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TechFlash: Artificial intelligence-enabled ischemic stroke detection, triage and notification

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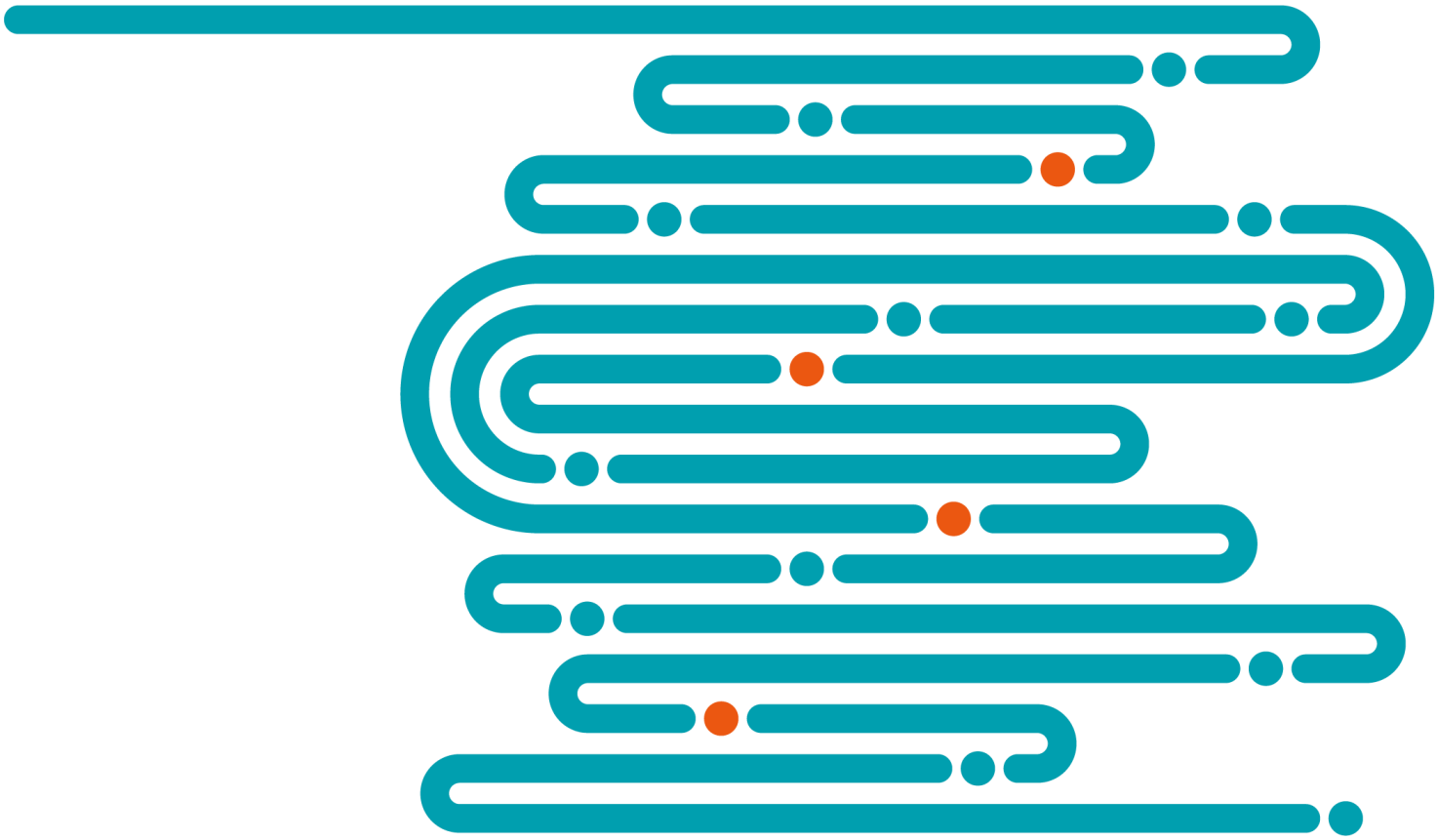

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This report comprises a review of abstracts identified through a search of the recent biomedical literature and does not constitute a comprehensive analysis. The report focus is on clinical evidence and outcomes.

