Fixed-Dose Combination Treatment After Stroke for Secondary Prevention in China
A National Community-Based Study

Wang Longde, MD; Yin Ling, MD; Hua Yang, MD; Zuoyi, MD; Wang Yongjun, MD; Ji Xunming, MD; Niu Xiaoyuan, MD; Qu Qiumin, MD; He Li, MD; Xu Yuming, MD; Li Mei, PhD; Sun Jiayi, MD; Liu Jing, MD; Zhao Dong, MD

Background and Purpose—There is evidence and international consensus on the advantages and potential of a polypill for established cardiovascular disease patients to improve adherence in the secondary prevention of cardiovascular disease. This study aimed to estimate the numbers of stroke patients who would be eligible for the polypill strategy in China, and the suitable composition of a polypill, based on data of the China National Stroke Prevention Project.

Methods—A total of 717,620 residents aged ≥240 years from 6 Chinese representative provinces were screened for prevalent stroke from 2011 to 2012 with an 84.4% response rate. Participants with a history of stroke received further investigation of risk factors and treatments. The potential need for treatment was classified according to the guidelines. Rates were standardized using the population composition of the Sixth National Population Census of China.

Results—The standardized prevalence rate of stroke was 1.9%. Up to 93.1% of stroke patients were eligible for a polypill containing at least 2 types of medications, with 75.3% eligible for a statin and antiplatelet agent and 70.6% for antihypertensive and antiplatelet medications. Considering 3 therapies, 54% were eligible for antihypertensive, statin, and antiplatelet medications. The current treatment rate with all required combinations of separate pills was only 6.9%.

Conclusions—A huge number of stroke patients in China require preventive therapy and would be eligible for a polypill. This study indicates that it would be reasonable to consider and assess the value of a polypill strategy to improve secondary prevention of stroke in China. (Stroke. 2015;46:00-00. DOI: 10.1161/STROKEAHA.114.007384.)

Key Words: cardiovascular diseases ■ prevention ■ risk factors ■ stroke

The potential benefit of a fixed-dose combination or a polypill for prevention of recurrent vascular events among patients with established cardiovascular disease is gaining interest internationally.1–6 There are several reasons for considering a low-cost polypill strategy in the secondary prevention of stroke in China. First, stroke is a leading cause of death and has a high recurrence rate among nonfatal cases because of extremely low treatment rates and poor adherence to essential treatments for secondary prevention.7–10 Second, most medical services accessed by the majority of stroke patients have a low capacity to handle complicated combination treatments that need separate prescriptions.11 Third, a polypill consisting of one tablet would be easier to integrate into the current public healthcare system, or to supply as a free treatment, compared with the constituent medications prescribed separately. However, to assess the value of a polypill strategy at a national level, we need to determine in advance how many stroke patients would be potential candidates for such a strategy, what composition of a polypill would meet the needs of the majority of stroke patients, and what is the current situation regarding combination therapy with separate pills in secondary prevention of stroke patients in China. Therefore, this study aimed to address these issues using data from the China National Stroke Prevention Project (CSPP).
Methods

Study Population of the CSPP

Of the 31 provinces in China, 6 were selected from regions with medium stroke rates based on available data for stroke incidence and mortality and represented western, central, and eastern areas of China. Within the 6 provinces, 40 administrative areas and 110 residential communities were further selected. A total of 849,874 adults aged ≥40 years within the 110 residential communities were registered at the local government office. Of these adults, 717,620 received stroke screening, giving a response rate of 84.4%, and these individuals were included in the final analysis of stroke prevalence.

The composition of the study population and the corresponding composition of the Chinese population aged ≥40 years according to the Sixth National Population Census of China in 2010 is listed in Table 1. In total, 14,333 stroke survivors were identified.

Organization and Implementation of the CSPP

The CSPP was supported by the China Ministry of Health and China Ministry of Finance as a key national action on stroke prevention and control. A CSPP office was established to coordinate the implementation of the program. A steering committee, including key neurologists, cardiologists, and epidemiologists, was established to provide ethical approval and technical support to the program. There were 40 designated provincial or large city hospitals, 82 Centers of Disease Control, and 205 local governments involved in field work in the 6 selected provinces. The national cross-sectional CSPP survey was conducted from March 2011 to February 2012.

