

Rationale and design of Patient-centered Retrospective Observation of Guideline-Recommended Execution for Stroke Sufferers in China: China PROGRESS

Zixiao Li,^{1,2,3,4} Chunjuan Wang,^{2,3,4} Yong Jiang,^{2,3,4} Xinmiao Zhang,^{1,3,4} Ying Xian,⁵ Liping Liu,^{2,3,4,6} Xingquan Zhao,^{1,2,3,4} Hongqiu Gu,^{2,3,4} Xia Meng,^{2,3,4} Hao Li,^{2,3,4} Yilong Wang,^{1,2,3,4} Yongjun Wang^{1,2,3,4}

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ZL, CW and YJ contributed equally.

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For numbered affiliations see end of article.

Correspondence to

Dr Yongjun Wang, Vascular Neurology, Department of Neurology Beijing Tiantan Hospital, Capital Medical University Beijing China; yongjunwang@ncrcnd.org.cn

ABSTRACT

Background In 2009, China launched ambitious healthcare reform plans to provide affordable and equitable basic healthcare for all patients, including the substantial number of patients who had a stroke. However, little is known about the pattern of evidence-based stroke care and outcomes across hospitals, regions and time during the last decade.

Aims The Patient-centered Retrospective Observation of Guideline-Recommended Execution for Stroke Sufferers in China (China PROGRESS) Study aims to use findings from a representative sample of Chinese hospitals over the last decade to improve future stroke care for patients hospitalised with ischaemic stroke (IS) or transient ischaemic attack (TIA).

Design The China PROGRESS Study will use a two-stage cluster sampling method to identify over 32000 patient records from 208 hospitals across the Eastern, Central and Western geographical regions in China. To assess the temporal trends in patient characteristics, treatment and outcomes, study investigators will select records from 2005, 2010 and 2015. A double data reading/entry system will be developed to conduct this assessment. A central coordinating centre will monitor case ascertainment, data abstraction and data management. Analyses will examine patient characteristics, testing patterns, in-hospital treatment and outcomes, and variations across regions and across time.

Conclusions The China PROGRESS Study is the first nationally representative study that aims to better understand care quality and outcomes for patients with IS or TIA before and after the national healthcare reform in China. This initiative will translate findings into clinical practices that improve care quality for patients who had a stroke and policy recommendations that allow these changes to be implemented widely.

Ethics approval

This study has also been approved by the central institutional review board (IRB) at Beijing Tiantan Hospital.

INTRODUCTION

Stroke is the leading cause of mortality in China (1.1 million), constituting nearly a sixth of the total number of deaths (6.5 million) from stroke in the world.^{1,2} Stroke burden

has risen over the past three decades and has demonstrated significant variations among various rural and urban regions/settings across China. There is a north-to-south gradient for stroke in China, with the greatest burden of stroke in the northern and central regions.¹ As population ageing accelerates over the next two decades, the incidence of stroke and regional variation are anticipated to increase as well.³

In the past decade and a half, the Chinese healthcare system has experienced substantial changes. In 2009, China launched healthcare reform plans to provide affordable and equitable basic healthcare for all by 2020, including medical insurance, drug supply security, medical service provision, public health service and reform in public hospitals (listed in online supplemental materials).⁴ Significant improvement has been achieved. Health insurance coverage in China has increased from 45% in 2006 to over 95% in 2017.⁵ An optimised hierarchical medical system was set up to improve services at county-level and township-level health centres, especially in less developed areas. Rural healthcare, in particular, has undergone significant expansion. The premium for the New Rural Cooperative Medical Scheme (NRCMS) increased from ¥30 (Chinese currency) in 2003 to ¥411 in 2014. By the end of 2014, 736 million rural residents—which is nearly the entire rural population—had joined the NRCMS.⁵

