Effect of a clinical decision support system on stroke care quality and outcomes in patients with acute ischaemic stroke (GOLDEN BRIDGE II): cluster randomised clinical trial

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ABSTRACT

OBJECTIVE

To evaluate the efficacy of a clinical decision support system (CDSS) on stroke care quality and clinical outcomes among patients with acute ischaemic stroke.

DESIGN

Multicentre, cluster randomised clinical trial.

SETTING

77 hospitals across China.

PARTICIPANTS

77 hospitals (38 randomised to intervention group, 39 to control group) enrolled 21 603 patients with acute ischaemic stroke admitted to hospital within seven days after symptom onset.

INTERVENTIONS

Hospitals in the intervention group received stroke CDSS support including artificial intelligence assisted imaging analysis, classification of stroke causes, and evidence based treatment recommendations. Hospitals in the control group provided usual care.

MAIN OUTCOMES MEASURES

The primary outcome was a new vascular event (composite of ischaemic stroke, haemorrhagic stroke, myocardial infarction, and vascular death) within three months after initial symptom onset. Secondary outcomes included the composite measure and all-or-none measure of evidence based performance measures for acute ischaemic stroke care quality, a new vascular event at six and 12 months, and disability (modified Rankin Scale score 3-6) and all cause mortality at three, six, and 12 months. Safety outcomes were moderate or severe bleeding events and all bleeding events at three, six, and 12 months.

RESULTS

11 054 patients in the intervention group and 10 549 patients in the control group were enrolled from January 2021 to June 2023. New vascular events at three months occurred in 2.9% (320/11 054) in the intervention group compared with 3.9% (416/10 549) in the control group (adjusted hazard ratio 0.74, 95% confidence interval (CI) 0.58 to 0.93, P=0.01). The CDSS intervention effect remained significant in the cluster level analysis (−0.01, −0.02 to −0.004, P=0.003). Patients in the intervention group were more likely to have a higher composite measure (91.4% (77 049/84 276) *v* 89.8% (70 794/78 834), adjusted odds ratio 1.21, 95% CI 1.17 to 1.26, P<0.001). New vascular events were significantly lower in the intervention group at 12 months (4.0% (440/11 054) *v* 5.5% (576/10 549), adjusted hazard ratio 0.73, 95% CI 0.56 to 0.95, P=0.02). No significant differences were found in disability and all cause mortality. Moderate or severe bleeding, and all bleeding did not differ significantly between the two groups.

CONCLUSIONS

Use of the stroke CDSS in patients with acute ischaemic stroke in China led to a significant decrease in new vascular events at three months. The stroke CDSS intervention was also effective in improving stroke care quality and decreasing long term vascular events.

TRIAL REGISTRATION

ClinicalTrials.gov NCT04524624

WHAT IS ALREADY KNOWN ON THIS TOPIC

The clinical decision support system (CDSS) is an innovative and promising approach for improving stroke outcomes and healthcare services

Artificial intelligence (AI) applications for stroke have not been rigorously evaluated through randomised controlled trials

Use of the CDSS to treat cerebrovascular disease is currently limited

WHAT THIS STUDY ADDS

A stroke CDSS system was developed, including AI assisted imaging analysis, classification of stroke causes, and evidence based treatment recommendations

Patients with acute ischemic stroke supported by the stroke CDSS had fewer new vascular events at three, six, and 12 months and improvement in stroke care quality compared with patients receiving usual care

Introduction

Artificial intelligence (AI) in healthcare has gained widespread attention, especially in assisting with disease diagnosis, treatment, prognosis, and enhancing clinical decision making.[1] The clinical decision support system (CDSS) is an innovative and promising approach for improving stroke outcomes and healthcare services.[2 3] However, the majority of AI applications for stroke healthcare have not been rigorously evaluated through randomised controlled trials. As a result, the use of CDSS in treating cerebrovascular disease is currently limited.[4 5]

Stroke is one of the major causes of disability and death in developing countries.[6] China bears the most serious burden with more than three million new strokes every year.[7 8] According to GOLDEN BRIDGE-AIS (Intervention to Bridge the Evidence-based Gap in Stroke Care Quality) and GWTG-Stroke (Get With The Guidelines-Stroke), implementing multifaceted quality improvement interventions improves acute ischaemic stroke care quality and outcomes.[9 10] However, diagnosing and managing patients with stroke is complicated. Patients with varying infarct characteristics (single or multiple infarcts, etc), the status of intracranial artery stenosis, and comorbidities (eg, atrial fibrillation) might have different clinical outcomes and therefore might need different treatment options.[11 12] Additionally, hospitals face major challenges in implementing evidence based care and intervention initiatives, including insufficient resources and high physician workloads.[9 13 14]

CDSS may provide a new way to facilitate clinical decision making and consequently improve care quality and clinical outcomes in patients with ischaemic cerebrovascular disease. We developed a stroke CDSS system that combined image analysis, classification of stroke causes, and evidence based treatment recommendations, which could be adopted in routine clinical practice.[15] The clustered randomised controlled GOLDEN BRIDGE II trial was designed to determine whether the stroke CDSS could improve care quality and clinical outcomes of patients with acute ischaemic stoke in China.

Methods

Study design

The GOLDEN BRIDGE II trial was a multicentre, open label, cluster randomised, multifaceted intervention trial conducted at 80 hospitals in China. We aimed to evaluate the effect of the stroke CDSS on stroke care quality and new vascular events at three, six, and 12 months after stroke onset. The study protocol has been reported previously.[15] The central institutional review board at Beijing Tiantan Hospital (KY 2020-016-02) and each participating site approved the trial protocol. Written informed consent was obtained. The study complied with the CONSORT-AI (consolidated standards of reporting trials—artificial intelligence) extension guidelines.

