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Kaleida Health Stroke Care Center at the Gates Vascular Institute Acute Stroke Study — Phase Three



ADVANCING STROKE CARE LEVERAGING ADVANCED IMAGING TECHNOLOGY THAT IMPROVES PATIENT OUTCOMES AND LOWER COSTS

Seventy-five percent of all strokes that occur within the United States happen to people over the age of 65. With the aging of the baby boomer generation, it is anticipated that 20 percent of the U.S. population will be over the age of 65 by 2030. That translates to 70 million Americans who will be on Medicare by that year.

For the provider community, this means that the volume of stroke cases will increase significantly over the course of the next 13 years. Each year, approximately 795,000 strokes occur within the U.S. — nearly 600,000 of them occurring in Medicare beneficiaries — resulting in more than 133,000 deaths. And while stroke might not be the leading cause of death in the U.S., it is the number one cause of long term disability.

Indirect and direct costs for stroke were \$71.6 billion in 2012. With the baby boomer generation continuing to age and medical costs continuing to escalate, it is anticipated that stroke care will consume a greater portion of healthcare spending. By 2030, it is estimated that stroke care will cost the U.S. economy \$184.1 billion.

Changes in healthcare move at a slower pace than other sectors of our economy. Politicians work to find solutions to meet the growing health care demands of an aging population while trying to keep the Medicare program solvent. Innovative approaches to treatment have been encouraged by the federal government over the course of the past two decades through a host of policies, the most significant enshrined within the Patient Protection and Affordable Care Act (ACA) of 2010.

The consequences of a stroke can be permanent. In stroke treatment, it is often said that "time is brain." The faster a clinician can detect decreased blood flow and determine a treatment plan, the better the patient's chance for survival, recovery, and improved outcome. Not only does improved intervention increase the probability of a better quality of life, but it also helps realize significant economic benefits.

The ACA and, most recently, the Medicare Access and CHIP (Children's Health Insurance Program) Reauthorization Act (MACRA) of 2015, advocate the adoption of advanced alternative payment models that are designed to improve quality of care, reduce spending, and improve the patient experience.

ACA provides the establishment of a pilot program focused on clinically defined episodes of care, specifically targeting high-cost, high-volume episodes that look at inpatient stays as the main trigger. MACRA adds physician-alignment to the mix with incentive payments to clinicians who elect to participate in a shared-risk, episode-based payment (EBP) model.

This EBP model uses the existing fee-for-service payment system to establish a baseline spending measurement. In addition, there are quality metrics with a focus on transitions of care, patient/physician/caregiver communication, and readmissions. Clinical episodes that are of high cost and resource utilization, such as stroke, are part of this program. At present, this program is running under the Bundled Payment for Care Improvement (BPCI) initiative overseen by the Center for Medicare and Medicaid Innovation (CMMI). Under bundled payment programs, stakeholders should work toward improving clinical utility, operational efficiency, and financial performance of technology.

Medical imaging plays a significant role in helping providers achieve these goals. The right medical imaging technology can deliver fast, accurate, and patient-focused diagnoses if appropriately implemented and leveraged by a multidisciplinary team.

Toshiba Medical offers advanced, medical imaging solutions that are supported with a multidimensional knowledge base, dynamic customer interaction, and a robust system of training and education to help medical teams transition and prosper within new delivery models of patient care.

To quantify and demonstrate the benefits of this type of approach, Toshiba Medical partnered with Kaleida Health's Stroke Care Center (SCC) at the Gates Vascular Institute, formerly Kaleida Health's Stroke Center at Millard Fillmore Gates Circle Hospital, to conduct a multi-phase study analyzing stroke patient outcomes using Toshiba Medical's Aquilion™ ONE CT system during diagnosis. The results demonstrate that a multidisciplinary, collaborative approach to patient care combined with the latest in imaging technology not only improves patient outcomes but also the bottom line.