Evidently, stroke care has become a national priority. In 2007, a series of stroke care quality assessment and improvement initiatives were launched by the National Health and Family Planning Commission (NHFPC) and the Ministry of Science and Technology to establish National Stroke Registries, increase the detection of high-risk populations with stroke, increase the adherence rate of evidence-based

process performance measures of stroke care, and promote stroke care organisation development, all of which aim to decrease the burden of stroke.^{6,7} Chinese guidelines for early management and secondary prevention of ischaemic stroke (IS) were also issued in 2010 and updated in 2014.^{8,9} Several China-based randomised control trials for stroke management and prevention, including the Clopidogrel in High-risk Patients with Acute Non-disabling Cerebrovascular Events Trial, were conducted to provide evidence and guidelines specific to the Chinese population for stroke physicians.¹⁰

These changes have influenced stroke care patterns and outcomes. Although previous research on the characteristics, treatments and outcomes for inpatients with stroke in China have contributed valuable knowledge, they have largely been limited to studies from hospitals in urban regions,^{7,11,12} major metropolitan areas,¹³ a small subset of provinces¹⁴ or to patients from clinical trial databases.^{10,15} These studies did not have nationally representative study samples, did not adequately represent rural regions and did not examine temporal trends in stroke treatment and outcomes before and after the national healthcare reform in 2009.

The Patient-centered Retrospective Observation of Guideline-Recommended Execution for Stroke Sufferers in China (China PROGRESS) Study aims to fill these gaps in knowledge by elucidating the clinical epidemiology and management for patients who had a stroke and their associations with in-hospital outcomes across patients, hospitals, regions and time using a nationally representative sample of more than 30 000 patients' records from 208 randomly selected hospitals in 2005, 2010 and 2015. We expect that there will be significant variations in practice and outcomes by demographic and geographical characteristics, and therefore substantial opportunities for improvement.

METHODS

Study aims

The objectives of the China PROGRESS Study are: (1) To describe the characteristics of hospitalised patients with IS or transient ischaemic attack (TIA) including their demographic and clinical characteristics such as age, gender, insurance status, vascular risk factors and comorbidity. (2) To characterise patterns of management during hospitalisation or at discharge, such as getting prescribed antithrombotics and statins. (3) To describe all-cause mortality rate, length of stay, hospital charges and other in-hospital complications such as pneumonia. (4) To identify trends over time in patient characteristics, care management and outcomes. (5) To compare variations in care management across regions and different hospital levels, and to identify whether these variations may be associated with differences in outcomes. (6) To assess the documentation quality of medical records and explore the development of electronic medical records. (7) To share study findings with participating sites

and the National Health Commission to drive nationwide improvements in stroke care quality and patient outcomes.

Design overview

The China PROGRESS Study aims to study temporal trends in patient characteristics, intervention patterns and outcomes across regions with different sociodemographic characteristics. As such, we will randomly select over 32 000 patient discharge records from a nationally representative sample of Chinese hospitals in 2005, 2010 and 2015. More specifically, we will include hospitalised patients with a primary diagnosis of IS/TIA (International Classification of Diseases, Tenth Revision (ICD-10) Clinical Modification codes I63.x or G45).

Sampling design

We sampled hospitals in eastern-urban, eastern-rural, central/western-urban, central-rural and western-rural regions to reflect the different quality of care across geographical regions, using a similar framework to the one established in the China PEACE Study to identify regional strata.¹⁶ An area was defined as urban if it is located in the downtown or suburban area within a direct-controlled municipality (Beijing, Tianjin, Shanghai, Chongqing) or one of 291 prefecture-level cities. An area was defined as rural if it is a county-level region, including counties and county-level cities. Within this framework, there are 295 urban areas and 1875 rural areas in Mainland China as of 2015.¹⁷