Participants

A total of 80 hospitals were approached from over 23 provinces, autonomous areas, and municipalities in mainland China, taking into account their geographical region and hospital grade. The categorisation of hospitals in China followed a three tiered grading system: primary level for community hospitals, secondary level for hospitals serving multiple communities, and tertiary level for central hospitals in specific districts or cities.[16] Hospital regions (eastern, central, and western areas) were based on the annual report on health statistics of China.[17] Hospitals were eligible if they were secondary or tertiary hospitals with emergency department and neurology wards for patients with stroke, with a 1.5 T or 3.0 T magnetic resonance imaging scanner to perform diffusion weighted imaging and magnetic resonance angiography scans. Primary hospitals and specialised hospitals were excluded.

Patients were consecutively enrolled between 13 January 2021 and 25 June 2023. Patients who were at least 18 years of age who had acute ischaemic stroke confirmed by brain scan (magnetic resonance imaging) within seven days after symptom onset were eligible for enrolment. Patients were excluded if they were diagnosed with other cerebrovascular diseases, such as transient ischaemic attack, haemorrhagic stroke, cerebral venous sinus thrombosis, or non-cerebrovascular diseases. All patients or their legal guardians provided written informed consent before enrolment. Detailed inclusion and exclusion criteria for the hospitals and patients are provided in supplementary appendix 1.

Randomisation and blinding

Hospitals were randomly assigned in a 1:1 ratio to the CDSS intervention group or the usual care group through a random number generator. Randomisation was stratified by the hospital location (eastern, central, or western region) and hospital grade (secondary or tertiary). A confirmation letter was provided to each hospital one month before implementing the intervention. To ensure blinding to cluster assignments, follow-up data were collected by interviewers who were masked to patients' cluster assignments. Statisticians were masked to the cluster allocation.

Interventions

The stroke CDSS provided physicians with clinical decision support for ischaemic stroke.[15] The overall functions of the stroke CDSS were as follows:

- Clinical information extraction: the stroke CDSS was integrated into the health information system, electronic medical records, and picture archiving and communication system to extract clinical information, give reminders of pending examinations, and support decision making of physicians.
- AI assisted imaging analysis: the system used deep learning algorithms that automatically segment ischaemic lesions to provide infarct characteristics, such as single or multiple infarcts. This algorithm was derived from a high quality dataset that underwent standardised annotation and rigorous review, sourced from the Third China National Stroke Registry (CNSR-III).
- Classification of stroke causes: the stroke CDSS used the collected data needed to classify stroke causes and analysed the cause of ischaemic stroke based on the decision algorithm according to the criteria of the Chinese ischaemic stroke subclassification.[18]
- Treatment recommendation: the system was designed with a comprehensive decision making process and a knowledge base rooted in clinical

guidelines and high level clinical evidence for stroke diagnosis and treatment.

- Stroke performance measures: the stroke CDSS systematically evaluated the implementation of the preset stroke care performance measures. Supplementary appendix 2 gives a detailed description of the stroke CDSS.

The stroke CDSS intervention and usual care were provided in the intervention group and control group, respectively. Figure 1 shows the intervention workflow in the CDSS group during hospital admission. To ensure the stroke CDSS was used correctly, physicians in the intervention group received system training for two weeks before transitioning to the intervention phase. An adequate technical support team and project personnel ensured comprehensive training, ensuring that all investigators used the system correctly during the study. The intervention process of the stroke CDSS consisted of the following steps.

On the day of enrolment, the stroke CDSS extracted the patients' clinical information (demographics, baseline NIHSS (National Institutes of Health Stroke Scale) score, baseline modified Rankin Scale score, medical history, etc), and provided recommendations on examinations, management in hospital, and treatment during the acute phase. The recommendations included early antithrombotics, dual antiplatelet treatment, anticoagulant treatment, statin treatment, antidiabetic treatment, antihypertensive treatment, dysphagia screening, and deep venous thrombosis (DVT) prophylaxis.

After completing brain magnetic resonance imaging, the stroke CDSS automatically conducted image analysis using deep learning technology and outputting infarct pattern and infarct characteristic parameters. During hospital admission, for patients with incomplete examinations, the stroke CDSS gave reminders of relevant examinations to further clarify the stroke cause.

Based on the clinical information, examinations, and imaging features, the cause of the ischaemic stroke was classified to provide guideline based treatment recommendations for secondary prevention. The treatment recommendations were based on the clinical guidelines of cerebrovascular disease in China and referred to international guidelines, including antithrombotics, anticoagulant treatment, statin treatment, antihypertensive treatment, and antidiabetic treatment at discharge.

During hospital admission, the stroke CDSS systematically evaluated the implementation of the stroke care performance measures. The stroke CDSS recommended diagnosis and treatment for each patient enrolled in the CDSS group. Whether to adopt these recommendations or not was at the discretion of the treating physician. Patients in the control group received normal routine diagnosis and treatment based on physicians' experience and knowledge of guidelines.

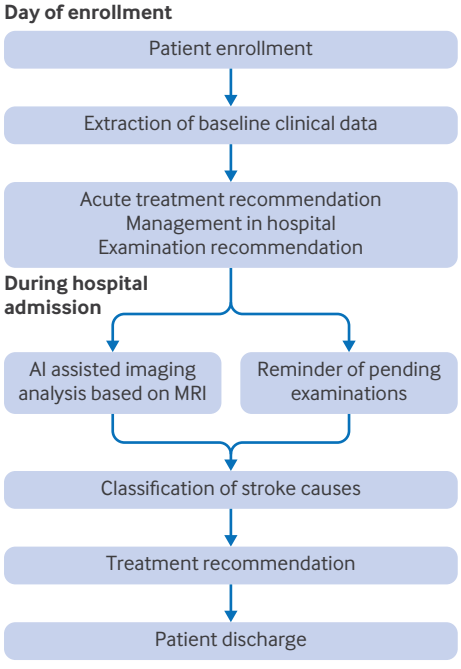

Fig 1 | The stroke clinical decision support system (CDSS) intervention workflow. AI=artificial intelligence; MRI=magnetic resonance imaging

Outcomes

The primary outcome was a new vascular event (composite of ischaemic stroke, haemorrhagic stroke, myocardial infarction, or vascular death) within three months after stroke onset.