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Technology overview and status

Artificial intelligence (AI) is a rapidly emerging disruptive technology with numerous applications in health care.[1-8] Acute stroke is one of the earliest targeted conditions for AI due to its time-critical evolution and imaging-driven diagnosis. Commercially available AI deep learning algorithms are well-suited to quickly analyze the computed tomography (CT) images that are used in stroke diagnosis.[9-11] Findings from the AI analysis can then be used to decrease the time to definitive diagnosis and subsequently expedite treatment. Because of the loss of viable brain tissue with each minute of delay and the narrow time window for effective therapy, the AI-based workflow paradigm could substantially improve stroke morbidity, mortality and functional outcomes.[12, 13]

Intracranial large vessel occlusions (LVOs) are the cause of many acute ischemic strokes. Because these large blood vessels supply blood flow to an extensive brain region, they are associated with large infarcts, poor functional outcomes and high mortality.[14] LVOs in the internal carotid artery (ICA) and the middle cerebral artery (MCA), however, can often be successfully treated with interventional endovascular mechanical thrombectomy to remove the clot and restore brain perfusion.[15]

Various AI systems have been developed for rapid LVO detection. These products typically acquire DICOM compliant CT angiography (CTA) images pushed to a cloud-based server for AI analysis. Scans may be processed and reformatted to ensure compatibility from a range of different scanner types and capabilities. Fully automated image analysis is then conducted using proprietary AI algorithms. Typical AI analytic times range from about one to five minutes. Results may then be distributed to a specified local user list through alerts, emails, texts and other information technology methods. Notification functions may include compressing images for mobile device viewing. Notably, this workflow is intended to run in parallel to conventional standard of care radiologic review; hence it will not completely replace human reading.

As of June 2021, there were five AI systems for LVO detection with Food and Drug Administration (FDA) marketing clearance (See Table 1). Current devices include: Viz LVO (Viz.ai, San Francisco, CA/Tel Aviv, Israel), Rapid LVO (RapidAI, Menlo Park, CA), CINA Head (Avicenna.ai, La Ciotat, France), BriefCase (Aidoc, Tel Aviv, Israel) and StrokeViewer (NiCo Lab, Amsterdam, Netherlands). A number of similar technologies are also in development (e.g., Brainomix, Oxford, England; Methinks AI, Barcelona, Spain).

The Viz.ai algorithm was the first to receive FDA clearance in February 2018 through the *de novo* process, which is an FDA pathway that can be used for certain low risk devices with no comparable previously approved predicate device.[16] Similar to a typical diagnostic device approval, the FDA reviewed performance data for sensitivity, specificity and accuracy. The technology was deemed low risk because its intended use was as a clinical decision support tool for triage able to speed up the workflow by sending a notification to the radiologist that the scan has an important finding with labeling that states it is not intended for final diagnosis beyond notification.

Once this new FDA category (product code QAS, radiological computer-assisted triage and notification software) was created, subsequent AI applications, like Aidoc and Rapid LVO, were approved through the conventional 510(k) process using Viz.ai as predicate.

In addition to LVO detection, some AI products also have separate applications for intracerebral hemorrhage (ICH) detection, CT perfusion (CTP) interpretation, Alberta stroke program early CT score (ASPECTS) estimation and other workflow related functions. Of note, there are many AI companies with a currently FDA-cleared ICH application who may be expected to expand to other stroke applications like LVO detection in the near future, including: MaxQ AI (Accipio Ix), Qure.ai (qER), Nines Inc. (NinesAI), Keya Medical (Curarad-ICH), Deep01 Ltd. (DeepCT) And Zebra Medical Vision (HealthICH).

Table 1. FDA cleared AI systems for LVO stroke diagnosis.

Manufacturer Device	FDA clearance	Clearance date
Aidoc BriefCase	K192383	12/20/2019
Avicenna.ai CINA Head	K200855	06/24/2020
NiCo Lab StrokeViewer	K200873	11/20/2020
RapidAI Rapid LVO	K200941	07/09/2020
Viz.ai Viz LVO	DEN170073	02/13/2018

Overall, the AI-assisted stroke triage and workflow platforms are in the early majority stage of dissemination and growing rapidly. The first FDA clearance was in early 2018 (~3 years ago) and Viz.ai also received a CE Mark for European sale around the same time. U.S. product commercial availability, however, did not begin until about October 2018 (~2.5 years ago). Since then, four more entrants have received marketing clearance, including one (Rapid AI) with an already established base of software users and others that have signed agreements with large imaging device companies to assist with distribution.

Further, in October 2020, the Centers for Medicare and Medicaid Services (CMS) established a new technology add-on payment (NTAP) for reimbursement that significantly contributed to more widespread technology dissemination.[17] As of May 2021, it is estimated that that these AI technologies are in use in more than 500 U.S. hospitals and they are cumulatively analyzing thousands of scans weekly.