We conducted a two-stage stratified cluster sampling. In the first stage, we selected hospitals using a stratified random sampling procedure within the 5-study strata. The list of national hospitals provided by the NHFPC was used as the sampling frame. Military hospitals, prison hospitals, specialised hospitals and traditional Chinese medicine hospitals were excluded. We sampled the central hospital, defined as the hospital in the region with the greatest capacity for treating acute conditions including IS, from each strata for rural regions (1875 central hospitals in rural regions as of 2015). We sampled secondary and tertiary hospitals in each of the strata for urban regions (2380 secondary or tertiary hospitals in 295 urban regions). Hospital-level classification by the Chinese government is based on clinical resources. Secondary hospitals include those with at least 100 beds and can provide acute care, short-term stay and preventive care services to a population of at least 100 000. Tertiary hospitals include large referral centres in provincial capitals and other major cities.¹⁶

In the second stage, we sample the cases from a patient list abstracted from the inpatient database of the local hospital information system for patients with IS/TIA at each sampled hospital. We determined the sample size to achieve an absolute error of 0.6% for describing the primary outcome, all-cause in-hospital mortality, which we estimated to be about 2%.⁷ With an α of 0.05 in each of the five strata, assuming the design effect of 1.7 and

case acceptance rate of 85%, we required a sample size of approximately 10 700 medical records among hospitals with an average cluster size of 60 for each year (2005, 2010 and 2015). Assuming a participation rate of 85% among selected hospitals, we approached 208 hospitals in five strata (100 urban and 108 rural). We selected representative hospitals from 2015 to reflect current clinical practices and traced this hospital cohort backwards to 2010 and 2005 to determine whether there were any temporal trends.

Data collection

The NHFPC appointed the National Centre of Stroke Care Management to take charge of the China PROGRESS Study, issued an official notice to 31 provincial centres for stroke care management in Mainland China and sampled hospitals to collect medical records. The National Centre of Stroke Care Management established a national coordinating centre to manage this project. First, this national coordinating centre held a meeting to introduce this project in detail to 31 directors and coordinators of provincial centres of stroke care management. Directors and coordinators were trained to identify all patients hospitalised with IS/TIA from the front sheet of medical records in their respective local hospital databases for the years 2005, 2010 and 2015. After the training, the 31 coordinators of provincial centres were responsible for passing on these instructions to staff at participating hospitals. These participating hospitals provided lists of patients diagnosed with IS/TIA (ICD-10 Code: I63.x and G45) at discharge in 2005, 2010 and 2015 to the National Centre of Stroke Care Management. We checked the accuracy of these lists and sampled cases at each site. These sampled cases were assigned a unique study ID. A high-speed scanner was provided to each participating hospital by the national coordinating centre. We then required local investigators to collect the original medical records, scan them and submit the scanned copies to the national coordinating centre. We also trained independent research staff from the national coordinating centre and visited study hospitals to conduct the case-finding process and check the integrity of the list of inpatients with IS/TIA.

After receiving the sampled cases from the national coordinating centre, participating hospitals scanned and submitted the copied records from their sites. Trained health information coordinators checked the completeness and quality of each scanned record; incomplete or scanned records that were missing or vague were rescanned and resubmitted by the participating hospital. Lastly, after removing patients' and physicians' private information, acceptable medical records were de-identified and uploaded to the National Centre of Stroke Care Management.

Double data entry

We developed a double reading and entry system that generated data reading entry tasks and divided medical records into different modules: the face sheet, discharge

summary, admission note, daily progress notes, procedure notes, laboratory test results, diagnostic procedure reports, medication administration record, physician orders and nurse notes.¹⁸ Inpatient medical records generally include these modules throughout China. These different modules were assigned to data specialists (DS) A and B, trained and certified personnel with sufficient background for the corresponding module who would perform data reading and data entry tasks and submit the entry values. To control the quality of data reading and data entry, we employed two independent DS to process these medical records. Discrepancies in double-entered information between DS A and B are adjudicated by a third senior DS (figure 1).