DIAGNOSING ACUTE STROKE AT GATES STROKE CENTER WITH 320-DETECTOR ROW CT IMAGING

Toshiba Medical and the SCC conducted a multi-year retrospective and prospective study on the effectiveness of utilizing the Aquilion ONE in the diagnosis and treatment of acute stroke. The goal of the non-controlled study was to measure the economic impact of 320-detector row, 640-slice CT on the diagnostic workup of patients presenting with symptoms of acute stroke and transient ischemic attack (TIA). It also tracked improvements over time. The SCC reviewed the patient diagnostic workup for stroke patients and analyzed the imaging procedures utilized during the acute inpatient episode of care, focusing on the changes in the diagnostic work-up, inpatient length of stay and discharging disposition since acquiring the Aquilion ONE.



Prior to installation, a retrospective, inpatient baseline data set was acquired from July to September 2007. Primary ICD-9-CM codes designating acute stroke and TIA were identified in the baseline group. These data sets were measured against the following four prospective, inpatient data sets:

- July to September 2009 (Phase I Study)
- July to September 2010 (Phase II Study)
- July to September 2011 (Phase III Study)
- July to September 2012 (Phase III Study)

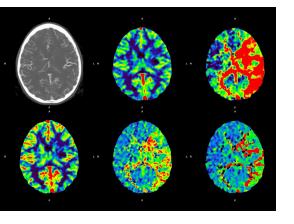
After the Aquilion ONE was used for diagnostic acquisition, the top three discharging ICD-9-CM codes were identified. The diagnostic patient work-ups were compared during these four time periods and identified significant differences of how acute stroke patients were diagnosed.

Retrospective Diagnostic Work-up 2007

- · Pre-MRI screening
- · X-ray imaging
- Limited brain MRI
- MR perfusion
- MRA of the head and neck

Prospective Diagnostic Work-up 2009

- Non-contrast head CT
- · CT perfusion
- CTA head and neck
- MRI brain non-contrast



Due to the technological limitations of CT brain perfusion in 2007, MR was the primary modality used for stroke diagnostic workup. Once the SCC installed the Aquilion ONE, the 2009 to 2012 data showed a significant shift in the diagnostic workup for acute stroke with the CT brain/CT perfusion/CTA head and neck protocol. MRI brain non-contrast was done on the backside; usually post-intervention. This clinical transformation of using a CT-based protocol for stroke diagnosis translated into a reduction in healthcare costs and improved patient outcomes. Furthermore, the images produced by CT allowed for improved patient selection to be moved more quickly into intervention.

COMBINING A MULTIDISCIPLINARY APPROACH WITH INNOVATIVE TECHNOLOGY

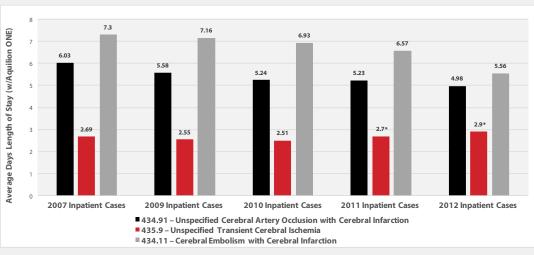
During this time period, the SCC also made significant shifts in other aspects of patient care, further contributing to improved clinical outcomes. Following the relocation of the SCC from Millard Fillmore Gates Circle Hospital to the Gates Vascular Institute, the facility consolidated its vascular services and repositioned its Aquilion ONE CT systems adjacent to areas of high need: the emergency department and catheterization lab.

"This set up enables us to get patients from the door of the ER to CT imaging, and to the CTA or perfusion exams they may need, within 10 minutes," said Dr. Nelson Hopkins, SUNY distinguished professor of neurosurgery and radiology, and founder of the Gates Vascular Institute and the Jacobs Institute. "We are also the only stroke care center in the world with all of our vascular disciplines located on the same floor, which has created new synergies between clinicians and significantly improved our workflow. And by having all of our specialists in one building, and standardizing all of our imaging equipment to Toshiba Medical systems, we can address virtually any patient need immediately and effectively."