Technology significance

Stroke is a highly prevalent and costly condition often leading to poor functional outcomes, disability and/or death. In the United States, there are about 800,000 cases of stroke each year.[18] Roughly 87% of these strokes are ischemic, while the remainder are hemorrhagic. LVOs may account for up to 40% of ischemic strokes.[14] The total direct and indirect cost burden of stroke is estimated to be more than $34 billion annually in the U.S.[18] Because of the poor clinical outcomes and high resource utilization associated with stroke, any effective technology has the potential to add significant value to the acute stroke management paradigm.[19]

In acute stroke, the timing of diagnosis and intervention is one of the most important factors correlating with outcomes.[20-25] Mechanistically, the evolution of an acute ischemic stroke involves blockage of cerebral blood flow followed by rapid death of affected neurons in a focal area known as the ischemic core. However, surrounding the ischemic core is a “penumbra” of neural tissue that may be salvageable. Notably, penumbra tissue can convert to infarct at a rate of 10.1 mL/hour.[26] Thus, minimizing permanent damage in the penumbra is the main goal of acute stroke therapy and this is facilitated by rapid initiation of treatment.

The mainstays of treatment for ischemic stroke are intravenous tissue plasminogen activator (tPA) and mechanical thrombectomy. Both have highly time-dependent outcomes. For example, one stroke workflow study noted a 91% probability of functional independence for patients with a symptom onset-to-reperfusion time of <150 minutes.[27] This functional outcome decreased by 10% over the next hour and by 20% for every subsequent hour of delay.

Delays in the stroke workflow are multifactorial. One significant source of delay may include the compilation of CT images and the reading of the images by the radiologist and/or the on-call neuroradiologist. General

radiologists may have multiple other cases, including trauma cases, that can delay reading. Off-hours, smaller hospitals, rural settings and use of fellows or residents may have their own delay issues associated with radiologist availability. The use of AI tools for initial screening could be expected to reduce some of these delays by prioritizing scan evaluation.

Further, prompt notification and mobilization of multiple personnel must be accomplished when there is a significant finding on CT. This function may fall to the emergency department (ED) physician or referring radiologist. It may be particularly difficult when the mechanical thrombectomy service is at another hospital and a transfer is necessary. Patient transfer is a well-known major source of delay with the potential for significant improvement in delay times. AI-based technologies that incorporate notification features may streamline some of the delays and inefficiencies associated with conventional notification processes.

Despite significant potential, there are also many barriers to the implementation of AI in acute stroke. These may include a lack of rigorous clinical evidence development impeding the ability of hospitals to evaluate the safety, efficacy and utility of stroke AI applications.[28] Cost, cost-effectiveness, and reimbursement are other issues typical of an emerging technology that must be resolved before more widespread dissemination. Difficulty with integration of AI into the established workflow is another potential implementation barrier.

Current practice and alternatives

Acute stroke is typically first identified through clinical symptoms, such as one-sided muscle weakness in the face or extremities and slurring of speech. Other diagnostic clues may be derived from medical history, family history, vital signs and other ED tests.

Basic non-contrast CT (NCCT) is the most widely used imaging test for stroke assessment due to its widespread availability and deployment speed. NCCT may be used to diagnose ICH and edema related to ischemia. Additional CTA of the head and neck may be used to detect LVO, dissection, stenosis and the location of the blockage. More advanced CT and MR perfusion studies are used as indicators for mechanical thrombectomy. Multimodal CT, the combination of NCCT, CTA and CTP, is a common stroke workup at comprehensive stroke centers (CSCs).[29-31] Multimodal MR imaging and conventional angiography may also be used for diagnosis and therapy selection.

When the CT imaging process is complete, it typical requires post-processing by a radiology technologist. Multimodal CT exams can result in thousands of images that need to be reviewed and this volume can itself be a source of delay.[32] The processed images are queued for the radiologist to read with the queue depending on local factors. The radiologist reports findings back to the ED physician who may initiate the referral to neurology and/or interventional neuroradiology. If mechanical thrombectomy is indicated, the neurointerventional service and staff are mobilized for the procedure.

