Artificial intelligence imaging decision support for acute stroke treatment in England: a prospective observational study

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Summary

Background Endovascular thrombectomy is a standard of care for patients with large vessel occlusion stroke. Artificial intelligence (AI) imaging software is increasingly used to support identification and selection of patients with stroke for this treatment. We aimed to evaluate the effect of AI stroke imaging software on endovascular treatment in England.

Methods This prospective observational study was undertaken with the use of data from stroke units in England's National Health Service (NHS). Data on all patients aged 16 years and older admitted to an NHS hospital with a primary diagnosis of stroke were collected through the national stroke audit registry (Sentinel Stroke National Audit Programme; SSNAP). Endovascular thrombectomy rates and interhospital transfer times were measured through SSNAP for all 107 NHS hospitals admitting patients with acute stroke in England from Jan 1, 2019, to Dec 31, 2023, before and after the systematic implementation of stroke AI software (Brainomix 360 Stroke) in 26 hospitals (six comprehensive stroke centres and 20 primary stroke centres; evaluation sites). Hospital-level data were collected for all hospitals, and patient-level data were collected at evaluation sites. The primary outcome was the proportion of patients with stroke receiving endovascular thrombectomy. Changes in endovascular treatment rates were compared for patients who were reviewed with the use of AI software for image interpretation versus those who were reviewed without AI software.

Findings 452 952 patients with stroke were admitted to 107 hospitals in England between Jan 1, 2019, and Dec 31, 2023. Patient-level data were available for 71 017 patients with ischaemic stroke who were admitted to one of the 26 evaluation sites. For evaluation sites, the pre-implementation endovascular thrombectomy rate was 2·3% (376 of 15 969 patients) and the post-implementation rate was 4·6% (751 of 15 428 patients), a relative increase of 100%. For non-evaluation sites, the pre-implementation rate was 1·6% (1431 of 88 712 patients) and the post-implementation rate was 2·6% (2410 of 89 900 patients), a relative increase of 62·5% (odds ratio [OR] for the interaction between site and time period 1·24 [95% CI 1·08–1·43]; p=0·0026). At the patient level, use of AI stroke software was associated with an increased likelihood of endovascular thrombectomy (OR 1·57 [95% CI 1·33–1·86]; p<0·0001) compared with patients for whom AI software was not used.

Interpretation Stroke AI imaging software was associated with increased endovascular thrombectomy rates across the English NHS. These results support the routine use of AI imaging software in the management of patients with stroke.

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Introduction

For patients with ischaemic stroke due to large vessel occlusion, reperfusion treatment with endovascular thrombectomy, alone or in combination with intravenous thrombolysis, can rescue potentially salvageable tissue and reduce brain damage, preventing and limiting long-term disability.[1–3] In England, nearly three-quarters of patients with stroke initially present to their nearest intravenous-thrombolysis-capable hospital, most commonly a primary stroke centre.[4] Primary stroke centres provide initial assessment, cross-sectional imaging (typically non-contrast CT and CT angiography), and intravenous thrombolysis administration if indicated, but mostly lack neuroradiology expertise and neurointerventional capability to deliver endovascular thrombectomy, which is available in comprehensive stroke centres. Timely identification of large vessel occlusion is crucial for enabling faster treatment decisions and transfer of eligible patients to a comprehensive stroke centre for endovascular thrombectomy.

Delays in patient identification and transfer lead to poorer patient outcomes or patients becoming ineligible for treatment.[5,6] In the UK, the 2024 Annual Report from the

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Research in context

Evidence before this study

Artificial intelligence (AI) software is increasingly used to support interpretation of acute stroke CT imaging and to aid identification and selection of patients who are eligible for treatment such as endovascular thrombectomy. Previous retrospective studies have validated the standalone performance of such software (eg, by comparison with the performance of expert neuroradiologists); others have shown that support from the software improves the performance of clinicians when interpreting imaging. Prospective evaluations of the real-world impact of the software on delivery of endovascular thrombectomy are limited and mostly from single centres or networks. No formal literature search was done before commencing this study.

Added value of this study

To our knowledge, this is the largest impact evaluation of stroke AI imaging software to date. It is the first to use data from across a whole country (England), where the software was implemented across multiple hospital networks (four stroke networks, comprising 26 sites), over a 5-year period. This study evaluated the effect of AI software on key patient outcomes, including rates of treatment with endovascular thrombectomy and intravenous thrombolysis, interhospital transfer times, and disability and mortality.

