM capsules or the main result was the Aspirin's mean effect on carotid intima medium thickness [6]. The time following ischemic events, lumen stenosis rate, lipid levels, and plaque scores, length, numbers, and vulnerability were considered secondary outcomes [7]. The findings of laboratory tests and adverse occurrences were noted as safety outcomes [8]. When the lower limit of the one-sided confidence of the difference in IMT between groups was more than -0.06 mm, the non-inferiority of DZSM was shown margin of noninferiority. Patients were enrolled in this experiment, which has been filed at ClinicalTrials [9]. gov, and there was no statistically significant demographic difference between the groups [10].

KEYWORDS: Carotid atherosclerotic plaque • Dengzhan Shengmai Capsule • Aspirin • Non-inferiority

Introduction

Specifically, stomach pain decreased according to a study of patients' intentions-to-treat data [11]. Although there was no discernible difference, bleeding generally happened less often. This experiment showed that DZSM was not less effective than when it comes to safety, it has been demonstrated to be superior to aspirin in the treatment of carotid atherosclerotic plaques [12]. This study offers a novel method for treating carotid plaques, particularly in those who are aspirin-intolerant [13]. **Abbreviations:** Common carotid arteries, cerebrovascular disorders, Dengzhan Shengmai, analysis of variance, external carotid arteries, and ANOVA Internal carotid arteries; GI, gastrointestinal; HDL-C, high-density lipoprotein cholesterol; Low-density lipoprotein cholesterol (LDL-C), informed consent form (ICF), intima-media thickness (IMT), and intention-to-treat (ITT) Total cholesterol; PP, per-protocol; RCT, randomised controlled trial; TG, triglycerides, TIA, transient ischemic attack, and WM, western medicine. TCM, traditional Chinese medicine. The Vascular and Endovascular Surgery Department of Changzheng Hospital carried out this non-inferiority, single-center, prospective, open-label, randomised controlled experiment [14]. The trial was registered at the China Clinical Trial Center and given the China

Hospital Ethics Review Committee permission number [15]. All participants were asked to sign an informed consent form, or their legal representatives did so. The definitions from the pertinent recommendations state that there are three phases of carotid atherosclerosis: increased IMT, carotid plaque development, and carotid stenosis. A thorough examination of a plaque's morphology, echo, and surface integrity yields a determination of the plaque's susceptibility. This trial's main goal was to see if DZSM was superior to aspirin in terms of the primary endpoint, which was the mean change in carotid IMT. Individuals who have carotid plaques. Patients had DUS to look for IMT in the external, internal, and common carotid arteries' far walls at baseline and then every six months after that. The trunk of the, beginning segment, distance from the bifurcation to, and complete bifurcation process were continually examined. IMT was assessed by a skilled ultrasound technician who, in order to reduce variability, was blinded to each patient's course of therapy. IMT, or the distance between the leading margins of the intima and media-adventitia interfaces on the far wall of the carotid artery, was assessed by ultrasonography. We calculated the maximal IMT as the total thickness of the carotid artery wall, including plaque lesions. If there were many plaques, the Plaque with the largest diameter the causative lesion was measured for examination. The

Jeske Dehne*

Department of Gastroenterology,
University of Findlay College of Pharmacy, USA

*Author for correspondence
JeskeDehne57@gmail.com

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reductions in maximum IMT values in the test and control groups from the start to the endpoint are given as, accordingly. Myocardial infarction and transient ischaemic attack were among the ischemic events. A thorough examination of a plaque's morphology, echo, and surface integrity yields a determination of the plaque's susceptibility. Myocardial infarction, transient ischaemic attack, and cerebral stroke were all ischemic events.

Discussion

We estimated the total of various plaque thicknesses as the plaque scores using the carotid plaque score that Crouse et al. provided. Changes from baseline in ischemic events, lumen stenosis rate, lipid levels (including total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglycerides), and triglyceride levels were among the secondary outcomes. Scores, numbers, lengths, and vulnerabilities for plaques. Laboratory testing and the frequency of adverse responses served as safety indicators. GI responses, bleeding incidents, and other side effects, including death, were among the adverse occurrences. During the follow-up, the incidents were noted and evaluated for drug-related incidents. Patients were disqualified if they refused to sign the informed consent form (ICF), displayed mild to moderate carotid artery stenosis symptoms, required surgery for amaurosis fugax, had a high risk of bleeding, or were taking drugs that raised the risk of bleeding. Additionally, patients with peptic ulcers, a history of gastrointestinal bleeding or other bleeding incidents, thrombocytopenia, a coagulation condition, a uneradicalized *Helicobacter pylori* infection, an allergic constitution, and significant liver or renal failure were excluded from the study. Standard blood, liver, and kidney tests were performed at laboratories. tests for blood sugar, coagulation, function, urinalysis, and occult blood found in the faeces. The test group's patients were given 0.36 g of oral DZSM. Every eight hours, national drug approval Every 24 hours, participants in the control group were given 100 mg of oral aspirin. The recruited patients were advised to take 20 mg atorvastatin calcium tablets hourly in accordance with the pertinent instructions. The disparities in the groups brought on by atorvastatin might be offset by the random assignment of these subjects, who all received the same dosage of the drug. All participants also changed their lifestyles in terms of nutrition, exercise, and quitting smoking when the therapy programme began. Patients were managed in