Important metrics in the stroke workflow may include: stroke onset-to-hospital arrival, arrival-to-baseline imaging, imaging-to-notification, transfer time from a primary stroke center (PSC)-to-CSC, notification-to-groin puncture and groin puncture-to-reperfusion times. Various subintervals may also be defined within these metrics, such as door-to-needle time for thrombolytic therapy and interventional procedural times. The overall time from symptom onset-to-reperfusion may be the most critical metric to improving clinical outcomes.[27]

Multiple professional society guidelines have proposed target times for stroke process metrics. For one example, the Society of Neurointerventional Surgery (SNIS) suggests the door-to-NCCT/CTA time should occur on arrival, door-to-stroke team notification <10 minutes, door-to-NCCT interpretation <15 minutes, door-to-CTA interpretation <20 minutes or 10 minutes after acquisition, door-to-intravenous tPA <30 minutes, door-to-groin puncture <60 minutes, CSC door-to-reperfusion <90 minutes and PSC picture-to-

CSC puncture <90 minutes.[33] These times are cited as “ideal” targets that may be achieved, though benchmark metrics may differ with individual hospital considerations.

Time metrics may potentially be reduced at every stage in the workflow to achieve optimization.[34-39] For example, the pre-hospital stage can be optimized for stroke evaluation and transport to the most appropriate hospital. Further, some patients can be transferred directly from the door to the scanner with pre-loading of patient records and parallel clinical assessment. Imaging times, post-processing and review are highly dependent on local hospital resources, practices and staffing. Notification and mobilization processes may be facilitated by hospital information technology infrastructure, but may also be highly affected by staffing levels and time of day. Timing and administration of tPA, anesthesia considerations and endovascular techniques may also affect delays.

Clinical evidence summary

The Medline/PubMed bibliographic database was searched in May 2021 to identify clinical evidence related to the use of AI for LVO detection and triage. Keywords used in the literature search strategy included*: artificial intelligence, AI, machine learning, deep learning, ischemic stroke, LVO, mechanical thrombectomy* and/or various product names. Manufacturer and professional society conference websites were also searched to identify clinical evidence.

Overall, the literature search identified a large and rapidly growing body of published evidence.[40-66] Most comprised clinical validation studies providing information on technology capability and diagnostic accuracy (Level 1 and 2 evidence, see Table 2). Some small retrospective studies, pilot studies and registries have begun to demonstrate clinical utility outcomes (Level 3 and 4). There were only a few studies available studying an effect on patient outcomes (Level 5) and there were no published randomized controlled trials (RCTs) identified.

Table 2. Hierarchy of clinical evidence for diagnostic technology.[67]

Level of Evidence	Outcomes
1. Technical capability	Performability, timing, interpretability
2. Diagnostic efficacy	Sensitivity, specificity, AUC
3. Diagnostic impact	Effects on ability to make diagnosis
4. Therapeutic impact	Effects on choice of therapy
5. Patient outcomes	Clinical value of test, morbidity, mortality
6. Societal outcomes	Cost-benefit

Evidence was available for eight different technologies, including: Viz.ai, RapidAI, Avicenna, NiCo Lab, Aidoc, Brainomix, Methinks and research platforms. The various technologies had an evidence base ranging from a few pivotal studies to dozens of published clinical trials. The most evidence pertained to Viz.ai (>12 identified studies), followed by RapidAI (>6 studies). The other technologies had only one or two clinical validation type studies. Typical of an emerging technology, some of the identified studies were available only as pre-publications and abstracts presented at conferences and these are a weak form of evidence for decision-making.

A 2020 systematic literature review on the use of AI for acute ischemic stroke and LVO detection analyzed 20 relevant studies.[52] The most common algorithmic approach to LVO detection was noted to be the

convolutional neural net (CNN) and CNNs had higher overall sensitivity for LVO detection compared to other machine learning approaches (85% vs. 68%). Wide variation between different approaches was noted in this review, but direct comparative studies were not available for rigorous comparison. Of note, another systematic literature review is underway that may help to better define AI diagnostic performance when it becomes available.[68]

Viz.ai clinical evidence

As part of the FDA approval process for Viz LVO, performance data for was submitted for sensitivity, specificity and accuracy from a study of CT scans in 300 patients.[69] Sensitivity and specificity for detection of LVO were reportedly 87.8% and 89.6% and the area under the curve (AUC) from the receiver operating characteristic (ROC) analysis was 0.91. Subsequent manufacturer-sponsored larger studies (ALADIN and DISTINCTION) have further corroborated these results. In the ALADIN study, 750 acute ischemic stroke patients were retrospectively enrolled from three comprehensive stroke centers.[56] AI interpretation demonstrated a 92% sensitivity and 90% specificity for detection of LVO. Notably, changes have periodically been made to update the CNN software (e.g., ver. 3.04 versus ver. 4.1.2) and the newer versions have been used to reanalyze the cohort with reportedly improved accuracy results.[42, 43]

In a recent “real world” type study, 1,167 total CTAs and 404 stroke protocol CTAs at a CSC were analyzed using Viz.[59] LVO was eventually diagnosed in 72/404 (17.8%) and 59 of these were correctly identified by the algorithm. The reported sensitivity was 82%, negative predictive value was 96% and overall accuracy was 89%. Another large retrospective real-world study of 2,544 patients at 139 hospitals identified 163 true LVOs.[48] For these cases, Viz LVO demonstrated a sensitivity of 96.3% and a specificity of 93.8%.