Implications of all the available evidence

This study supports the widespread generalisability of previous findings showing that the use of AI imaging software can increase the number of patients receiving hyperacute stroke treatments and reduce the delays in door-in door-out time at primary stroke centres between admitting a patient and transferring them to a specialised centre for endovascular thrombectomy. The evidence supports guideline recommendations for the routine use of AI imaging software in the evaluation of patients with stroke.

Sentinel Stroke National Audit Programme (SSNAP) showed that the national treatment rate for endovascular thrombectomy was 3·9%, which was lower than the European average, and far below the potential 15% of patients likely to be eligible for treatment. This report also highlighted delays in receiving specialised stroke treatment, with only 46·7% of patients with stroke being admitted to a stroke unit within 4 h of hospital admission.[7] Optimisation of stroke care workflow can improve treatment rates and reduce time from onset to treatment, leading to better clinical outcomes.[8,9] Speed of referral from primary stroke centres to comprehensive stroke centres is measured by the door-in door-out time (the time between patient arrival at a primary stroke centre and departure to a comprehensive stroke centre). However, many primary stroke centres do not have access to specialist neuroradiology expertise necessary for image interpretation, which can result in failure or delays in identifying and transferring patients with large vessel occlusion.

For **SSNAP** see https://www.strokeaudit.org

See Online for appendix

Imaging decision support software with artificial intelligence (AI) technology is advocated by stroke guidelines in the UK[10] and the USA[11] as it has been shown to improve patient identification and shorten decision making time for endovascular thrombectomy.[12,13] The mechanism by which decision support software might improve treatment rates and efficiency is multifactorial, including: confident identification and accurate quantification of ischaemia extent on non-contrast CT,[12–14] identification of large vessel occlusion on CT angiography,[15,16] and support with CT perfusion or MRI post-processing.[12,13,17,18]

We aimed to use a real-world evaluation to validate the hypothesis that use of AI software would improve access to mechanical thrombectomy, as evidenced by an increase in treatment rates. We aimed to evaluate the effect of stroke AI software implementation on the delivery of treatment (endovascular thrombectomy and intravenous thrombolysis) as well as door-in door-out times. We also assessed the effect of AI software on treatment at the individual patient level.

Methods

Study design and participants

This was a prospective observational study evaluating the clinical impact of AI imaging software in stroke units in England's National Health Service (NHS). We used data collected through the national stroke audit registry (SSNAP at King's College London, London, UK). For further details on study design and data collection, see appendix pp 1–3.

The study duration was 5 years, from Jan 1, 2019, to Dec 31, 2023, which spanned before, during, and after implementation of AI software in 26 hospitals (20 primary stroke centres and six comprehensive stroke centres; the evaluation sites) in England within four regional stroke thrombectomy networks. Brainomix 360 Stroke software was prospectively deployed for the purposes of the evaluation. Evaluation sites were selected to represent a range of network configurations in both rural and urban locations. National data from all other NHS stroke units in England, minus the evaluation sites, were used for comparison (81 non-evaluation sites).

A pre-implementation period, when no evaluation sites were using AI software, was defined as Jan 1, 2019, to Feb 29, 2020. A post-implementation period, when all evaluation sites were using AI software, was defined as Jan 1, 2022, to Feb 28, 2023.

Data were prospectively collected from NHS sites in England using registry data from SSNAP. In July, 2021, SSNAP introduced an additional data field to record at the patient level whether AI software was used to support the interpretation of the acute brain imaging. This variable was available for patients from the evaluation sites to assess the

effect of AI software use (with AI *vs* without AI) on patient outcome measures.

Pseudonymised clinical data from Jan 1, 2019, to Dec 31, 2023, were extracted from the national SSNAP dataset, which includes all patients aged 16 years or older admitted to an NHS hospital with a primary diagnosis of stroke. Individual patient-level data were available for patients within the 26 evaluation sites. The patient-level datapoints are reported in the appendix (pp 9–10). Hospital-level data were available for non-evaluation sites over the same period as for the evaluation sites. Clinical and demographic data were not available for patients from the non-evaluation sites. Patient gender was collected from SSNAP records, and was categorised as male, female, or indeterminate as per SSNAP protocol.

As a pseudonymised, mandated, national quality improvement audit and disease registry, SSNAP collects patient-level clinical data without explicit consent under Section 251 approval from the UK Health Research Authority's Confidentiality Advisory Group. The data are securely stored and shared with authorised researchers and health-care professionals for health-care improvement and research through an approvals process governed by the Healthcare Quality Improvement Partnership (HQIP; joint data controller with NHS England). Access to pseudonymised data was approved by the independent Data Access Review Group of the HQIP, which commissions SSNAP on behalf of NHS England. Ethics approval for data collection and quality improvement was not required. All analyses were conducted by the evaluation body (Health Innovation Oxford and Thames Valley, Oxford, UK) and clinical investigators independent of the device company (Brainomix, Oxford, UK). This study was reported following STROBE guidelines.