The screening program was implemented in 2 stages. All residents of the selected communities aged ≥40 years were invited to join the first stage of the screening program, conducted in community hospitals or health centers, and were provided with clear information regarding the purpose of the study, the content of the program, and the screening process. The participants were asked questions by trained medical staff regarding their stroke history and risk factor status, using a standardized questionnaire. Written informed consent was obtained from each participant on the first page of the questionnaire. All participants with a stroke history identified in the first-stage screening were examined further by a neurologist or a trained physician to obtain more detailed information, including demographic data, diagnosis date and type of hospital, clinical manifestations of the claimed acute stroke, and measurements of all risk factors recommended as treatment targets by the guidelines on secondary stroke prevention. The status of treatments was defined as the medications received during the 2 weeks before the survey. Physical examinations included assessment of the sequelae of stroke and capacity for physical activity. Laboratory examinations included measurements of serum lipids (total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol), serum glucose, serum creatinine, serum fasting C-reactive protein, and D-dimer.

Table 1. Comparison Between the CSPP Study Population and the Sixth National China Census Population

<table>
<thead>
<tr>
<th>Provinces</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CSPP</td>
<td>All China</td>
<td>CSPP</td>
</tr>
<tr>
<td>N</td>
<td>%</td>
<td>%†</td>
<td>N</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td>Female</td>
</tr>
<tr>
<td>Total</td>
<td>330,644</td>
<td>46.1</td>
<td>50.3</td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>40–49</td>
<td>114,614</td>
<td>34.7</td>
<td>41.1</td>
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<tr>
<td>50–59</td>
<td>95,875</td>
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<td>28.5</td>
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<tr>
<td>60–69</td>
<td>69,852</td>
<td>21.1</td>
<td>17.7</td>
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<tr>
<td>70–79</td>
<td>39,312</td>
<td>11.9</td>
<td>9.7</td>
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<tr>
<td>≥80</td>
<td>10,991</td>
<td>3.3</td>
<td>3.1</td>
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<tr>
<td>Provinces</td>
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<td></td>
</tr>
<tr>
<td>Beijing</td>
<td>35,565</td>
<td>10.8</td>
<td>5.4</td>
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<td>Shandong</td>
<td>108,230</td>
<td>32.7</td>
<td>27.9</td>
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<tr>
<td>Henan</td>
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<td>23.4</td>
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<tr>
<td>Shanxi</td>
<td>63,847</td>
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<td>9.5</td>
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<tr>
<td>Shanxi</td>
<td>30,800</td>
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<td>10.3</td>
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<tr>
<td>Sichuan</td>
<td>56,673</td>
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<tr>
<td>Educational level [1]</td>
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<td></td>
<td></td>
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<tr>
<td>Low</td>
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<td>37.3</td>
</tr>
<tr>
<td>Medium-low</td>
<td>109,299</td>
<td>33.0</td>
<td>42.1</td>
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<tr>
<td>Medium-high</td>
<td>53,119</td>
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<td>13.9</td>
</tr>
<tr>
<td>High</td>
<td>26,970</td>
<td>8.2</td>
<td>6.7</td>
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<tr>
<td>Urban and rural</td>
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<td></td>
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<tr>
<td>Urban</td>
<td>186,217</td>
<td>56.3</td>
<td>48.2</td>
</tr>
<tr>
<td>Rural</td>
<td>144,427</td>
<td>43.7</td>
<td>51.9</td>
</tr>
</tbody>
</table>

CSPP indicates China National Stroke Prevention Program.

