**Chosen Clinical AI Tool: Aidoc (stroke package / BriefCase)**Zhenyu Zhang (z5037788)

**Brief Description:**

Aidoc's CT stroke package is an AI-powered diagnostic tool designed to detect and prioritize cases of acute intracranial hemorrhage and vessel occlusion (LVO and MEVO) in CT scans. Aidoc's software integrates seamlessly with existing hospital imaging systems, providing real-time alerts to radiologists and medical teams. This facilitates prompt diagnosis and treatment, which is critical in acute stroke care. The company reports having 17 FDA-cleared algorithms in radiology across various pathologies, indicating a broad and robust application of their AI technology.

**Use and Impact:**

Aidoc’s CT Stroke is primarily used in emergency departments and radiology units to enhance the workflow of stroke diagnosis. The tool's real-time analysis and alert system allow for the rapid identification of critical cases, ensuring that patients receive timely intervention. This not only improves patient outcomes by reducing the time to treatment but also optimizes the use of healthcare resources by streamlining the diagnostic process.

* Improved Detection Rates: Aidoc’s AI significantly increased the detection of ICH by 12.2% in emergency settings, particularly enhancing off-hour diagnostics where discrepancies are more common.
* Enhanced Triage and Prioritization: The AI algorithm facilitated faster triage and prioritization, reducing radiology turnaround times and expediting patient care, crucial for conditions requiring timely interventions.
* Clinical Outcome Improvement: Implementing Aidoc’s AI in emergency departments led to a significant reduction in 30- and 120-day all-cause mortality and morbidity for ICH patients, demonstrating its clinical value in improving patient outcomes.

**Performance:**

Clinical studies have demonstrated that Aidoc’s CT Stroke tool has high sensitivity and specificity in detecting acute intracranial hemorrhage and LVO. These performance metrics underscore the tool’s reliability in a clinical setting, making it a valuable asset in emergency and radiology departments for improving stroke diagnosis and management.

Study 1: "The impact on clinical outcomes after 1 year of implementation of an artificial intelligence solution for the detection of intracranial hemorrhage"

This retrospective cohort study assessed the impact of implementing Aidoc’s AI solution for detecting intracranial hemorrhage (ICH) in a level 1 trauma center over two periods: pre-AI (1.1.2017–1.1.2018) and post-AI (1.1.2019–1.1.2020). The study involved 587 consecutive patients with confirmed ICH on head CT scans upon admission to the emergency department. Key findings included:

* Mortality Reduction: The study observed a significant reduction in 30- and 120-day all-cause mortality in the post-AI group compared to the pre-AI group (30-day: 27.7% vs. 17.5%, p = 0.004; 120-day: 31.8% vs. 21.7%, p = 0.017).
* Improved Neurologic Outcomes: The Modified Rankin Scale (mRS) for neurologic disability at discharge was significantly reduced post-AI implementation (3.2 vs. 2.8; p = 0.044), indicating improved neurologic outcomes.

Conclusion: The implementation of Aidoc’s AI solution significantly reduced both short-term (30-day) and medium-term (120-day) mortality rates, as well as morbidity among patients with ICH, demonstrating the clinical value of AI in emergency care settings.

Study 2: "A prospective randomized clinical trial for measuring radiology study reporting time on Artificial Intelligence-based detection of intracranial hemorrhage in emergent care head CT"

This prospective randomized clinical trial evaluated the effect of AI-based detection of ICH on radiology study turnaround time (TAT) in a large academic hospital. The study involved 620 consecutive non-contrast head CT scans from emergency and inpatient settings, analyzed using Aidoc’s AI software. Key findings included:

* Reduced Turnaround Time: The TAT for cases flagged by AI as positive for ICH (ICH-AI+) was significantly lower than for non-flagged cases (flagged: 73 ± 143 min vs. non-flagged: 132 ± 193 min; p < 0.05).
* High Diagnostic Accuracy: The AI demonstrated high sensitivity, specificity, and accuracy in detecting ICH (sensitivity: 95.0%, specificity: 96.7%, accuracy: 96.4%).

Conclusion: The use of Aidoc’s AI for the automatic identification of ICH significantly reduced the radiology study TAT, potentially expediting therapeutic interventions and improving patient management in emergent care settings..

**Technical Infrastructure (information find in AWS case-study in 2019):**

Aidoc uses Amazon Web Services (AWS) for its technical infrastructure:

- Amazon Elastic Compute Cloud (Amazon EC2) P3 instances are used to train machine learning (ML) models and execute inference processes.