Imaging

Imaging protocols used at each hospital for patients with suspected stroke were determined locally but typically included non-contrast CT brain scans and craniocervical CT angiography. Brain CT perfusion was used predominantly in comprehensive stroke centres. Hyperacute MRI brain imaging was available to a limited extent mainly in comprehensive stroke centres. Image formatting was configured at the time of software installation to ensure the optimised image reconstructions were sent for processing on the software server according to the requirements of the manufacturer (appendix pp 2–3), in addition to the locally determined standard reconstructions that were sent to the imaging viewer.

The AI imaging software implemented for the evaluation was Brainomix 360 Stroke (version 10 or 11, upgraded prospectively as per manufacturer policy; Brainomix, Oxford, UK), including e-ASPECTS, e-CTA, and e-CTP modules. The software processed non-contrast CT, craniocervical CT angiography, or CT perfusion brain imaging from patients with suspected stroke at the time of scan acquisition.

Outcomes and statistical analysis

The primary outcome was the proportion of patients with stroke receiving endovascular thrombectomy. Monthly endovascular thrombectomy rates were calculated for evaluation and non-evaluation sites by dividing the number of patients receiving endovascular thrombectomy by the total number of patients in the SSNAP database for those sites (including patients with intracerebral haemorrhage, reflecting SSNAP reporting standards).

Endovascular thrombectomy rates at evaluation and non-evaluation sites were also calculated for pre-implementation and post-implementation time periods. The effects of site (evaluation *vs* non-evaluation) and time period (pre-implementation *vs* post-implementation) on endovascular thrombectomy delivery were tested using logistic regression.

To assess the effect of AI software use at an individual patient level after software implementation (ie, from Jan 1, 2022, onwards), data from evaluation sites were divided into patients for whom AI software was used for imaging interpretation, versus those for whom it was not. Multivariate logistic regression was used to quantify the effect of software usage on the likelihood of receiving endovascular thrombectomy. Details of the regression analysis are provided in the appendix (pp 3–4). The regression accounted for relevant clinical variables of age; gender; pre-stroke modified Rankin Scale (mRS); National Institutes of Health Stroke Scale (NIHSS) on admission; arrival time; arrival day, month, and year; site; and intravenous thrombolysis. Odds ratios (ORs; with 95% CIs) are reported for each regressor in the model, and model fit is reported using McFadden's pseudo-R^2 and area under the curve as appropriate.

As an exploratory analysis, the endovascular thrombectomy regression was repeated twice, including data from either primary stroke centres or comprehensive stroke centres only. As a sensitivity analysis, a propensity score weighting analysis was used to address confounding (see appendix p 4 for details).

For **STROBE guidelines** see https://www.strobe-statement.org/checklists/

The secondary outcome measures were the door-in door-out time for patients presenting to primary stroke centres who were transferred to a comprehensive stroke centre to receive endovascular thrombectomy; intravenous thrombolysis rates; and clinical outcomes assessed using the mRS at discharge.

Door-in door-out times were calculated by taking the time difference between the first arrival and the departure from the referring hospital. Door-in door-out times for patients for whom AI software was or was not used were compared using the Mann–Whitney test. Multivariate linear regression was performed to evaluate the association between the use of AI software and door-in door-out time (using the same variables as the endovascular thrombectomy analysis).

Intravenous thrombolysis rates for evaluation and non-evaluation sites were analysed following methods used for endovascular thrombectomy rates. The effects of site (evaluation *vs* non-evaluation) and time period

	Overall (n=71 017)	After AI implementation (n=28 670)		
		Patients reviewed with AI support (n=15 377)	Patients reviewed without AI support (n=13 293)	p value*
Median age, years†	75–79	75–79	75–79	..
Gender				<0·033
Female	33 323 (46·9%)	7051 (45·9%)	6264 (47·1%)	..
Male	37 694 (53·1%)	8326 (54·1%)	7029 (52·9%)	..
Median premorbid mRS score	1 (0–2)	0 (0–2)	1 (0–2)	<0·0001
Median onset to admission time, h*	12–16	12–16	12–16	..
Median NIHSS score at presentation	4 (2–9)	5 (2–10)	4 (2–8)	<0·0001

Data are median bin, n (%), or median (IQR). AI=artificial intelligence. mRS=modified Rankin Scale. NIHSS=National Institutes of Health Stroke Scale. *p values are for between-group comparison of with versus without AI subgroups. †Age and onset times were coded in bins rather than precise values, so the median bin is reported; IQR cannot be calculated for these variables.