Secondary outcomes included the composite measure and the all-or-none measure of evidence based performance measures for acute ischaemic stroke care quality. Thirteen prespecified performance measures were involved in this study, including eight acute performance measures at the beginning of hospital admission (early antithrombotics, dual antiplatelet treatment, statin treatment, anticoagulation for atrial fibrillation, antidiabetic treatment for diabetes, antihypertensive treatment for hypertension, dysphagia screening, DVT prophylaxis) and five performance measures at discharge (antithrombotics, antihypertensive treatment for hypertension, statin treatment, antidiabetic treatment for diabetes, anticoagulation for atrial fibrillation).[15 19 20]

Detailed definitions and specifications of performance measures included in this study are available in supplementary appendix 3. The composite measure was defined as the total number of performance measures performed among eligible patients divided by the total number of possible performance measures among eligible patients.[19 21] The all-or-none measure was defined as the proportion of patients who received all eligible performance measures.[22] Eligible patients were those without any contraindications (eg, treatment intolerance, allergy, serious side effects, risk of bleeding, patient or family refusal, terminal illness or comfort care only, etc).[21] Supplementary appendix 3 gives detailed contraindications for each performance measure. The secondary outcomes also included a

new vascular event at six and 12 months, disability (assessed according to mRS score of 3-6), and all cause mortality at three, six, and 12 months after stroke onset.

Safety outcomes included moderate or severe bleeding events (assessed according to the global utilisation of streptokinase and tissue plasminogen activator for occluded coronary arteries (GUSTO) definition),[23] and all bleeding events at three, six, and 12 months after stroke onset.

Data collection

During hospital admission, data were collected through the electronic data capture system by a locally trained independent research coordinator and verified by the clinical research associate. A face-to-face or telephone follow-up was conducted at three, six, and 12 months by professional and trained interviewers who were masked to the patients' cluster assignments. Each participant's address and two or more contact telephone numbers were collected to reduce loss to follow-up. An independent data safety monitoring board reviewed the safety data regularly to ensure quality.

Sample size

We assumed the rate of new vascular events at three months would be reduced to 4.7% (a relative decrease of 26% based on the results of the GOLDEN BRIDGE trial[9] compared with 6.4% reported in CNSR-III[24]).

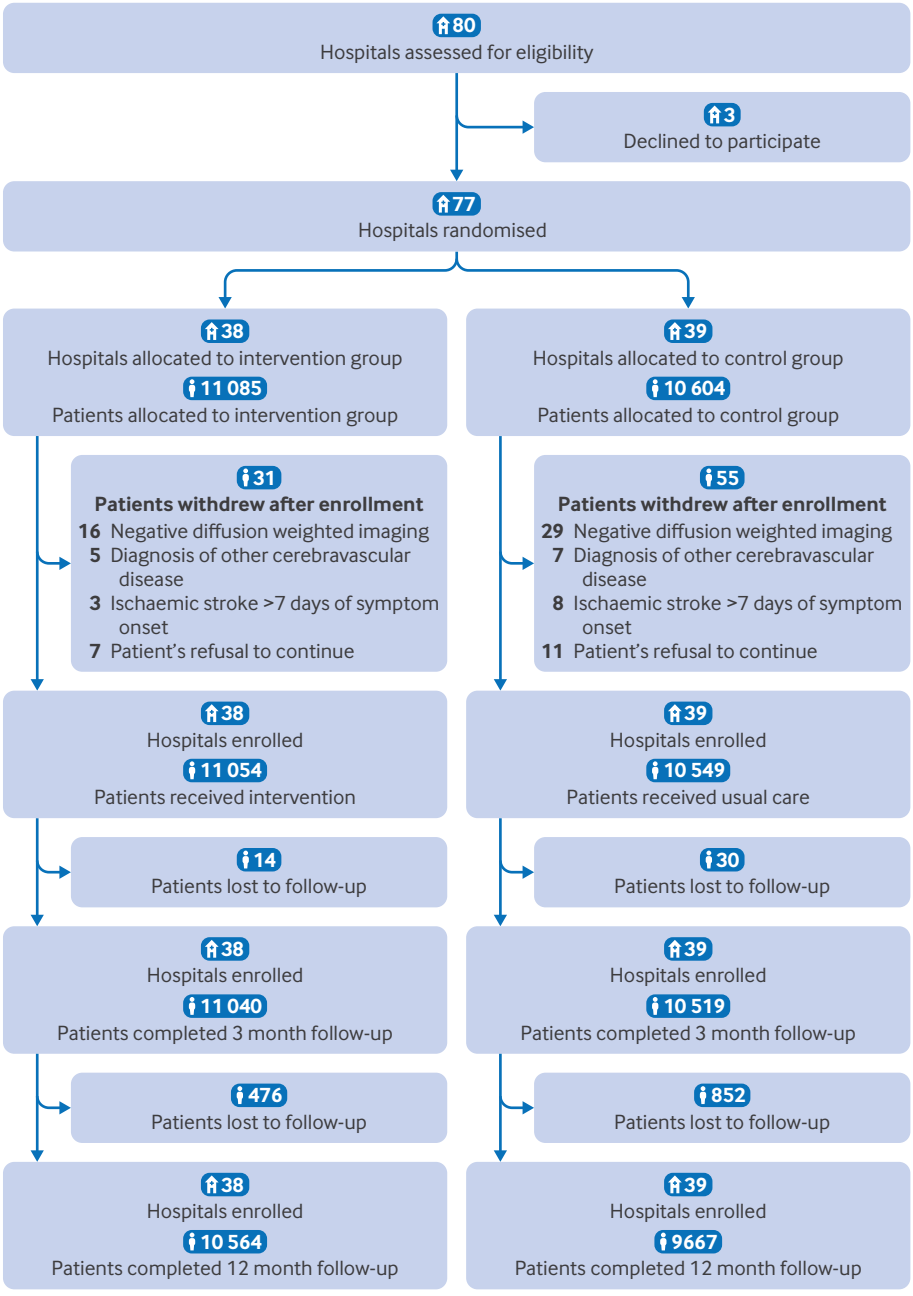

Fig 2 | Trial flowchart

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Therefore, we estimated that 21 689 participants from 80 hospitals would provide 80% power to detect a 26% relative reduction in the primary outcome, with a two sided significance level of 5%, an intraclass correlation coefficient of 0.01, and a 10% loss to follow-up.