Data quality management

After data reading and entry are complete, the system can detect any potential inconsistencies between independent entries. When inconsistencies are detected, quality control tasks are submitted to a data specialist of quality management (DS-QM). This DS-QM checks the unstructured scanned images of medical records and judges the postquality control values for those inconsistencies. After this initial adjudication, DS-QM sends the query back to DS A and B without revealing postquality control values, and requests that the DS in question repeat the data entry. The DS-QM will compare these values again once the entries are resubmitted by DS A and B. Once a consensus is reached, DS-QM will submit adjudicated values to the final structured database system. However, if a DS has doubts about the validity of values entered by DS-QM, the DS-QM can submit this case to a higher level of quality control by a senior DS-QM who will then make a final decision on the appropriate value.¹⁸

In summary, the China PROGRESS Study took several measures to ensure the accuracy of abstraction. We employed abstractors with formal medical education who then received training courses in the following: the items of abstracted data, origins of these data in medical records, advanced stroke-related medical knowledge for recognition of stroke signs and symptoms, vascular risk factors, evidence-based treatment and presence of comorbidities. We developed a web-based data entry and quality management platform for the China PROGRESS Study to carry out medical record transmission, de-identification, classification, data abstraction and entry, quality check, and assessment of values to ensure that they are logical. Experienced medical staff was available online to answer questions in real time through an online consulting service on WeChat. These questions and answers were summarised and listed on the web-based platform for reference of other study personnel. We also developed a common drug database to expedite medication identification. Lastly, we assigned medical records from the same site and year to the same abstractors to leverage familiarity and proficiency.

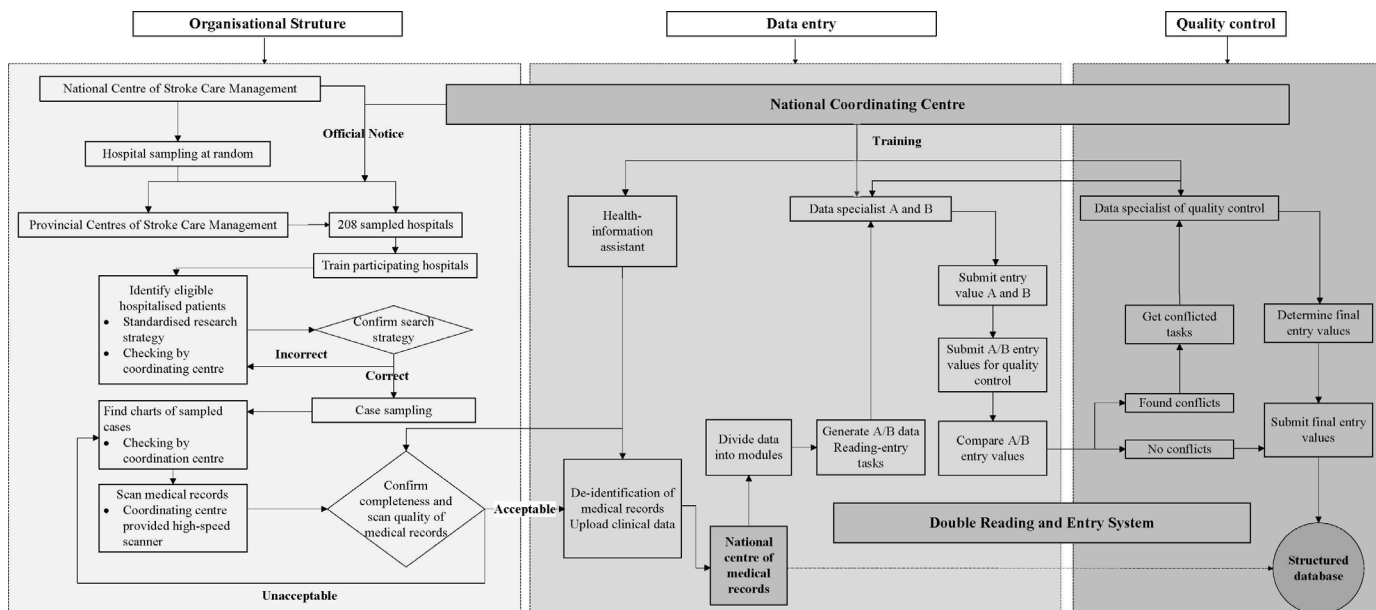


Figure 1 The Patient-centered Retrospective Observation of Guideline-Recommended Execution for Stroke Sufferers in China (China PROGRESS) Study flow chart of data collection, data entry and data quality control.