Table 1: **Demographic and clinical data for patients with ischaemic stroke from evaluation sites**

(pre-implementation *vs* post-implementation) on intravenous thrombolysis delivery were tested using logistic regression. The patient-level association between AI software usage and intravenous thrombolysis after implementation (after Jan 1, 2022, at evaluation sites only) was explored by comparing the subgroup of patients reviewed with AI software versus those reviewed without AI using multivariate logistic regression, taking relevant variables into account (as listed for the endovascular thrombectomy analysis).

The association between AI software use and clinical outcomes was assessed using the mRS at discharge. Although mRS score is collected as part of SSNAP at the 6-month follow-up, poor data availability (22·6%) precluded use of this as an outcome measure. The association between AI software usage and discharge mRS score was assessed in the post-evaluation data using a Cochran–Mantel–Haenszel analysis. The mRS data were also dichotomised to explore the association between AI software use and good clinical outcomes (defined as mRS 0–2) or mortality (mRS 6) using χ^2 tests and multivariate logistic regression as described for the endovascular thrombectomy analysis.

Statistical analyses were conducted using R (version 4.4.0) and RStudio (version 2024.04.0).

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Within the hospital-level SSNAP dataset, 452 952 patients with stroke were admitted to 107 hospitals in England between Jan 1, 2019, and Dec 31, 2023. Patient-level data were available for 71 017 patients with ischaemic stroke who were admitted to one of the evaluation sites. To compare any systematic differences in patients for whom decision support software was used, a summary of demographic and clinical variables for these patients is shown in table 1. Data completeness for these variables was 97%. The distribution of time from stroke onset to admission for patients reviewed with and without AI support is shown in the appendix (p 5).

Of the 28 670 patients admitted to the evaluation sites from Jan 1, 2022, onwards (after AI software implementation), 15 377 (53·6%) were reviewed with AI support and 13 293 (46·4%) were reviewed without AI support (table 1).

The endovascular thrombectomy rates over the entire study period in evaluation and non-evaluation sites are shown in figure 1. For evaluation sites, the pre-implementation endovascular thrombectomy rate was 2·3% (376 of 15 969 patients) and the post-implementation rate was 4·6% (751 of 15 428 patients), a relative increase of 100%. For non-evaluation sites, the pre-implementation rate was 1·6% (1431 of 88 712 patients) and the post-implementation rate was 2·6% (2410 of 89 900 patients), a relative increase of 62·5%. Logistic regression showed a significantly higher likelihood of endovascular thrombectomy at evaluation versus non-evaluation sites (OR 1·46 [95% CI 1·30–1·64]; p<0·0001) and a significantly higher likelihood of endovascular thrombectomy post-implementation versus pre-implementation (OR 1·66 [1·56–1·78]; p<0·0001). The interaction between site and time period was significant (OR 1·24 [1·08–1·43]; p=0·0026), indicating a larger increase in the endovascular thrombectomy rate for the evaluation sites compared with the non-evaluation sites. The area under the curve of the model was 0·59.

As noted previously, none of the evaluation sites were using AI software in the pre-implementation period, and all of them were using AI software by the post-implementation period (0% to 100% adoption). Within the non-evaluation sites, five (6%) of 81 sites were using AI software (Brainomix 360 Stroke or an alternative software) by the end of the pre-implementation period, increasing to 56 (69%) sites by the end of the post-implementation period (appendix p 4).

The trend over time for the rate of endovascular thrombectomy with and without AI support after implementation within the 26 evaluation sites is shown in figure 2. A significantly greater proportion of patients reviewed with AI support received endovascular thrombectomy than patients reviewed without AI support (912 [5·9%] of 14 465 patients *vs* 453 [3·4%] of 12 840 patients; p<0·0001).

Multivariate logistic regression, accounting for variables that influence the likelihood of receiving endovascular thrombectomy, is shown in table 2. The OR for having an endovascular thrombectomy was 1·57 (95% CI 1·33–1·86; p<0·0001) in the group with AI support relative to the group without AI support. The overall model fit (McFadden's pseudo-R^2) was 0·320. See the appendix (p 6) for assumption checks for the regression.