Statistical analysis

All primary and secondary analyses were based on the intention-to-treat principle. Categorical variables are presented as numbers and percentages, while continuous variables are presented as means and standard deviations or medians with interquartile ranges. T tests or Wilcoxon rank sum tests were used for continuous variables, while χ^2 tests or Fisher's exact tests were performed for categorical variables. We conducted a cluster level analysis using weighted generalised linear regression for the primary outcome. The model was weighted by the patient number of each hospital. The primary outcome of new vascular events at three months was assessed using a mixed effects Cox regression with a random effect of hospital. The method used for the primary outcome was also used to analyse secondary outcomes of new vascular events, all cause mortality, severe or moderate bleeding, and all bleeding. We used a mixed effects linear regression model to evaluate continuous outcomes. Clinical outcomes of new vascular event, ischaemic stroke, all cause mortality, and severe or moderate bleeding are represented by Kaplan-Meier curves.

To determine whether the improvement in performance measures in the intervention group was because of better documentation of contraindications, a sensitivity analysis was performed that included patients with contraindications in the denominator.[9 25] Furthermore, all multivariable models were adjusted to account for hospital and patient characteristics in which the absolute differences between intervention and control groups were greater than 10%.[26] Additionally, we performed post hoc subgroup analyses to evaluate the heterogeneity of treatment effect based on hospital level (secondary or tertiary), hospital region (eastern, western, or central), and stroke unit. We did not make a multiple comparison adjustment for the primary outcome. All secondary analyses were interpreted to be exploratory. A P value less than 0.05 or an absolute difference more than 10% were considered statistically significant; all tests were two sided. All the analyses were performed using SAS software, version 9.4 (SAS Institute).

Patient and public involvement

We were unable to involve patients and members of the public in this study owing to lack of expertise in conducting patient and public involvement focus groups. Clinical practice neurologists will be involved in disseminating study findings to patients, members of the public, and healthcare professionals.

Results

Characteristics of hospitals and patients

After excluding three hospitals that declined to participate, 77 hospitals from 23 provinces were included and randomly assigned to the stroke CDSS intervention group (38 hospitals) and control group

Table 1 | Baseline characteristics of hospitals and patients with acute ischaemic stroke in intervention group versus control group

Characteristics	Intervention group	Control group	Absolute difference (%)
Hospital characteristics			
No of hospitals	38	39	—
Hospital grade			
Secondary	25/38 (65.8)	23/39 (59.0)	—
Tertiary	13/38 (34.2)	16/39 (41.0)	—
Region			
Eastern	11/38 (28.9)	12/39 (30.8)	—
Western	11/38 (28.9)	12/39 (30.8)	—
Central	16/38 (42.1)	15/39 (38.5)	—
Stroke unit	33/38 (86.8)	36/39 (92.3)	—
Patient characteristics			
No of patients	11 054	10 549	—
Demographics			
Age (years), median (IQR)	67 (58-74)	66 (57-74)	3.2
Men	7129 (64.5)	6796 (64.4)	0.1
Body mass index, median (IQR)	23.8 (21.8-26.0)	23.9 (21.7-26.0)	2.2
Medical history			
Stroke	2701 (24.4)	2413 (22.9)	3.7
Diabetes	2359 (21.3)	2379 (22.6)	2.9
Hypertension	6782 (61.4)	6344 (60.1)	2.5
Dyslipidaemia	149 (1.3)	252 (2.4)	7.7
CAD or previous myocardial infarction	917 (8.3)	1017 (9.6)	4.7
Atrial fibrillation	304 (2.8)	264 (2.5)	1.5
Ever smoking	3892 (35.2)	3222 (30.5)	9.9
NIHSS score at admission, median (IQR)	3 (1-5)	3 (1-5)	8.1
Prestroke mRS score ≥3	724 (6.5)	405 (3.8)	12.2

Data are numbers (%) unless stated otherwise.
CAD=coronary artery disease; mRS=modified Rankin Scale; NIHSS=National Institutes of Health Stroke Scale.

(39 hospitals). Between 13 January 2021 and 25 June 2023, 21 689 patients were prospectively enrolled. After excluding 86 patients who withdrew within one day after enrolment, 21 603 patients (11 054 in the intervention group and 10 549 in the control group) were included in the final analysis (fig 2). Among the enrolled participants, 21 559 patients (99.8%) completed the three month follow-up, and 20 231 (93.6%) completed the 12 month follow-up. Because the three month follow-up period coincided with the covid-19 pandemic, 13 474 (62.5%) patients were followed up face to face and 8085 (37.5%) by telephone.

Table 1 shows baseline characteristics of hospitals and patients. Among the participating hospitals, 62.3% were secondary hospitals and 89.6% had stroke units. Supplementary figure S1 and table S1 show the distribution of participating hospitals and the number of enrolled patients for each hospital. The median age of patients was 67 (57-74) years and 7678 (35.5%) were female. Patient characteristics were balanced between the two groups except for prestroke mRS score ≥3 (absolute difference >10%).

Primary outcome

The primary outcome of new vascular events at three months occurred in 2.9% of patients in the stroke CDSS intervention group compared with 3.9% in the control group, with adjusted hazard ratio 0.74 (95% confidence interval (CI) 0.58 to 0.93, P=0.01). The stroke CDSS intervention effect remained significant in the cluster level linear regression analysis (−0.01, 95% CI −0.02 to −0.004, P=0.003; table 2).

Supplementary table S2 shows individual new vascular events (ischaemic stroke, haemorrhagic stroke, myocardial infarction, and vascular death). Ischaemic stroke was significantly lower in the stroke CDSS intervention group at three months (2.4% *v* 3.4%, adjusted hazard ratio 0.70, 95% CI 0.54 to 0.90, P=0.006). No significant differences were found for haemorrhagic stroke, myocardial infarction, and vascular death at three months. We found no significant heterogeneity in the stroke CDSS intervention effect on the primary outcome across the subgroups (supplementary figure S2).