- Amazon Simple Storage Service (Amazon S3) stores anonymized medical imagery for analysis.

- Amazon Relational Database Service (Amazon RDS) stores image metadata.

**References:**

1. FDA Approval:

Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices. (May 13, 2024 update). [FDA](<https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>)

Include Automated Radiological Image Processing Software and Radiological Computer-Assisted Triage and Notification Software

-module for the triage of Large-Vessel Occlusion (LVO) in head CTA scans

-module for Intracranial hemorrhage

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices | FDA | | | | | |
| **Date of Final Decision** | **Submission Number** | **Device** | **Company** | **Panel (Lead)** | **Primary Product Code** |
| 11/28/2023 | [K231631](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K231631) | BriefCase-Quantification | Aidoc Medical, Ltd. | Radiology | JAK |
| 11/13/2023 | [K232083](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K232083) | BriefCase-Quantification | Aidoc Medical, Ltd. | Radiology | QIH |
| 11/08/2023 | [K230534](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K230534) | BriefCase-Quantification | Aidoc Medical, Ltd. | Radiology | QIH |
| 10/30/2023 | [K232751](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K232751) | BriefCase-Triage | Aidoc Medical, Ltd. | Radiology | QAS |
| 02/01/2023 | [K230020](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K230020) | BriefCase | Aidoc Medical, Ltd. | Radiology | QFM |
| 12/05/2022 | [K222692](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K222692) | BriefCase | Aidoc Medical, Ltd. | Radiology | QFM |
| 11/18/2022 | [K221330](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K221330) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 10/07/2022 | [K220709](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K220709) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 09/28/2022 | [K222329](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K222329) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 08/26/2022 | [K222277](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K222277) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 06/03/2022 | [K221314](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K221314) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 05/17/2022 | [K221240](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K221240) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 04/26/2022 | [K213886](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K213886) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 03/21/2022 | [K213721](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K213721) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 03/14/2022 | [K214043](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K214043) | BriefCase | Aidoc Medical, Ltd. | Radiology | QFM |
| 04/14/2021 | [K202992](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202992) | BriefCase, RIB Fractures Triage (RibFx) | Aidoc Medical, Ltd. | Radiology | QFM |
| 12/29/2020 | [K203508](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K203508) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 08/26/2020 | [K201020](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K201020) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 06/19/2020 | [K193298](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K193298) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 12/20/2019 | [K192383](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K192383) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 05/31/2019 | [K190896](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K190896) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |
| 04/15/2019 | [K190072](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K190072) | Briefcase | Aidoc Medical, Ltd. | Radiology | QAS |
| 08/01/2018 | [K180647](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K180647) | BriefCase | Aidoc Medical, Ltd. | Radiology | QAS |

2. Clinical Use and Impact:

"Deep learning algorithm in detecting intracranial hemorrhages on emergency computed tomographies" *PloS one*, 2021 November (<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0260560>)

"A Prospective Randomized Clinical Trial for Measuring Radiology Study Reporting Time on Artificial Intelligence-Based Detection of Intracranial Hemorrhage in Emergent Care Head CT" Progress in Biomedical Optics and Imaging - Proceedings of SPIE, 2020. ( <https://www-spiedigitallibrary-org.wwwproxy1.library.unsw.edu.au/conference-proceedings-of-spie/11317/2552400/A-prospective-randomized-clinical-trial-for-measuring-radiology-study-reporting/10.1117/12.2552400.full#_=_>)

"The impact on clinical outcomes after 1 year of implementation of an artificial intelligence solution for the detection of intracranial hemorrhage" *International Journal of Emergency Medicine,* 2023. [BMC](<https://intjem.biomedcentral.com/articles/10.1186/s12245-023-00523-y>)

3. Review Articles:

"Artificial Intelligence and Acute Stroke Imaging" *AJNR*, 2021 Jan [PubMed](<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7814792/#:~:text=Artificial%20intelligence%20can%20help%20with,CT%20Score%20grading%2C%20and%20prognostication>)

"Accuracy of Automated Computer-Aided Diagnosis for Stroke Imaging: A Critical Evaluation of Current Evidence" *Stroke*, 2022 April [AHAIASA Journals]( <https://www.ahajournals.org/doi/full/10.1161/STROKEAHA.121.036204>)

"Cost-effectiveness of artificial intelligence aided vessel occlusion detection in acute stroke: an early health technology assessment" *Insights Imaging*, 2021 Dec [PubMed](<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8464539/>)