In exploratory analyses, when repeating the multivariate regression with only data from the primary stroke centres, the OR for the effect of AI on endovascular thrombectomy

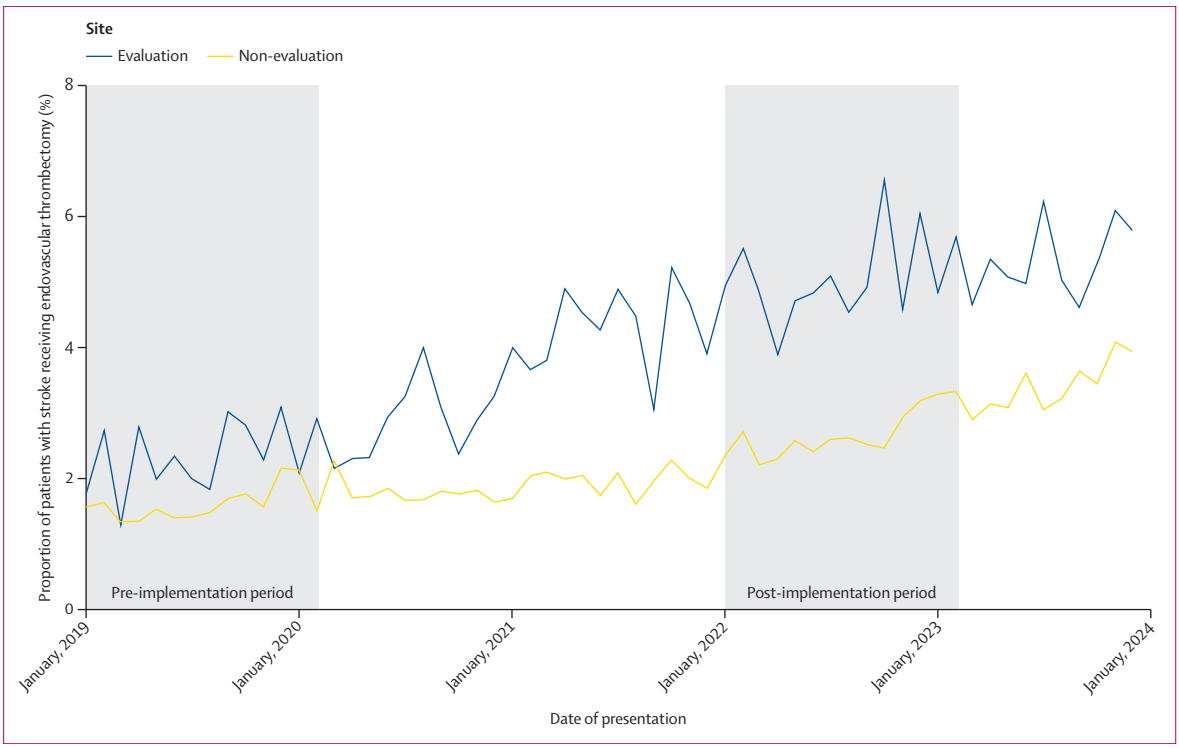

Figure 1: **Endovascular thrombectomy rates per month in the evaluation and non-evaluation sites for all patients with primary diagnosis of stroke admitted to hospitals in England**
Total patients across this time period N=452 952.

was 2·34 (95% CI 1·78–3·10; p<0·0001). For comprehensive stroke centres, the OR was smaller but still significant (OR 1·28 [95% CI 1·03–1·58]; p=0·023; appendix pp 12–13).

The sensitivity analysis using propensity score weighting created balanced groups for the measured covariates (see appendix p 7 for love plot). The weighted logistic regression analysis showed a statistically significant positive association between AI use and the odds of receiving endovascular thrombectomy (OR 1·29 [95% CI 1·05–1·58]; p=0·016). This finding remained consistent in further sensitivity analyses that used propensity score matching, alternative methods for estimating the propensity score, analyses using a subset of the covariates, and approaches incorporating trimming of extreme weights.

Door-in door-out times were available for 747 patients from the evaluation sites after implementation of AI software. Of these, 536 (72%) were reviewed with AI software and 211 (28%) were reviewed without AI software. The median door-in door-out time for patients where software was used was 128 min (IQR 96–185) compared with 192 min (119–308) when AI software was not used (Mann–Whitney test, W=74 480, p<0·0001; figure 3). Multivariate linear regression showed that AI software use was a significant predictor of shorter door-in door-out times (b=–90·84, SE 21·20 t=–4·29, p<0·0001; overall model fit R^2=0·275) after accounting for other variables (appendix p 14).

Monthly intravenous thrombolysis rates at evaluation and non-evaluation sites are shown in the appendix (pp 7–8). The intravenous thrombolysis rate was consistently higher at evaluation sites than non-evaluation sites (OR 1·60 [95% CI 1·52–1·68]; p<0·0001). There was a decrease in intravenous thrombolysis rate at both evaluation and non-evaluation sites over the course of the study (OR 0·91 [0·89–0·94]; p<0·0001). At evaluation sites, the intravenous thrombolysis rate decreased from 15·0% (2451 of 16 345) in the pre-implementation period to 13·2% (2134 of 16 179) in the post-implementation period; at non-evaluation sites, the rate decreased from 10·0% (9798 of 98 506) to 9·2% (9081 of 89 899). The time by site interaction was not significant (OR 0·94 [0·88–1·01]; p=0·09).