Another retrospective single-center study of their first 100 LVO alert patients analyzed with Viz noted 68 true positives, of which Viz correctly identified 45 (66.2%) and missed 23 (33.8%).[47] The majority of missed diagnoses were reportedly for LVOs in the posterior circulation. Overall reported sensitivity was 66%, specificity was 91%, positive predictive value was 45% and negative predictive value was 96%. These data suggest high value as a rule out test, but there may be some added burden associated with false positives.

Timing is an important intermediate outcome noted in many studies. In the Viz LVO studies, reported typical run times for the algorithm are about 3 minutes and the average imaging-to-notification time is about 6 to 7 minutes for the AI workflow.

Comparative timing studies have typically used a before-and-after design. Notably, comparative times are highly dependent on local factors and practices. One group noted the median door-to-puncture time was 20 minutes shorter in the post-Viz cohort and the door-to-neuroendovascular team notification was 15 minutes shorter with less variability.[50, 51]

In a hub-and-spoke model, another group noted the time interval between CTA at a PSC-to-door in at the CSC was 22.5 minutes shorter (132.5 min versus 110 min; $P = 0.047$).[49] In another analysis, they reported the door in-to-door out time interval within the PSC improved by 102.3 minutes (226.7 versus 124.4 minutes; $P = 0.037$).[65] Further, they reported Viz LVO improved the mean door in-to-groin puncture time within the CSC by 86.7 minutes (206.6 vs 119.9 minutes; $p < 0.0001$).[66] Preliminary data from these studies suggest there may be associated improvements in patient outcomes, like recanalization rates, NIH stroke scale score (NIHSS) and modified Rankin score (mRS) at discharge and 90-days.

RapidAI clinical evidence

In a study comprising 217 CTAs (109 with LVO) compiled from multiple sources, the RapidAI algorithm demonstrated a sensitivity of 96%, specificity of 98% and AUC of 99%.[45] Another larger accuracy study compiled 926 CTAs from different sources.[41] Anterior circulation LVO was present in 395 patients. Sensitivity and specificity for anterior LVO detection were 97% and 74%, respectively. The accuracy when

M2 MCA occlusions were included in the analysis showed a sensitivity of 95% and specificity was 79%. The AUC for ICA was 0.997, M1 MCA AUC was 0.962 and M2 MCA AUC was 0.874.

In a real-world single-center case series, 477 consecutive CTAs with 106 LVOs were analyzed.[61] Sensitivity for LVO detection was 94%, specificity was 76% and negative predictive value 98%. Another real-world independently-conducted study reported on 151 consecutive acute ischemic stroke patients processed by Rapid LVO.[54] The reported sensitivity was 63.6% and specificity was 85.8% for LVO detection. This accuracy was noted to be lower than that previously reported and potentially attributable to differences in imaging hardware, software versions and patient mix. In particular, a low sensitivity was noted for more distal MCA occlusions.

Timing outcomes showed a mean processing and notification of about 3 minutes in one study, ~2.5 minutes in another and ~18 minutes in a different study.[45, 54, 61] Use of the Rapid Mobile App for notification was reported to reduce the door-to-groin puncture time by about 33 minutes in a 33 patient study.[40] NIHSS at discharge was also reportedly lower in the post-app group. In a one-year cumulative single-site experience with the Rapid CTA product, imaging-to-groin puncture time was reportedly reduced by about 25 minutes (93 minutes vs. 68 minutes; $P<0.05$).[60] The 90-day mRS score and functional independence showed a trend toward better outcomes in the AI treated group.