*Proportion in CSPP population.
†Proportion in population of sixth national census.
‡Shanxi in north.
§Shanxi in north-west.
[1] Educational level was divided into low (primary school or lower), medium-low (junior high school), medium–high (high school), and high (college or university or higher).
Definition of Stroke History and Risk Factors

Stroke history was established by a combination of self-reporting and the judgment of a neurologist or physician according to WHO criteria. Among the stroke patients identified in this program, 75% received a diagnosis of acute stroke in a secondary or a tertiary hospital and 25% were diagnosed in a community hospital. Patients with a history of a transient ischemic attack only were excluded. The Table in the online-only Data Supplement lists the criteria for the risk factors for recurrent stroke used in this survey.15–18

Data Management and Analysis

A paper-based questionnaire was used to collect data during the survey. All data from the questionnaires were entered into a Web-based electronic database by trained students, nurses, and other staff. The data were checked for completeness and potential errors by experienced data management staff according to a standardized procedure. To cope with the needs of the multiple variable adjustments, the standardized stroke prevalence rate among the population aged ≥40 years and standardized proportions of risk factors for recurrent stroke and of combination treatments among stroke patients were estimated from 1000 random proportional probability samples of 100,000 individuals sampled from the 717,620 study population by the bootstrap method, in line with proportions according to sex, age, educational level, region, and residential status groups in the census population. Each of the 1000 samples was analyzed separately for stroke prevalence rates.15 A mean prevalence rate and 95% confidence intervals were calculated based on the 1000 randomly selected samples from this large population.

The criteria for eligibility for antihypertensive medication, statins, antiplatelet agents, glucose-lowering agents, and anticoagulants were mainly based on recommendations of updated guidelines issued by Chinese or well established, international, professional organizations.16–18 Antithrombotic drugs were assumed to be suitable for all patients. The requirement for glucose-lowering drugs was determined when patients had an elevated fasting glucose level (≥7 mmol/L) or they were taking glucose-lowering drugs in the previous 2 weeks. The need for an anticoagulant was identified if a patient had atrial fibrillation. Eligibility for a particular combination treatment was determined from the requirement of patients for the constituent treatments in that combination. The status of treatment was determined according to receipt of the relevant medications as mentioned above in the previous 2 weeks. The duration period of 2 weeks before the survey was an arbitrary definition that was used by the China National Health Service Survey.21

A standardized proportion of patients who needed certain combination treatments was calculated based on a sum of that proportion among stroke patients in each of the 1000 randomly selected samples divided by 1000 with 95% confidence intervals; and a standardized proportion of patients who received all needed treatments in combination among those who needed that combination treatment was calculated by the same method. The control rates of hypertension or hypercholesterolemia were defined as the percentage of patients taking relevant medication who had BP or LDL-C levels below the definition of elevated risk (Table in the online-only Data Supplement). Extrapolation to determine the total numbers of stroke patients aged ≥40 years in China and the numbers requiring different combination treatments was performed. All statistical analyses were conducted using SAS version 9.2 (SAS Institute Inc, Cary, NC).

Results

A total of 717,620 individuals participated in the first-stage screening for stroke survivors. Table 1 shows the composition of the study population. The corresponding composition of the Chinese population aged ≥40 according to the Sixth Census of China in 2010 is listed as a reference for comparison with a nationally representative population.

Prevalence and Total Numbers of Stroke Patients

Crude prevalence rates of stroke survivors among the 717,620 study population aged ≥40 years was 2.0% overall, 2.3% for men, and 1.8% for women. The standardized prevalence rate of stroke was 1.9% (95% confidence intervals, 1.913–1.918%).
Extrapolating to the Chinese population aged ≥40 years, there were an estimated 10,883,045 (95% confidence intervals, 10,867,709–10,897,813) surviving stroke patients. Among the stroke patients in this study, 54.0% were aged <65 years, 79% had a low educational level, and 79.4% had no or very low reimbursement of their expenses for medical treatments, based on standardized estimates.

### Numbers of Stroke Patients Requiring Combination Treatment

The standardized prevalence rates of risk factors among 14,333 stroke patients identified by the screening are shown in Figure. Three-quarters (75.3%) of patients had elevated LDL-C levels, 70.6% had hypertension, 56.9% were overweight or obese, 47.3% of male patients were current smokers, 28.4% drank alcohol frequently, 16.3% had diabetes mellitus, and 5.5% had atrial fibrillations.