Data management

All data with protected health information were stored in an encrypted and password-protected database at the national coordinating centre. These data were cleaned systematically and concurrently with data collection. Data managers regularly query data for invalid and illogical values as well as for duplicate entries. They identify potentially invalid values by analysing outliers in a continuous data distribution. Data managers identify duplicate records by searching for identical study identification numbers, hospital identification numbers, medical record identification numbers and dates of discharge. Once a potential error is identified, data managers trace and review the relevant records to revise this error.

Data elements

We reviewed relevant Chinese and English language studies to create a list of variables for which we planned to collect information, including variables pertaining to traditional Chinese medicine. This was supplemented with variables in the China National Stroke Registries and the US-based Get With The Guidelines-Stroke (GWTG-Stroke) database, the largest registry of stroke care quality improvement worldwide that uses standardised elements and is helpful in conducting cross-country comparisons (listed in online supplemental materials).^{11 19}

Where possible, we collected data that would track the adherent rate of evidence-based performance metrics during hospitalisation and at discharge reported by the Chinese National Centre of Stroke Care Management and GWTG-Stroke.

Ethical and privacy considerations

This study is performed in accordance with the Declaration of Helsinki and evidence-based clinical practice

guidelines. As this is a retrospective study, written informed consent by individual patients or family members was waived by the institutional review board. All medical records and abstracted clinical data are strictly confidential. After removing patients' and physicians' private information, such as name, ID, address, phone number, and so on, a de-identified clinical data file was created and uploaded.

Organisational structure

The NHFPC has established a national system of stroke care management in collaboration with the National Centre of Stroke Care Management and 31 provincial centres of stroke care management in Mainland China. The China PROGRESS Study is administered by an academic steering committee composed of a principle investigator and members from national and provincial centres of stroke care management. This committee is responsible for directing and supporting research, for addressing policy issues about the protocol, and for meeting periodically to evaluate the progress of the study.

Statistical analyses

To account for the disproportionate stratified sampling, sampling weight coefficients of each sampling stage were calculated and the non-response weight was considered. Weighted adherent percentages of performance indicators (95% CIs) and composite index means (95% CIs) of stroke care in years 2005, 2010 and 2015 were calculated to reflect the current situation and trends from 2005 or 2010 to 2015. We weighted calculations to generalise our results to the Chinese population over the age of 18 years.

Demographic clinical characteristics of participants will be first analysed for the entire study population. We will then conduct analyses of subgroups for age, sex,

geographical location (urban or rural), insurance status and economic development. Means and 95% CIs will be calculated for continuous variables, and proportions and 95% CIs will be calculated for categorical variables. The Taylor series linearisation method will be used to calculate standard errors. Missing values will be analysed whether missing is at random or not. If missing is at random, the weight coefficient will be calculated, and the weighting method will be employed. If missing is not at random, the multiple imputation method will be used.

All *p* values will be two-tailed and *p*<0.05 will be considered statistically significant. All analyses will be conducted using the SAS system, V.9.4 (SAS Institute).

Progress to date

As of October 2018, 189 hospitals have agreed to participate in the China PROGRESS Study and completed medical record collection. Of the 19 that did not participate, 9 did not have patients with IS/TIA and 10 declined participation. There were 381 896 hospitalisations for IS/TIA (41 591 in 2005, 113 592 in 2010, 236 713 in 2015) among patient databases from the 189 participating hospitals, of which we sampled 32 430 for the China PROGRESS Study. The use of electronic medical records has increased over time: 3% of the hospitals used electronic medical records in 2005, 29% in 2010 and 95% in 2015. We will code hospital-level variables for the use of electronic medical records to better understand whether these factors introduce bias into study results.