Other device clinical evidence

A CNN algorithm developed by Aidoc reported a sensitivity of 87.6% and specificity of 91.0% with overall accuracy of 89.3% for detecting LVO and sensitivity of a sensitivity of 92.3% and specificity of 94.9% for identifying the site of occlusion.[63]

A CNN algorithm from NiCo Lab reported LVO detection sensitivity of 86% and specificity of 65%.[58]

The Avicenna algorithm reported an accuracy of 98.1%, sensitivity of 98.1% and specificity of 98.2% for LVO detection.[62]

The Canon AutoStroke platform reported sensitivity of 90% and accuracy of 95% for detection of ICA occlusion and sensitivity of 77% and accuracy of 89% for detection of M1 MCA occlusion.[55]

The Brainomix e-CTA algorithm reported sensitivity of 84% and specificity of 96% for detection of LVOs.[64]

The Methinks algorithm reported an AUC of 0.87, sensitivity of 83%, specificity of 71%, positive predictive value of 79% and negative predictive value of 76%.[53] Accuracy reportedly improved when the NIHSS score and time-from-onset were added to the model.

Financial issues

Stroke AI algorithms can be acquired individually or as part of a comprehensive platform, including different apps for LVO, CTA, CTP, ASPECTS, ICH, mobile notification, etc. Costs are typically subscription based with an annual fee (e.g., $25,000/year per hospital). The actual rate may vary with hospital size and other factors. Usage cost per patient may then be calculated from the number of stroke protocol scans conducted per year. In a cost estimate submitted by Viz.ai to CMS, they estimated an average cost of $1,600/patient based on customer data.[70] Other pricing models may charge a set fee for each scan analyzed.

Reimbursement for CMS patients undergoing AI LVO analysis is available through the New Technology Add-on Payment program as of October 1, 2020.[70] Eligible cases are identified using the ICD-10-PCS procedure code 4A03x5D. Under NTAP reimbursement rules, CMS will pay more for Medicare patients who end up as inpatients when their cost of care exceeds the standard DRG payment.[71] The NTAP payment rate

is set at 65% of the cost of either the technology or the excess DRG cost (whichever is lower) and is capped at a maximum of $1,040/case.

In one example, a hospital noted that not all ischemic stroke scans are read with AI, only about 50% of their stroke cases were Medicare eligible and <50% of these cases exceeded the DRG; therefore < 25% of cases using the technology could be eligible for up to $1,040 extra reimbursement.[17] Further, the reimbursement rate may not always reach the $1,040 maximum rate.

The NTAP was initially granted to Viz.ai technology after they demonstrated it met the criteria of newness, added cost and clinical efficacy. Since then, multiple companies (including RapidAI, Avicenna, and Aidoc) have claimed substantial similarity to the Viz.ai technology to qualify for the NTAP add-on payment.[72] Substantial similarity is based on similar mechanism of action, indications and DRGs. CMS is expected to reconsider NTAP rates and eligibility on an annual basis; hence, it could be significantly different or gone altogether for fiscal year 2022.

In addition to incremental reimbursement, AI algorithms may drive revenue growth by increasing the number of mechanical thrombectomies performed due to missed or delayed LVO detection. Thrombectomy is billed under MS-DRG 23 and 24 with an average CMS reimbursement rate of about $28,100. Notably, the CMS interventional reimbursement rate is approximately twice the average payment for stroke thrombolytic therapy (MS-DRGs 61-63). In addition, eligible patients not receiving mechanical thrombectomy are more likely to have worse outcomes with costs that exceed reimbursement rates.

Cost-effectiveness of mechanical thrombectomy, however, may depend on offsetting the incremental procedural costs (e.g., stent retrievers, guidewires, catheters, sedation/anesthesia, overhead and supplies) through better functional outcomes and subsequent savings in both acute and long-term costs.[73] The former could include significantly reduced hospital and ICU LOS. Further, better functional outcomes such as that represented by an mRS ≤ 2 represents a significant gain in quality-of-life that favorably affects cost-effectiveness calculations. Overall, cost-benefit models of mechanical endovascular therapies suggest potentially favorable incremental cost-effectiveness ratios (ICERs) can be achieved based on improved functional outcomes despite added upfront costs.[74-76]

Patient selection criteria

Since detection and rapid triage of potential acute ischemic stroke is the main purpose of these AI technologies, usage may include all patients where stroke is included in the differential diagnosis after stroke protocol assessment in the ED. Further criteria may be dictated by the availability of the appropriate imaging scan, such as CTA, the potential for successful stroke treatment and personal/family directives. As the technology matures, more data on risk-benefit and cost-benefit may help to better define appropriate usage criteria.

If LVO is detected by the algorithm, patient selection criteria for mechanical thrombectomy may be derived from professional society guidelines.[19, 77] Criteria may include consideration of pre-existing patient characteristics, such as pre-stroke disability, life expectancy and co-morbidities predisposing the patient to procedural complications. Neurological analysis of the amount and severity of brain injury, clot characteristics, collateral blood flow pattern and probability of successful recanalization should also be considered in criteria.