After implementation, patients reviewed with AI software were more likely to receive intravenous thrombolysis than patients reviewed without it (2723 [17·7%] of 15 377 versus 1191 [9·0%] of 13 293; χ^2 462; p<0·0001) in the evaluation sites. The multivariate analysis showed that the use of AI software was also a significant predictor of intravenous thrombolysis (OR 1·99 [95% CI 1·79–2·22]; p<0·0001). For full results of the multivariate analysis, see appendix p 15.

The mRS at discharge was used as a surrogate of clinical outcome. The mRS scores for the subgroups for whom decision support was or was not used are shown in the appendix (p 8). A Cochran–Mantel–Haenszel analysis showed that patients for whom AI software was used had a lower mRS score (indicating less disability) compared with patients for whom AI was not used (p<0·0001). The proportion of patients with a good outcome, defined as mRS

***Figure 2*: Endovascular thrombectomy rates per month after implementation (January, 2022, onwards) at the evaluation sites, in patients reviewed with AI imaging support (n=15 377) or without AI imaging support (n=13 293)**
AI=artificial intelligence.

0–2, was higher in those for whom AI software was used than for those reviewed without AI (7249 [47·1%] of 15 377 *vs* 7238 [45·6%] of 13 293; p=0·0073). The use of AI was associated with an OR of 1·16 (95% CI 1·07–1·25; p=0·0002; appendix p 16) for a good clinical outcome. There was no association between AI use and in-hospital mortality (mRS 6: 1610 [10·5%] of 15 377 with AI and 1399 [10·5%] of 13 293 without AI]).

Discussion

This prospective, real-world observational study showed that the use of AI imaging software for stroke was associated with a greater proportion of patients being treated with endovascular thrombectomy than those reviewed without AI software. A greater increase in endovascular thrombectomy rate was associated with AI software use when comparing before and after implementation in evaluation versus non-evaluation sites. For those patients presenting to a primary stroke centre and transferred to a comprehensive stroke centre, the median door-in door-out time was 64 min shorter when AI software was used than when it was not. The association of software use with endovascular thrombectomy was greater at primary stroke centres than at comprehensive stroke centres, consistent with the value of decision support software being greatest at sites without endovascular thrombectomy capability.[4]

This study showed the positive association between the use of AI imaging software and the effective and timely triage of patients for standard of care treatment. The results capture the effect of AI software in a real-world system and in a large, representative cohort of patients with stroke at a supra-regional level. The effects of software implementation on endovascular thrombectomy delivery rate and door-in door-out times were clinically meaningful.[19] Improved clinical outcomes at discharge were consistent with higher treatment rates and shorter times to treatment, although longer term clinical outcomes (typically used in stroke trials) were not available.

To our knowledge, this is the largest evaluation of AI software for acute stroke imaging. The observed effect across diverse networks in England is consistent with trends towards increased treatment rates and improved treatment times seen in single centre studies.[12,13,20,21] This pragmatic, real-world study evaluated the effect of the software as a whole, rather than the mechanistic contributions of its component parts, as reported elsewhere.[12–16,18,22–24] Specific benefits of software component parts might include improved clinician sensitivity and confidence when identifying large vessel occlusion through the e-CTA module,[16] or improved identification of early ischaemic change on non-contrast CT from the e-ASPECTS module.[22] It is likely that the relative contribution of the software's components will differ between hospitals and patients according to specific unmet needs.

Much of the validation of AI imaging software has focused on standalone diagnostic performance[24,25] or the effect of the software on image interpretation in a research setting.[16] Although standalone diagnostic performance studies are important and necessary for regulatory approval, they can overlook benefits that such technology provides when deployed in hospitals. In addition to supporting the speed and accuracy of non-radiologist physicians interpreting imaging, stroke AI imaging software allows the ability to share images between primary and comprehensive stroke centre teams in real time, enabling faster decision making and improving access to expert input.[20,21,26]