Secondary outcomes

Patients in the CDSS intervention group were more likely to have a higher composite measure of evidence based performance measures (91.4% *v* 89.8%, odds ratio 1.21, 95% CI 1.17 to 1.26, P<0.001). The all-or-none measure was numerically higher in the intervention group (58.8%) than in the control group (53.3%), but did not reach statistical significance (adjusted odds ratio 1.18, 95% CI 0.87 to 1.61, P=0.29; table 2).

Table 2 | Clinical outcomes in intervention group versus control group

Outcomes	Intervention group	Control group	Unadjusted hazard ratio or odds ratio (95% CI)*	Adjusted hazard ratio or odds ratio (95% CI)*†	Effect size (95% CI)	P value
Primary outcome						
New vascular events‡ at 3 months	320/11 054 (2.9)	416/10 549 (3.9)	0.75 (0.60 to 0.95)	0.74 (0.58 to 0.93)	—	0.01
Cluster level regression of primary outcome incidence§	0.03 (0.02)	0.04 (0.02)	—	—	−0.01 (−0.02 to −0.004)	0.003
Secondary outcomes						
Composite measure	77 049/84 276 (91.4)	70 794/78 834 (89.8)	1.21 (1.16 to 1.26)	1.21 (1.17 to 1.26)	—	<0.001
All-or-none measure	6504/11 054 (58.8)	5619/10 549 (53.3)	1.16 (0.85 to 1.58)	1.18 (0.87 to 1.61)	—	0.29
New vascular events‡						
6 months	379/11 054 (3.4)	503/10 549 (4.8)	0.73 (0.58 to 0.93)	0.71 (0.56 to 0.91)	—	0.006
12 months	440/11 054 (4.0)	576/10 549 (5.5)	0.75 (0.57 to 0.98)	0.73 (0.56 to 0.95)	—	0.02
Disability (mRS ≥3)						
3 months	1297/11 040 (11.8)	996/10 519 (9.5)	1.26 (1.01 to 1.58)	1.14 (0.90 to 1.44)	—	0.29
6 months	1015/10 807 (9.4)	740/10 147 (7.3)	1.31 (1.00 to 1.71)	1.18 (0.89 to 1.56)	—	0.26
12 months	841/10 557 (8.0)	663/9652 (6.9)	1.23 (0.92 to 1.66)	1.11 (0.81 to 1.52)	—	0.51
All cause mortality						
3 months	141/11 054 (1.3)	138/10 549 (1.3)	1.00 (0.66 to 1.52)	0.91 (0.60 to 1.40)	—	0.68
6 months	218/11 054 (2.0)	243/10 549(2.3)	0.86 (0.58 to 1.27)	0.79 (0.53 to 1.17)	—	0.24
12 months	335/11 054 (3.0)	372/10 549 (3.5)	0.83 (0.56 to 1.23)	0.77 (0.52 to 1.13)	—	0.18
Safety outcomes						
Severe or moderate bleeding						
3 months	32/11 054 (0.3)	32/10 549 (0.3)	0.96 (0.47 to 1.96)	0.89 (0.44 to 1.79)	—	0.74
6 months	39/11 054 (0.4)	46/10 549 (0.4)	0.84 (0.45 to 1.57)	0.79 (0.43 to 1.46)	—	0.44
12 months	49/11 054 (0.4)	51/10 549 (0.5)	0.95 (0.51 to 1.76)	0.89 (0.49 to 1.65)	—	0.72
All bleeding						
3 months	88/11 054 (0.8)	129/10 549 (1.2)	0.74 (0.44 to 1.23)	0.68 (0.41 to 1.12)	—	0.13
6 months	96/11 054 (0.9)	143/10 549 (1.4)	0.72 (0.44 to 1.17)	0.67 (0.42 to 1.07)	—	0.09
12 months	106/11 054 (1.0)	151/10 549 (1.4)	0.71 (0.44 to 1.17)	0.66 (0.41 to 1.07)	—	0.09

Data are No of events/No of patients (%).
CI=confidence interval; mRS=modified Rankin Scale.
*Hazard ratio for new vascular events, all cause mortality, severe or moderate bleeding, and all bleeding. Odds ratio for composite score, all-or-none measure, and disability.
†Adjusted for prestroke mRS.
‡New vascular events included ischaemic stroke, haemorrhagic stroke, myocardial infarction, or vascular death.
§Cluster level analysis conducted using weighted generalised linear regression. The model was weighted by patient number for each hospital.

The reduction in new vascular events persisted through longer term follow-up, with significantly lower rates in the intervention group at six months (3.4% *v* 4.8%, adjusted hazard ratio 0.71, 95% CI 0.56 to 0.91, P=0.006) and 12 months (4.0% *v* 5.5%, 0.73, 0.56 to 0.95, P=0.02). We found no significant differences in disability (mRS ≥3) at three months (11.8% *v* 9.5%, adjusted odds ratio 1.14, 95% CI 0.90 to 1.44, P=0.29), six months (9.4% *v* 7.3%, 1.18, 0.89 to 1.56, P=0.26), and 12 months (8.0% *v* 6.9%, 1.11, 0.81 to 1.52, P=0.51). No significant differences were observed in all cause mortality at three months (1.3% *v* 1.3%, adjusted hazard ratio 0.91, 95% CI 0.60 to 1.40, P=0.68), six months (2.0% *v* 2.3%, 0.79, 0.53 to 1.17, P=0.24), and 12 months (3.0% *v* 3.5%, 0.77, 0.52 to 1.13, P=0.18; table 2). Figure 3 shows the Kaplan-Meier curves of new vascular event, ischaemic stroke, all cause mortality, and severe or moderate bleeding at 12 months.