accordance with the pertinent guidelines for additional comorbidities, such as diabetes and hypertension. Months passed throughout the follow-up period. Following enrolment, the patients reported two face-to-face visits: one on the day of enrolment and one in the months that followed. Every three months, testing in the lab were carried out. In order to track changes in IMT, plaque area and stability, and the degree of lumen stenosis, carotid artery DUS was conducted on a monthly basis. Adverse incidents were reported over the phone or in person. Participants received advice on how to take their prescriptions as prescribed and how to record how much pills they ingested at each follow-up appointment. The participant-used pharmaceutical packets that were empty were given back. To gauge adherence, the amount of unutilized drugs was counted in front of the participants. If there were any inconsistencies, the participants were contacted right away for an explanation. The proper steps were taken to increase participant medication adherence, through free online counselling services, frequent follow-up visits, and subsidised travel costs for some participants. Patients in the test group each acquired a national drug approval from Bio valley Pharmaceutical. Patients in the control group got treatment. The enrolled individuals were advised to take 20 mg atorvastatin calcium tablets Pharmaceutical in accordance with the pertinent instructions. The disparities in the groups brought on by atorvastatin might be offset by the random assignment of these subjects, who all received the same dosage of the drug. All participants also changed their lifestyles in terms of nutrition, exercise, and quitting smoking when the therapy programme began. Patients were managed in accordance with the pertinent recommendations for treating comorbid conditions including diabetes and hypertension. There were no significant ischemic incidents in any of the groups. However, the DZSM and aspirin groups, respectively, saw three and two TIA incidents. There was no discernible distinction between the groups. All patients experienced amaurosis fugax or transitory vertigo after a thorough examination, which may be caused by the rupture of tiny plaques. Acute myocardial infarction, ischemic stroke, hemorrhagic stroke, significant cardiovascular events, peripheral artery events, or mortality did not occur in the DZSM and aspirin group during the course of the month-long follow-up period. Plaque lengths, numbers, and ratings all considerably decreased across groups, but there was no discernible difference between the groups. Non-parametric tests were used since

the plaque scores, lengths, and counts did not pass the normalcy test. All patients who experienced negative effects received the proper care. Five patients received fewer DZSM pills and aspirin tablets than usual. Myalgia is a side effect of atorvastatin usage, and seven myalgia instances were treated with a lower dose of the medication. Four people who had bleeding stopped using aspirin. Endoscopy was used to identify stomach ulcers and haemorrhoids in patients with haematochezia. Meningiomas and lymphomas patients were not included in the research. According to laboratory testing, some patients in both groups displayed momentary abnormalities in a few indicators, but after a specific amount of time, they went back to normal, and no substantial abnormalities happened. The outcomes of the lab tests did not substantially differ across the groups. In terms of regressing IMT, DZSM wasn't any worse than aspirin. Individuals with carotid plaque; 2) DZSM's lower dose made it less dangerous than aspirin adverse event occurrence; and 3) DZSM combined with statins. The treatment of high-risk variables might halt the development of carotid plaque, ischemic events, and cholesterol levels. Consequently, DZSM might be a Feasible substitute for aspirin in the management of carotid plaque patients. Carotid atherosclerosis is currently a major problem for the entire world. Approximately 2 billion people globally, aged years and older, have carotid atherosclerosis, million have carotid plaques, and 58 million have carotid stenosis, according to a recent meta-analysis. Carotid plaques' ongoing advancement is a sign of inadequate cerebral perfusion. Acute cerebrovascular events can arise from the rupture of susceptible plaques because these events can trigger thrombosis and distal embolism. In their report, Goldstein The success of the treatment was shown by decreasing plaque scores, lengths, and numbers, increased plaque stability, and decreased LDL-C levels. As a result, DZSM seems to be the best aspirin substitute for slowing plaque development and lowering the risk of CVD events. There were no clear contraindications for using statins. The anatomical and hemodynamic properties of the left CCA, which is derived directly from the aortic arch, lacks a buffering angle, and is susceptible to the impact of blood flow, may be to blame for our discovery that the IMT on the left side was greater than that on the right. The incidence of elevated IMT and carotid plaque on the left side was much higher in our research than it was in Chen's. Superior than that to the right numerous studies have shown that antiplatelet aggregation, anticoagulation, blood