	Odds ratio (95% CI)	p value
Intercept	0·0000 (0·0000–0·0011)	<0·0001
AI used (yes)	1·57 (1·33–1·86)	<0·0001
Age 40–44 years	1·09 (0·64–1·84)	0·75
Age 45–49 years	0·86 (0·53–1·40)	0·54
Age 50–54 years	0·67 (0·43–1·05)	0·083
Age 55–59 years	0·75 (0·49–1·13)	0·17
Age 60–64 years	0·69 (0·46–1·04)	0·077
Age 65–69 years	0·68 (0·45–1·01)	0·058
Age 70–74 years	0·59 (0·40–0·88)	0·0090
Age 75–79 years	0·55 (0·38–0·82)	0·0027
Age 80–84 years	0·52 (0·35–0·76)	0·0010
Age 85–89 years	0·45 (0·30–0·67)	0·0001
Age ≥90 years	0·23 (0·14–0·36)	<0·0001
Gender (male)	0·83 (0·73–0·94)	0·0037
Month and year	1·0005 (1·0002–1·0008)	0·0022
Onset time (0400–0800 h)	1·98 (1·58–2·49)	<0·0001
Onset time (0801–1200 h)	1·68 (1·37–2·05)	<0·0001
Onset time (1201–1600 h)	1·39 (1·12–1·73)	0·0031
Onset time (1601–2000 h)	0·98 (0·77–1·25)	0·90
Onset time (2001–2400 h)	1·34 (1·04–1·72)	0·021
Onset day (Monday)	0·75 (0·60–0·94)	0·013
Onset day (Tuesday)	0·84 (0·67–1·05)	0·13
Onset day (Wednesday)	0·91 (0·72–1·13)	0·38
Onset day (Thursday)	0·95 (0·77–1·19)	0·67
Onset day (Saturday)	0·56 (0·44–0·71)	<0·0001
Onset day (Sunday)	0·74 (0·58–0·93)	0·010
NIHSS score at presentation	1·18 (1·17–1·19)	<0·0001
Premorbid mRS score	0·54 (0·51–0·58)	<0·0001
Thrombolysis	2·18 (1·89–2·51)	<0·0001

The overall model fit (using McFadden's pseudo-R^2) was 0·320. N=28 670. AI=artificial intelligence. mRS=modified Rankin Scale. NIHSS=National Institutes of Health Stroke Scale.

Table 2: **Multivariate logistic regression of whether a patient receives endovascular thrombectomy**

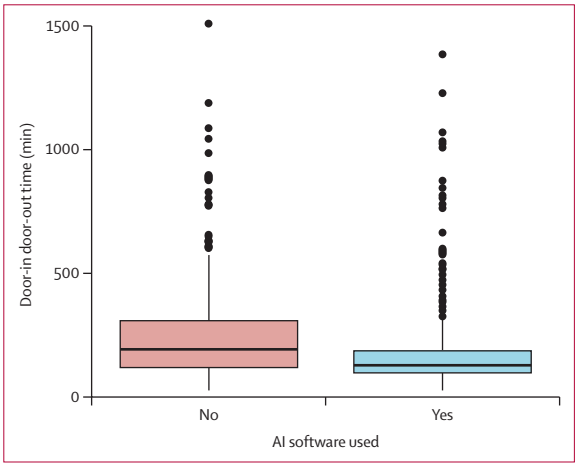

Figure 3: **Door-in door-out times in patients where AI was or was not used in image interpretation at evaluation sites after implementation**
Box and whisker plots show median (IQR) and range of values. AI=artificial intelligence.

This study showed larger improvements in treatment rates in primary stroke centres than comprehensive stroke centres, supporting the hypothesis that the greatest benefit of stroke decision support software is at centres with fewer specialist doctors, using routinely accessible imaging such as non-contrast CT and CT angiography.[27] Failure to identify and transfer eligible patients with large vessel occlusion from primary stroke centres is a barrier to timely and comprehensive access to endovascular thrombectomy: patients at primary stroke centres are 50% less likely to receive endovascular thrombectomy than patients presenting directly to comprehensive stroke centres in the UK.[4] Access to real-time specialist radiology expertise for high quality and consistent image interpretation is often limited at primary stroke centres (and out of hours at comprehensive stroke centres), but is essential for quick identification of patients eligible for treatment. The recommendation to use AI imaging software in stroke guidelines[11] is an attempt to address this unmet need. Evidence to support this recommendation has been scarce to date.[28]

Although consistent with the clinical benefits of timely access to endovascular thrombectomy for eligible patients, the improved mRS outcomes at evaluation sites should be interpreted with caution. In evaluation sites, patients for whom the software was used tended to have more severe stroke at presentation (ie, higher NIHSS) but better pre-stroke baseline function (ie, lower premorbid mRS): this difference in baseline severity is a limitation of the study. Although this was adjusted for in the regression analysis, it could have confounded the magnitude of the association of AI imaging support with likelihood of endovascular thrombectomy. Further adjustment for this difference was undertaken with the propensity score weighting analysis, in which the effect of AI software on endovascular thrombectomy remained significant. The limited availability of long-term clinical outcome data is a limitation of this study; however, the observed clinical impact at discharge is consistent with the known clinical benefits of improving access to endovascular thrombectomy.