Safety outcomes

Moderate or severe bleeding events did not differ significantly between the two groups at three months (0.3% *v* 0.3%, adjusted hazard ratio 0.89, 95% CI 0.44 to 1.79, P=0.74), six months (0.4% *v* 0.4%, 0.79, 0.43 to 1.46, P=0.44), and 12 months (0.4% *v* 0.5%, 0.89, 0.49 to 1.65, P=0.72). Similarly, no significant differences were observed in all bleeding events between the two groups at three months (0.8% *v* 1.2%, adjusted hazard ratio 0.68, 95% CI 0.41 to 1.12, P=0.13), six months (0.9% *v* 1.4%, 0.67, 0.42 to 1.07, P=0.09), and 12 months (1.0% *v* 1.4%, 0.66, 0.41 to 1.07, P=0.09; table 2)

Adherence to evidence based performance measures

Table 3 shows adherence to each individual performance measure. Patients in the CDSS intervention group were more likely to have a higher

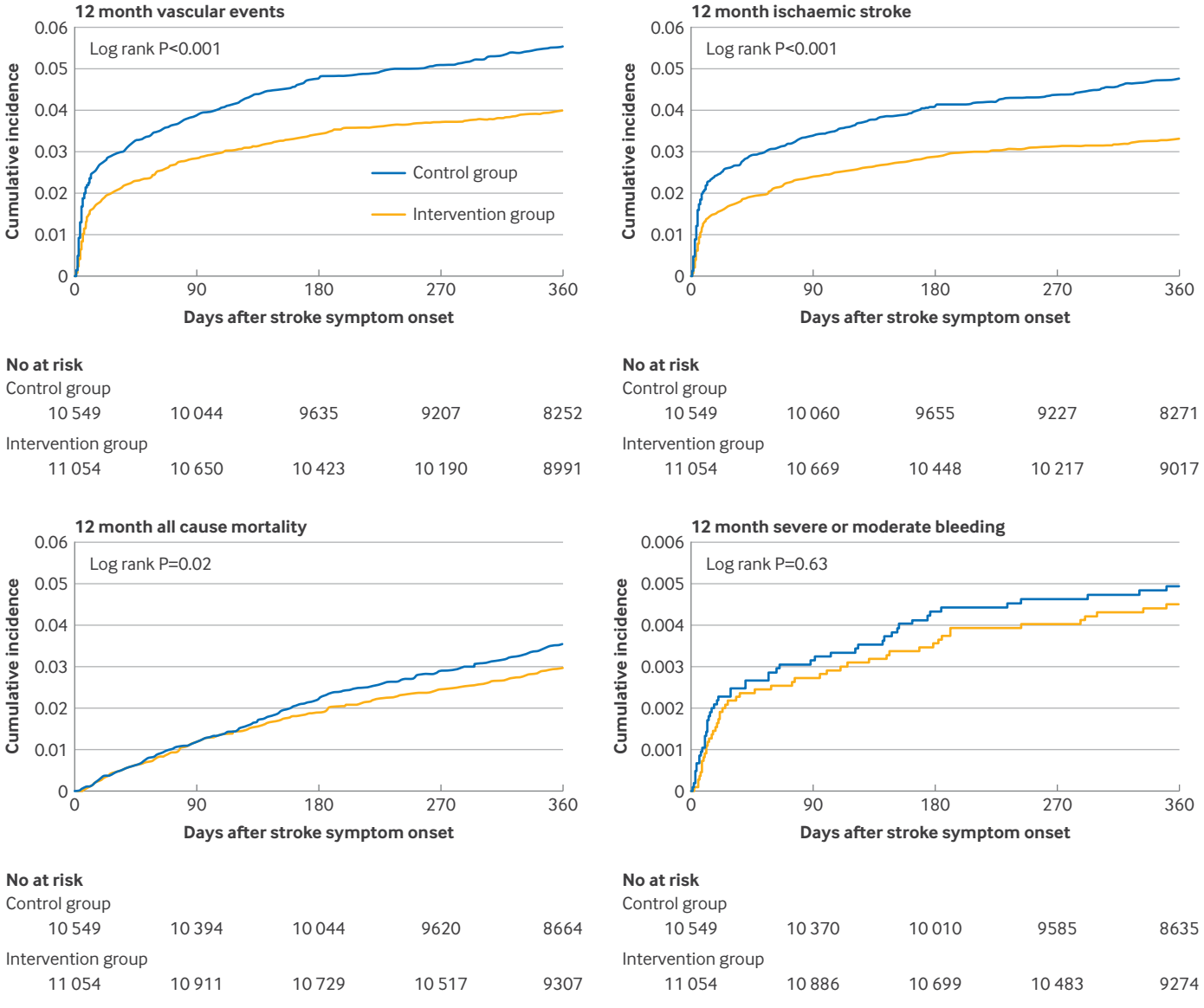

Fig 3 | Cumulative probability of 12 month outcomes

Table 3 | Evidence based performance measures for stroke care quality in intervention group versus control group.

Indicators	Intervention group	Control group	Difference (95% CI)	Absolute difference (%)
Acute performance measures				
Early antithrombotics*	8582/8735 (98.2)	8234/8361 (98.5)	0.1 (−0.3 to 0.5)	0.9
Dual antiplatelet therapy†	4249/5578 (76.2)	3139/4508 (69.6)	6.5 (4.8 to 8.3)	14.8
Statin treatment	11 012/11 040 (99.7)	10 478/10 523 (99.6)	0.2 (0.0 to 0.3)	3.0
Anticoagulation for atrial fibrillation	442/574 (77.0)	337/486 (69.3)	7.7 (2.3 to 13.0)	17.4
Antidiabetic treatment for diabetes	2727/2935 (92.9)	2654/2890 (91.8)	1.1 (−0.3 to 2.4)	4.1
Antihypertensive treatment for hypertension	6568/8096 (81.1)	6000/7645 (78.5)	2.6 (1.4 to 3.9)	6.6
Dysphagia screening	10 893/11 054 (98.5)	9625/10 549 (91.2)	7.3 (6.7 to 7.9)	33.6
Deep venous thrombosis prophylaxis	831/2240 (37.1)	486/1622 (30.0)	7.1 (4.1 to 10.1)	15.2
Discharge performance measures				
Antithrombotics	10 711/10 932 (98.0)	10 212/10 437 (97.8)	0.1 (−0.2 to 0.5)	0.9
Antihypertensive treatment for hypertension	6855/8354 (82.1)	6212/7757 (80.1)	2.0 (0.8 to 3.2)	5.0
Statin treatment	10 894/11 023 (98.8)	10 350/10 497 (98.6)	0.2 (−0.1 to 0.5)	2.0
Antidiabetic treatment for diabetes	2814/3106 (90.6)	2710/3030 (89.4)	1.2 (−0.3 to 2.7)	3.9
Anticoagulation for atrial fibrillation	471/609 (77.3)	357/529 (67.5)	9.9 (4.7 to 15.0)	22.2