The crude and standardized rates of different combinations of medications that were identified as being required by the stroke patients according to their risk factor status are shown in Table 2. A polypill including at least 2 of the 5 key therapy options was potentially needed by 93.1% of patients. Considering a polypill of any 2 therapies, 75.3% of patients would require a statin and an antiplatelet agent and 70.6% would require an antihypertensive and an antiplatelet agent. Considering a polypill of 3 of the therapies, 53.9% of patients would require an antihypertensive, a statin, and an antiplatelet agent. The proportion of patients requiring a polypill that included glucose-lowering agents for diabetes mellitus was 16.3%, and one that included an anticoagulant for atrial fibrillation was required by only 5.5%.

Based on the proportions of different combination treatments that may be required by stroke patients, ≈8.9 million stroke patients nationally would potentially need combination treatment, including at least a statin and an antiplatelet agent; ≈8.4 million would need combination treatment including at least an antihypertensive and an antiplatelet agent; and ≈6.4 million would need a combination of an antihypertensive, a statin, and an antiplatelet agent.

### Current Use of Combination Treatment Among Stroke Patients

Among the stroke patients identified as requiring combination treatment of at least 2 drugs, only 6.9% received the required treatment with separate pills (Table 2). Among stroke patients identified as requiring triple combination treatment, only...
Elevated LDL-C 11538
HTN+elevated LDL-C 8528
cations.22 The reasons may include the complexity of treat-
China showed that intensive patient education had no effect
A recent randomized clinical trial among stroke patients in
solution, and there is evidence that this can lead to a reduction
ment with different drugs for both physicians in community
hospitals and stroke patients. Use of a polypill is a possible
The very low treatment rates or low adherence rates to essen-
tial treatments represent a key barrier for improvement in the
secondary prevention of stroke in China and also in many other
low- and middle-income countries, even though there is
adequate evidence for the benefits of secondary prevention.20
A recent randomized clinical trial among stroke patients in
China showed that intensive patient education had no effect
on adherence to combination treatment using separate medi-
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ment with different drugs for both physicians in community
hospitals and stroke patients. Use of a polypill is a possible
solution, and there is evidence that this can lead to a reduction
in risk factors and increased adherence rates.5

This study provided important basic information for further
assessment of the value of a polypill strategy in the secondary
prevention of stroke in China. First, over 10 million stroke
patients nationally are potential candidates for combination
treatment. Second, most of these patients would benefit from
low cost or free combination treatment because they have no
or low reimbursement from medical insurance, and most
patients have a low educational level and live in rural areas
with low accessibility to comprehensive medical services.
Third, the proportion of patients who receive the necessary
combination treatment is as low as 6.9%.

This study also provided details of the type of combination
treatments that the majority of stroke patients in China are
likely to require. Antihypertensive agent should be included
in a polypill whatever other agents are considered because
hypertension has the greatest attributable risk for stroke in
Chinese.21 However, only 33.3% of patients receiving antihy-
pertensive treatment reached the treatment target in this study,
suggesting that >1 antihypertensive agent or an increased dose
may be required in a polypill. If a polypill with 3 types of
medications was considered feasible according to resources
available, 53.9% of stroke patients would require an antihy-
pertensive agent, a statin, and an antiplatelet agent.

It is obvious that more research is needed to provide fur-
ther evidence for policy decision-making regarding polypill
preventative therapy, including the comparative effectiveness
research for the benefits of a polypill, or different types of
polypill, over combination treatment with separate medica-
tions, and an assessment of the health economic effect of a
polypill policy. It is also important to estimate the potential
risk of a polypill strategy from a public health perspective.
Given the heterogeneous pathogenesis of stroke, a comparison
of the expected effect of the various risk factor modifications
is necessary to select an appropriate polypill.

It is also important to recognize that 47.3% of male stroke
patients were current smokers and 28.4% drank alcohol fre-
quently, and these habits should be priority targets because
lifestyle change is the most cost-effective approach.