Time from symptom onset is an important consideration, with the strongest recommendations for eligible patients within 6 hours of symptom onset and reasonable consideration in patients up to 24 hours after onset when meeting pivotal trial criteria. Similarly, strong recommendations include occlusions in the ICA and M1 segment of the MCA, with weaker recommendations for M2 and M3 MCA occlusions.

Future developments

AI is a rapidly emerging technology with expansion into many areas of radiology and stroke. Its rapid evolution is due to many factors, including faster and more powerful computer hardware, advances in cloud computing, fine-tuning of existing deep learning algorithms and larger data sets used for training algorithms. All of these factors are expected to continue with rapid progress in the years ahead leading to enhancement of existing applications.

The next phase in the evolution of AI stroke applications is already underway. This phase involves developing clinical proof of safety and efficacy through rigorous clinical trials. Clinical trials have begun to move beyond proof of technical performance and accuracy in contrived cohorts ("in silico" analysis) and into real-world studies of patient outcomes and cost-benefit. Full publication of the clinical data now being presented at conferences can be expected in the near future and many new studies will also become available. Because of rapid developments in the field, efforts should be made to update the literature search to account for new clinical evidence.

Summary and recommendations

The following conclusions and recommendations are based on the material presented in this report:

- Acute ischemic stroke is a high-value focus area for hospital performance improvement. Stroke is highly prevalent, costly, and associated with significant patient morbidity, mortality and reduced quality-of-life. It is well established that quicker detection and intervention is one of the most important factors correlating with acute stroke outcomes. Currently available AI technology is intended to speed up the detection and notification process and therefore may significantly improve patient outcomes.
- Dozens of companies worldwide are developing AI-related tools for stroke. These tools can detect stroke types, like LVO and ICH, automatically locate and outline disease segments, calculate involved volumes, tissue viability and progression, automate classification algorithms and facilitate the use of more advanced imaging modalities and techniques. AI tools can improve the stroke workflow by managing the radiology queue, expediting review of serious cases, assisting the radiologist ability to read and quantify scans and facilitate readings in scenarios with limited availability of a neuroradiologist.
- In the last few years, 5 companies have received FDA marketing clearance for computer-assisted LVO triage and notification applications. Many new companies, including start-ups and established large imaging device companies, are expected to enter into the marketplace in the near future. Hundreds of hospitals have reportedly adopted AI tools for LVO stroke detection and rapid growth is ongoing.
- Generally, the clinical evidence for AI-assisted LVO detection has reported high diagnostic accuracy, sensitivity and specificity. Some studies have noted results similar to or better than human readings. Though further studies are needed to corroborate and expand on these results, these provide a significant proof-of-concept base for AI in the management of LVO stroke.
- LVO detection algorithms are typically designed to achieve high sensitivity and negative predictive value to rule out LVO stroke that might benefit from rapid notification. Specificity may be somewhat lower secondary to false positives that result in a rapid human review. Due to inaccuracies, the parallel conventional review process by a human radiologist remains a critical step in the workflow.

- The biggest advantage associated with these AI products is time savings. Published clinical utility studies have consistently shown reduced time metrics, like door in-to-transfer, imaging-to-notification and imaging-to-groin puncture times. The magnitude of these time reductions, however, will depend on unique health system and hospital resources and practices. Though intuitive, rigorous proof of an effect on patient outcomes is still limited and more studies are needed to quantify functional improvements and resource utilization savings.
- CMS NTAP reimbursement for FY2021 was a significant factor facilitating the adoption of this new technology. Under the CMS paradigm, a proportion of Medicare covered patients may be eligible for reimbursement of up to $1,040 to offset the incremental technology cost. Hospitals using AI are also reporting significantly higher rates of mechanical thrombectomy and associated revenue. Hospital's should conduct their own financial analyses using their unique patient and payer mix to determine financial viability.
- AI algorithms are a medical technology used in the clinical care paradigm, hence should be reviewed through hospital processes and committees equipped to evaluate innovative new technology. Deliberative processes should include consideration of the clinical evidence, financial issues and overall hospital strategic plan. Hospitals implementing AI at this early stage may experience many barriers and implementation challenges.
- AI is a rapidly growing field expected to disrupt and transform many of the current processes for stroke management within the next 5 to 10 years. Because of this, hospitals and health systems should be actively involved in learning about the technology, applications, evidence and economics. Where warranted, hospitals should proactively implement AI technologies as a strategy to maintain current and future market competitiveness.