Data are No of events/No of patients (%).
CI=confidence interval.
*Antithrombotic treatment prescribed within 48 hours of hospital admission.
†Dual antiplatelet therapy in patients with non-disabling ischaemic cerebrovascular disease within 24 hours of disease onset.

rate of some performance measures, including dual antiplatelet treatment in patients with non-disabling ischaemic cerebrovascular disease within 24 hours of disease onset (76.2% *v* 69.6%, absolute difference 14.8%), anticoagulation for atrial fibrillation in hospital admission (77.0% *v* 69.3%, 17.4%), dysphagia screening (98.5% *v* 91.2%, 33.6%), DVT prophylaxis (37.1% *v* 30.0%, 15.2%), and anticoagulation in patients with atrial fibrillation at discharge (77.3% *v* 67.5%, 22.2%). We found no significant differences in early antithrombotics, statin treatment, antidiabetic treatment for diabetes, or antihypertensive treatment for hypertension in the two groups. The sensitivity analysis showed similar results, which included patients with contraindications for performance measures in the denominator (supplementary table S3).

Discussion

Principal findings

In this large, cluster randomised controlled trial of 77 hospitals in China, application of the stroke CDSS led to a 25.6% decrease in new vascular events within three months in patients with acute ischaemic stroke. The stroke CDSS intervention was statistically significant in improving stroke care quality and reducing long term vascular events.

Strengths of this study

Our study showed the effectiveness of the stroke CDSS for enhancing management in hospital and improving clinical outcomes in patients with acute ischaemic stroke during hospital admission. This study has several strengths. The stroke CDSS was easy to use and has good transportability across diverse clinical settings. The CDSS was integrated into the health information system, electronic medical records, and picture archiving and communication system, which could extract patients' clinical information, analyse magnetic resonance imaging, and provide recommendations automatically. This process made the stroke CDSS well accepted to physicians without interrupting clinical practice. In our study, the stroke CDSS was successfully deployed and operated in 38 secondary and tertiary hospitals across different regions in China. We have continuously optimised the compatibility and scalability of the stroke CDSS, ensuring its transportability. The stroke CDSS applied multisource integration of examination region, imaging sequence, and scanning parameters to ensure the compatibility and standardisation of magnetic resonance imaging across hospitals. Additionally, the stroke CDSS designed a set of hierarchically decoupled and configurable interface templates to address the integration of clinical data and images from heterogeneous sources and different vendors. This design enabled efficient adaptation to different hospital information systems while maintaining a unified data representation, thereby supporting scalability, interoperability, and multicentre clinical use.

The stroke CDSS could serve as an AI based comprehensive management tool focusing on management in hospital and secondary prevention strategies. Our study identified that the stroke CDSS was effective in improving clinical outcomes. We considered the positive impact resulted from the combined effects of various system components. Firstly, AI assisted imaging analysis in the stroke CDSS provided infarction patterns that could help determine stroke cause and subsequently guide secondary prevention strategies.[27 28] For example, scattered emboli in multiple territories would suggest a cardioembolic mechanism such as atrial fibrillation; watershed distribution of lesions would suggest large vessel disease; a single lacune in a deep structure would suggest small vessel disease.[29 30] Secondly, the formulation of precise evidence based secondary prevention strategies could enhance

guideline adherence to treatment and improve patient outcomes.[31-35] In the CDSS group, a higher proportion of patients with atrial fibrillation received anticoagulants (77.0% *v* 69.3%, absolute difference >10%), and more patients received dual antiplatelet treatment (76.2% *v* 69.6%, absolute difference >10%). Thirdly, the stroke CDSS facilitated management in hospital, reminding physicians to complete necessary examinations and implement assessments. Timely management improved key stroke performance measures, which may have led to better outcomes.[9 10] On the first day of enrolment, the stroke CDSS prompted physicians to perform dysphagia screening and DVT prophylaxis assessment, which have the potential to prevent complications after stroke. In our study, the CDSS group showed higher rates of dysphagia screening (98.5% *v* 91.2%, absolute difference >10%) and DVT prophylaxis (37.1% *v* 30.0%, absolute difference >10%) than the control group.

The stroke CDSS could help improve stroke care quality. The composite measure of stroke performance measures was higher in the stroke CDSS intervention group (91.4% *v* 89.8%), as were several specific stroke medical indicators including dual antiplatelet treatment, anticoagulation for atrial fibrillation, dysphagia screening, and DVT prophylaxis. The stroke CDSS was an efficient and sustainable method to improve stroke care quality, facilitating clinical decision making, automating processes, and standardising assessments.[36] Additionally, the system might exert some influence by assisting physicians in systematically reviewing patients' data when confirming data within it. Previous studies have shown that the data registry itself can improve the quality of stroke care.[37 38] Some performance measures in the intervention group were similar to those in the control group, including early antithrombotics, statin treatment, antidiabetic treatment, and antihypertensive treatment. Our analysis indicated that the stroke CDSS improved performance measures with initially suboptimal adherence (dual antiplatelet treatment 69.6%, anticoagulation for atrial fibrillation 69.3%, and DVT prophylaxis 30.0%), but was subject to a ceiling effect when the baseline adherence to performance measures was already high (eg, early antithrombotics, statin treatment, antidiabetic treatment, antihypertensive treatment >90%).