There were several notable limitations of this study. One
is that the survey did not collect details of the dosages of
medications used by the stroke patients, which is important
because the low control rates likely arose from inappropriate
dosages, and such information could provide an indication
of the dosage required in a polypill. The second is that the
CSPP used a multistage nonrandom sampling design, pos-
sibly resulting in biased estimation of the prevalence rate of
stroke and of the total number of stroke survivors, although
efforts were made to correct this through a standardized pro-
cedure. The third is that this survey was not able to verify with
a high degree of accuracy the stroke history or obtain accurate
information about the subtype of stroke by checking hospital
records. All stroke patients in this study were assumed to be

5.6% received an antihypertensive, a statin, and an antiplatelet
agent.

The effects of combination treatment on BP and LDL-C
were further analyzed (Table 3). Of 7020 patients taking an
antihypertensive agent, 75.9% used one drug, and the BP con-
tral rate was 33.3%. For all patients taking a statin, the LDL-C
control rate was 14.3%, and for all patients taking a combina-
tion of an antihypertensive and a statin, the control rates of BP
and LDL-C were 44.0% and 14.9%, respectively.

Discussion

The very low treatment rates or low adherence rates to essen-
tial treatments represent a key barrier for improvement in the
secondary prevention of stroke in China and also in many other
low- and middle-income countries, even though there is
adequate evidence for the benefits of secondary prevention.20

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with low accessibility to comprehensive medical services.
Third, the proportion of patients who receive the necessary
combination treatment is as low as 6.9%.

This study also provided details of the type of combination
treatments that the majority of stroke patients in China are
likely to require. Antihypertensive agent should be included
potentially eligible for antplatelet treatment, which may overestimate the number of patients who were eligible. Finally, the judgment regarding the need for a certain treatment was based on one measurement of the risk factor, which may lead to overestimation.

Conclusions
In conclusion, this study indicated that a potentially huge number of stroke patients in China require preventive therapy and would be eligible for a combination treatment or a polypill. The majority of stroke patients may derive benefit from an inexpensive combination, including at least an antihypertensive and an antplatelet agent. A combination of an antihypertensive, a statin, and an antplatelet agent is indicated for 53.9% of stroke patients, estimated to be 6.4 million patients nationwide. Further research is needed to identify the most cost-effective fixed-dose combination options for polypill products in China and to evaluate the necessity of a public health policy with resource support to promote polypill use in the secondary prevention of stroke in China.

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Disclosures
None.

References
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Data Supplement (unedited) at:
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Short Title: Polypill for Stroke Treatment

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Tel.: + 86 10 64456524, Fax: + 86 10 64419738
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<thead>
<tr>
<th>Risk factors</th>
<th>Criteria</th>
<th>References</th>
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<tr>
<td>Smoking</td>
<td>≥1 cigarette per day in last 3 months</td>
<td>WHO MONICA project¹</td>
</tr>
<tr>
<td>Alcohol drinking</td>
<td>≥ 100mL spirit alcohol more than three times a week (Self report)</td>
<td>CSPP definition</td>
</tr>
<tr>
<td>Hypertension</td>
<td>SBP ≥140mmHg or DBP ≥90mmHg, or taking BP-lowering drugs</td>
<td>Chinese guidelines for hypertension management 2010²</td>
</tr>
<tr>
<td>Elevated LDL-C</td>
<td>LDL-C ≥1.8mmol/L</td>
<td>IAS guidelines³</td>
</tr>
<tr>
<td>Low HDL-C</td>
<td>HDL-C &lt;1.04mmol/L</td>
<td>IAS guidelines³</td>
</tr>
<tr>
<td>Overweight or obese</td>
<td>BMI ≥25 kg/m²</td>
<td>IAS guidelines³</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Fasting glucose ≥7 mmol/L or taking glucose-lowering drugs</td>
<td>IDF definition⁴</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>Self-report or ECG records</td>
<td>AF was defined by either with history of persistent AF or supported by past ECG or ECG examination in this survey</td>
</tr>
</tbody>
</table>

Abbreviation: SBP, systolic blood pressure; DBP, diastolic blood pressure; AF, atrial fibrillation; WHO, World Health Organization; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; BMI, body mass index; IAS, International Atherosclerosis Society; IDF, International Diabetes Federation.
References