Related links

Manufacturer web pages: Viz.ai, RapidAI, Avicenna.ai, Aidoc, NiCo Lab, Brainomix, Methinks AI, MaxQ AI, Qure.ai, Nines Inc. , Keya Medical, Deep01 Ltd., Zebra Medical Vision

FDA documents: product code QAS

CMS NTAP descriptions: Federal Register Vol. 85, No.182, Healthcare blog, Healthimaging article

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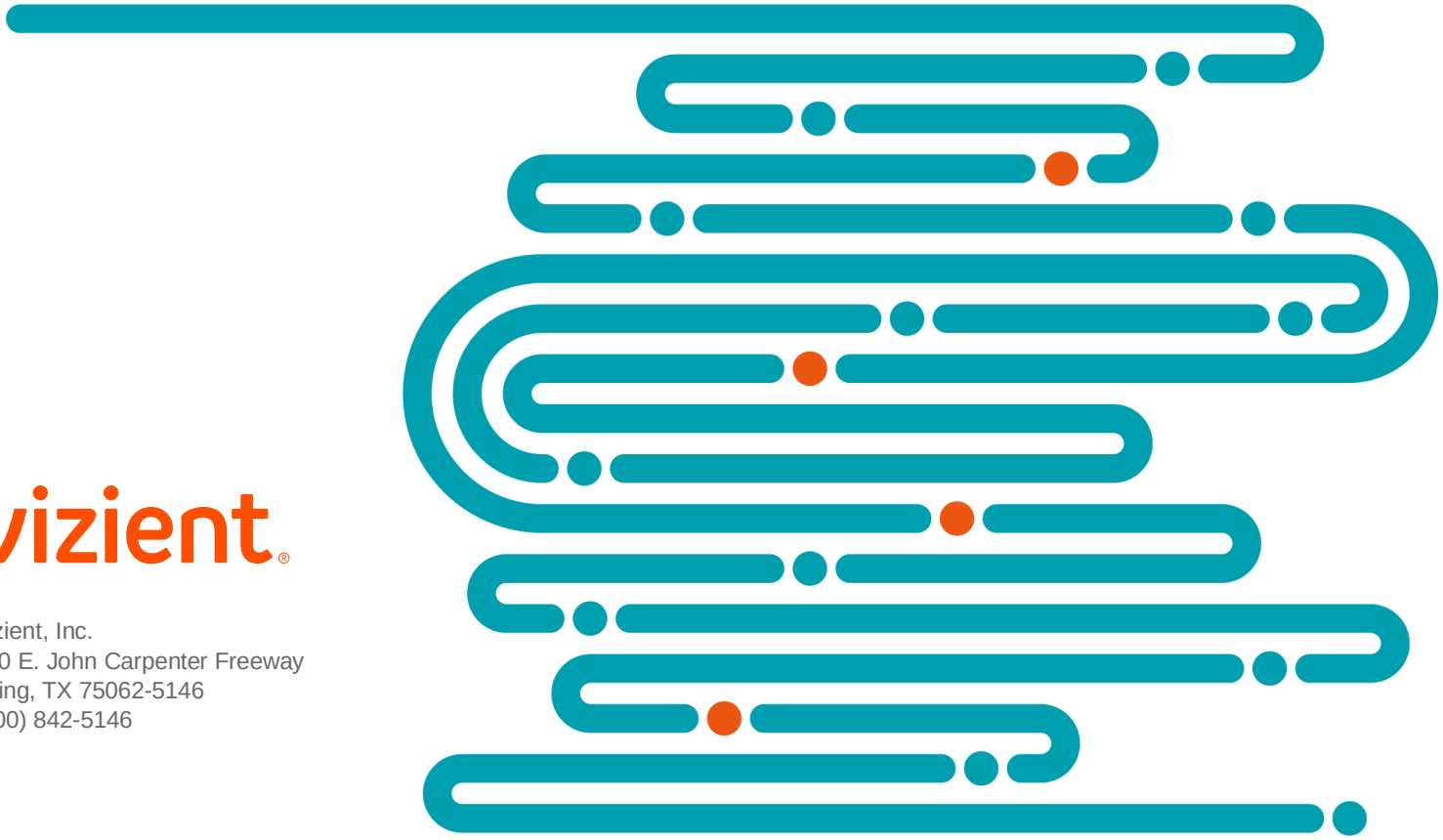

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