lipid regulation, scavenging of oxygen free radicals, regulation of vascular endothelial function, immune regulation, and anti-inflammation are among the potential mechanisms of DZSM progression inhibition and ischaemic stroke prevention. Recent data from a meta-analysis suggested that DZSM could enhance lipid metabolism and haem rheology, including the modulation of. Jiang used liquid chromatography in conjunction with a diode array detector and electrospray ionization-ion-trap mass spectrometry to identify 55 chemical components in DZSM, including flavonoids, chlorogenic acid, Caffeic acid, scutellarin, ginsenoside, and ophiopogonin. The "pleiotropic" actions of DZSM, which affect carotid atherosclerosis across a variety of pharmacological mechanisms, may help to explain this. DZSM was shown to be more effective than aspirin in treating carotid atherosclerotic plaques. Terms of security, aspirin. Our results supported those of earlier studies that showed carotid atherosclerosis may be effectively treated with DZSM, statins, and control of high-risk variables. This may offer a fresh approach to treating carotid atherosclerotic plaques, particularly in aspirin-resistant individuals. This experiment is a preliminary exploratory investigation, and more extensive, double-blind, placebo-controlled studies involving several centres are needed to confirm our findings. Even though there were no significant or fatal bleeding incidents, the reported bleeding incidents including haematochezia, subcutaneous bleeding, and mucosal bleeding could potentially have serious repercussions if not addressed properly. The DZSM group in this study, however, did not experience any bleeding incidents, further proving the superiority of DZSM in terms of safety. No statistically significant differences between the groups were found. Categories, albeit the limited sample size could account for this. Patients in the DZSM group also saw fewer additional negative side effects overall. The effectiveness of DZSM as a TCM was modest and long-lasting. It has little impact on physiological coagulation function and is safe in terms of antiplatelet and anticoagulant effects. Designing and overseeing the study were Lefeng Qu and Xu Shen. The manuscript was written by Xu Shen and Sili Zou. Jie Jin and Xu Shen gathered the data and carried out the statistical analysis. Data validation was the responsibility of Yandong Liu and Jianjin Wu. The work was updated by Lefeng Qu The finished work has been read and approved by all writers. No paper mill was utilised, and all data were created

internally. Each author Accept responsibility for the work's integrity and correctness in all its elements. Our study has a number of advantages. TCM's beneficial properties and low toxicity have drawn more attention to it. However, there aren't many high-quality RCTs that have been done to compare TCM with western medicine. For the treatment of carotid atherosclerotic plaques, this is the first prospective, non-inferiority RCT to assess the effectiveness and safety of DZSM with aspirin.

Conclusion

Few studies have compared DZSM with aspirin in the past, and most have concentrated on the safety and effectiveness of adding DZSM to conventional medication. Advancement in the custom of replacing aspirin with TCM has been a fruitful investigation. DZSM has been positioned in earlier research as an auxiliary rather than a substitute. Traditional treatment the study's participants all supplied written informed consent, and the data will be made public. The authors affirm that there are no known conflicts of interest related to this publication and that no pharmaceutical business provided significant financial or medical assistance for this work that

would have affected its conclusion. Our study has a number of advantages. TCM has drawn more attention as a result of its beneficial benefits and low toxicity. However, there aren't many high-quality RCTs that have been done to compare TCM with western medicine. For the treatment of carotid atherosclerotic plaques, this is the first prospective, non-inferiority RCT to assess the effectiveness and safety of DZSM with aspirin. Prior research has mostly focused on Few studies have examined DZSM with aspirin to evaluate the safety and effectiveness of adding DZSM to standard treatment. Advancement in the custom of replacing aspirin with TCM has been a fruitful investigation. Previous studies have positioned DZSM as an addition to traditional therapy rather than as a replacement for it. It is difficult to balance its advantages and hazards, though. Rarely do these circumstances exist, and DZSM may be an alternate medication for those with carotid plaque, particularly those who have a high risk of bleeding. Thus, a novel and effective method of treating carotid atherosclerosis may include combining TCM with WM. This study has a number of drawbacks. First of all, just a limited sample size and a single centre were used in this investigation. Moreover, it's possible that the participants.

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