Comparison with other studies

Over the past few years, the potential of AI technology in enhancing healthcare delivery has become increasingly evident.[39 40] Previous studies of AI in the stroke field focused on specific aspects, such as imaging diagnosis,[16 41] stroke classification,[42] or decision making tools.[43 44] Because stroke is a complex disease, we have lacked a stroke CDSS that is capable of supporting the comprehensive management of patients with stroke admitted to hospital, integrating imaging analysis, determining cause, complication management, and secondary prevention. The stroke CDSS in our study represented a successful application to improve clinical outcomes of acute ischaemic stroke and was evaluated through a randomised controlled trial.

We observed that the rate of three month vascular events in our study (3.9% in the control group) was lower than the estimated rate of 6.4%, resulting in a smaller rate difference of 1% (compared with the estimated 1.7%). However, the relative reduction in our study reached 25.6%, which was closely aligned with our initial research hypothesis of 26%. Additionally, given the increasing high incidence and disability rates of stroke,[8] the 1% decrease could carry significance in clinical practice. In the study by the TIAregistry.org Investigators, the three month stroke rate was 3.7%, which was similar to that in our study.[45] We considered the following points as possible explanations for the lower three month vascular event rate in our study. Firstly, improved adherence to stroke performance measures may have led to a decrease in the vascular event rate. The GWTG-Stroke and the GOLDEN BRIDGE-AIS showed that sustaining stroke care quality could improve outcomes and reduce event rates.[9 19] We compared performance measures between 2015 and 2021, and observed substantial improvement over time, even among the controlled sites (supplementary table S4).[46] Secondly, widespread adoption of dual antiplatelet treatment after the CHANCE and POINT trials might further reduce the vascular event rate among patients with minor stroke.[32 33 35]

We further analysed individual new vascular events at three months, showing a decrease in ischaemic stroke in the intervention group. This outcome might be attributed to improved secondary prevention in the CDSS group. Specifically, the CDSS group showed higher rates of dual antiplatelet treatment (76.2% *v* 69.6%) and anticoagulation during hospital admission (77.0% *v* 69.3%), and higher anticoagulation rates at discharge (77.3% *v* 67.5%). As shown in the CHANCE, POINT, THALES, and CATALYST trials,[32 33 35 47] appropriate use of antiplatelet and anticoagulant treatment could significantly reduce recurrent ischaemic stroke without a significant increase in moderate or severe bleeding complications. We observed a significant reduction in ischaemic events, but no differences in all cause mortality and moderate or severe bleeding events. These findings also showed the safety of the stroke CDSS.

Limitations of this study

This study has several limitations. The trial randomised hospitals rather than individual patients. Differences in care patterns and outcomes among the hospitals and subsequent outpatient care might affect these findings. Median baseline NIHSS score of enrolled patients in our study was 3 (interquartile range 1-6). Although these scores are similar to those in the large registry study in China (CNSR-III, median baseline NIHSS score 3 with interquartile range 1-6),[24] a high proportion of strokes in our study were mild. Therefore, our study might provide limited insight into the effects of the stroke CDSS on patients with severe stroke.

The stroke CDSS did not cover decision making for endovascular thrombectomy. The development of CDSS, including endovascular thrombectomy management, is encouraged in future research. Finally, our study did not include an analysis of days in hospital and hospital admission costs. A detailed cost effectiveness analysis of the stroke CDSS will be presented in future research.

Implications of the study

Our study could help to strengthen stroke management by leveraging advances in the stroke CDSS in China and in resource limited countries with a high burden of cerebrovascular diseases. Insufficient medical resources and non-adherence to guidelines have long been challenges in the Chinese stroke healthcare system.[14] Compared with resource intensive multifaceted strategies,[9] the stroke CDSS offers a more efficient and scalable method for improving stroke care and prognosis, with the added benefits of lower cost and greater sustainability.

Although the stroke CDSS successfully showed effectiveness in improving patient outcomes, further improvement in its functionality and module performance remains critical. Future research could incorporate several technologies, such as generative AI or explainable AI, to enhance the efficacy of the stroke CDSS.[40 48] Our study found that some specific measures of stroke care quality—such as DVT prophylaxis and anticoagulation for atrial fibrillation—remained inadequate despite the stroke CDSS intervention, which might be attributed to the variability in physician experience, prescribing preferences, or oversight.[14] This finding highlights a critical focus for the next phase of stroke care quality improvement initiatives in China.

Conclusions

Use of the stroke CDSS in patients with acute ischaemic stroke in China led to a significant decrease in new vascular events at three months. The system was also effective in improving stroke care quality and decreasing long term vascular events. The stroke CDSS offers a promising approach to providing high quality care for patients with acute ischaemic stroke admitted to hospital, particularly for resource constrained regions with a heavy burden of cerebrovascular diseases like China.

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Contributors: XZ, LD, JJ, and CW are joint first authors and contributed equally. XZ, LD, JJ, CW, and ZL analysed and interpreted the data and drafted the manuscript. XM, TL, XX, MX, MH, YZ, HF, PL, CD, and MW assisted in promoting the project's progress. KejD, HG, and YJ completed the statistical work. XM, HL, XG, KehD, YuX, YiW, LL, YiX, EP, GCF, LHS, XZ, ZL, and YoW conceived and designed the research. All other authors were local investigators or co-investigators and recruited participants, collected data, revised the final version of the manuscript, and critically reviewed the report and approved the final version before submission. The steering committee was responsible for the overall design, protocol development, interpretation, and supervision of the trial. The trial executive committee implemented the study. The corresponding author (ZL) acts as the guarantor for the study, had full access to all the data in the study, had final responsibility for the decision to submit for publication, and attested that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Ethical approval: This study was approved by the ethics committees of Beijing Tiantan Hospital (KY 2020-016-02) and all participating institutes in China. All participants provided informed consent.

Data sharing: The code used to analyse the data in the paper can be found in the supplementary appendix. The data underlying the study findings are openly and publicly available (https://www.ncmi.cn/

phda/dataDetails.do?id=CSTR:17970.11.A004X.202603.36.V2.0). If you encounter problems when accessing the data, please contact the corresponding author.

Transparency: The corresponding author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: The findings of this study will be disseminated to participants and the public in a press release. To increase the impact of the study, the findings will also be shared with researchers and policy makers through conferences and social media.

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Web appendix: Supplementary appendix