Data were not available on why clinicians opted not to use AI software for some patients but this might have occurred when workflows required patient information to be manually sent to the AI software at the request of a physician. A clinician's unfamiliarity with the software or their confidence in interpreting the imaging might have made them disinclined to use it. This highlights the importance of optimising imaging workflows, systematic implementation to process all suspected stroke scans, and robust user training to maximise the value extracted from innovative technology in a health-care setting.

The national-level evaluation and pragmatic design of our study supports the generalisability of the results, but its observational nature presents some limitations. Treatment trends have changed over time, including expanding treatment eligibility to more severe strokes and later time windows. To address this potential confounder, we compared the association of AI with endovascular

thrombectomy in multiple ways: contemporaneous performance of non-evaluation hospitals in the same health-care setting; evaluation between patients for whom AI software was and was not used in evaluation sites over the same period; and regression analysis and propensity weighting to adjust for individual patient factors. Nonetheless, residual confounders might have affected some of the results.

In terms of generalisability, we were not able to explore the interaction of AI software use and models of care. Different effects might be observed in other models of care, for example in telestroke networks. Such studies have typically had small sample sizes, which has limited the statistical power; but the impact of AI software implementation has been positive, consistent with our results.[26,29] Furthermore, to improve treatment rates, it is necessary to have a suboptimal baseline performance, and the absolute effect of AI software might be less marked in systems of care with a higher performing baseline. This might prevent the generalisability of the results to health-care systems with very high performing baseline treatment rates.

Although our observational results cannot prove a causal relationship between AI software use and improvements in patient outcome measures, they are consistent with such a causal link. As with any digital innovation, the act of evaluation might result in changes in clinician behaviour and patient treatment that are not a direct result of the innovation under evaluation. Such confounding factors might include improved clinician awareness of patient pathways, workflow optimisation, or other concurrent pathway improvements. It is not possible to dissociate the effect of these concomitant benefits of introducing the software. It is worth noting that the COVID-19 pandemic began following the pre-implementation period of this evaluation (after February, 2020) and this might have effected endovascular thrombectomy rates.[30] However, any changes in stroke care due to COVID-19 would have systematically affected both evaluation and non-evaluation sites.

For **HQIP** see https://www.hqip.org.uk/national-programmes/accessing-ncapop-data/

As site selection was not randomised, there might have been a selection bias in the evaluation sites; however, this would not explain the patient-level effect of software use on treatment within evaluation sites. In contrast to a therapeutic intervention, hospital team engagement is a prerequisite for a digital innovation to improve patient care, and broader changes required to implement technology are difficult to separate from the intervention itself.

In the comparison between evaluation and non-evaluation sites, 69% of the non-evaluation hospitals adopted AI software independently over the course of the study. This might explain some of the increase in endovascular thrombectomy rates in non-evaluation sites. The greater effect of AI software at evaluation sites than non-evaluation sites might indicate the benefit of widespread, systematic, network-level adoption of the software.

To our knowledge, this study is the largest prospective evaluation of the effect of AI technology on clinical care in the setting of stroke. The results demonstrate a positive effect of AI support on access to endovascular thrombectomy, and support guideline recommendations that AI software should be integrated into stroke pathways.

Contributors

Conception or design of the study: GH, GAF, TM, ME, CF, MP, LF, and KN. Acquisition, analysis, or interpretation of the data: all authors. AAN, LF, and ME have directly accessed and verified the underlying data reported in the manuscript. Access to the raw data was restricted to these members of the project team, according to the terms of the SSNAP data sharing agreement. All authors drafted or reviewed the manuscript, approved the final version, and had final responsibility for the decision to submit for publication.

Declaration of interests

ZW, CF, MP, and GH are employees of and have share options in Brainomix. PB has share options in Brainomix. GAF reports receiving consulting fees from AstraZeneca for management of stroke due to intracerebral haemorrhage (payment to his employer), Bayer for a lecture on models of NHS industry working, and CSL Behring for stroke trial consultancy, and being Chief Executive of Health Innovation Oxford and Thames Valley, which has multiple joint working agreements and medical education grants with industry partners that are contracts with Oxford University Hospitals NHS Trust, the host organisation for Health Innovation Oxford and Thames Valley. KN, OS, and PM have consulting agreements with Brainomix and have received reimbursement. All other authors declare no competing interests.

Data sharing

The data for this study were obtained via a data access request to the data controller, HQIP. The data were then provided by SSNAP. The data access agreement restricts data sharing to members of the study team. Requests for data access should be directed to HQIP.

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