DISCUSSION

The China PROGRESS Study is developing a retrospective, longitudinal, nationally representative database of patients hospitalised with IS/TIA to track the temporal trends and regional variations in the clinical epidemiology of IS/TIA including patients' clinical characteristics, management and clinical outcomes. This knowledge will be provided to government officials, healthcare providers and research organisations to improve stroke care.

This is the first truly national evaluation of practice patterns and outcomes for stroke conducted in China as the hospitals included in this study represent the range of Chinese economic-geographical characteristics and have stroke facilities that vary widely in their capacity and quality of care. Similar to GWTC-Stroke, a prospective and voluntary stroke care quality improvement initiative, the China PROGRESS Study aims to track trends in the quality of stroke care nationwide by abstracting data from medical records. However, our study cannot provide quality improvement tools for participating hospitals due to its retrospective nature.¹⁹

Although China has adopted several strategies to improve stroke care delivery,⁶ adherence to evidence-based treatments varies across the country.²⁰ We anticipate that the findings from the China PROGRESS Study will elucidate the effects of recent guideline dissemination,

clinical trials and healthcare reforms on the adherence to evidence-based management of stroke care.

Relevant results will be disseminated to participating hospitals to ensure that findings are used in implementing new programmes and formulating new policies. Findings will also be made available to Chinese government agencies that are partners in China PROGRESS, including the NHFPC and the Ministry of Science and Technology. This will allow partner agencies to analyse study findings to identify the regional imbalances in stroke care delivery and priority areas requiring improvement, as well as to use these findings to develop policies to improve patient outcomes.

The study has placed great importance on data quality at multiple stages, including case ascertainment, data abstraction and data management. For instance, to increase the quality of abstracted data, the study developed a double reading/entry and quality management system. Medical records are divided into relatively different modules, which are assigned to different DS. Double entry of data, in combination with subsequent data comparison and quality management, will contribute to lower error rates in data entry.

There are several limitations in the China PROGRESS Study, including those inherent to its retrospective design. The integrity and accuracy of the abstracted medical records such as contraindications of performance measures, symptom onset time and *NIH Stroke Scale* (*NIHSS*) will affect the validity of our study findings. This limitation is an intrinsic property of all retrospective chart reviews. Our efforts to identify potentially subpar documentation of key variables will be vital to improving future assessments. Furthermore, this study is limited to measuring acute care outcomes because management and clinical outcomes after discharge were not recorded.

In summary, the China PROGRESS Study is largely descriptive and aims to demonstrate the trend of demographic and clinical characteristics, care management and outcomes of inpatients with ischaemic stroke via a nationally representative sample of hospitals over the last decade. These findings will provide a foundation for future research and quality improvement initiatives.

Author affiliations

¹Vascular Neurology, Department of Neurology, Beijing Tiantan Hospital, Capital Medical University, Beijing, China

²China National Clinical Research Center for Neurological Diseases, Beijing, China

³Center of Stroke, Beijing Institute for Brain Disorders, Beijing, China

⁴Beijing Key Laboratory of Translational Medicine for Cerebrovascular Disease, Beijing, China

⁵Duke Clinical Research Institute, North Carolina, USA

⁶Neuro-intensive Care Unit, Department of Neurology, Beijing Tiantan Hospital, Capital Medical University, Beijing, China

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Contributors ZL, JY, XinmZ, YX, XingZ, HG, HL, YiW and YoW conceived the study and oversaw all scientific aspects of its implementation. ZL, CW and JY drafted

the manuscript. HG conducted the data analysis. CW, XinmZ, LL and XM recruited hospitals and operated the China PROGRESS programme.

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Data sharing statement Data are available upon reasonable request.

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