Other key changes, including a state-of-the-art video conferencing system, allow SCC clinicians to provide real-time feedback to patients' families during procedures and more efficiently share crucial post-operative information. "The improvements we've implemented in the SCC itself have helped us deliver better care to more patients," said Dr. Hopkins. "The concept of our complete vascular center has vastly expanded our referral base from physicians all over the world and we've seen better reviews of our services."

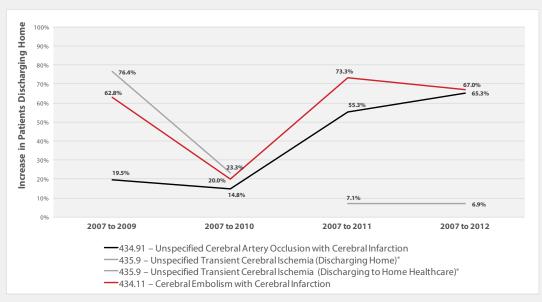
As part of its multi-year study to quantify how improved imaging technology has impacted patient care, the SCC analyzed the length of stay, discharge disposition, and healthcare costs for the top three ICD-9-CM codes for stroke and compared the 2007 and 2009 to 2012 data sets. The results demonstrated the continued benefits the 320-detector row technology brought to the facility and patient community. Highlights of the multi-year findings include the following (full data set on file):

2009 - 2012 Length of Stay Data



In 2011 and 2012, the SCC saw an even greater reduction in patient length of stay, demonstrating quicker recovery times and ultimately lower healthcare costs.

2009 – 2012 Change in Discharge Disposition

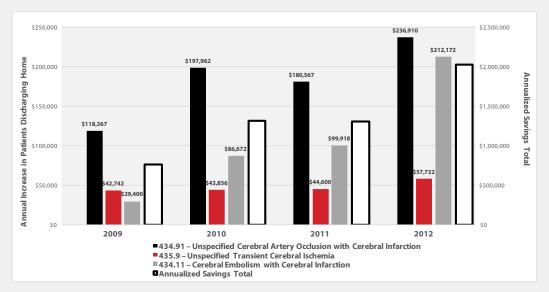


^{* 2009-2010} data for ICD-9-CM code 435.9 reflects the increase in patients discharging to home healthcare. 2011 saw the first increase in discharge to home for ICD-9-CM code 435.9 thanks in part to the improved patient care facilitated by the Aquilion ONE.

The discharge disposition for patients at the SCC continued to improve in 2011 and 2012 with further use of the Aquilion ONE. For example, patients falling under ICD-9-CM 434.11, the most resource intensive code, saw a more than 73 percent increase in patients discharged to home in the 2011 data, and a further 67 percent increase in home discharge in the 2012 data.

^{*}Length of stay for ICD-9-CM code 435.9 (Unspecified Transient Cerebral Ischemia) appeared to increase between 2007 and 2011, and between 2007 and 2012. This is in part attributable to correctly-identified Unspecified Transient Cerebral Ischemia cases being admitted to the hospital; other, non-Unspecified Transient Cerebral Ischemia cases would have been discharged out as outpatient, thereby increasing the weight of the length of stay for the true Unspecified Transient Cerebral Ischemia cases.

Cost Savings (Total Including Length of Stay and Diagnostic Workup Cost Savings)



In total, over the past four years, the SCC has achieved more than \$5.4 million in annualized savings by using the Aquilion ONE to diagnose stroke.

Toshiba Medical's Aquilion ONE — Changing Clinical Pathways

The introduction of Toshiba Medical's Aquilion ONE dynamic volume CT system changed the scope of cerebral perfusion analysis by enabling dynamic imaging of the entire brain and the ability to reduce diagnosis time from hours or days to minutes. Unlike any other CT system available, the Aquilion ONE covers up to 16 cm of anatomy using 320 ultra-high-resolution 0.5 mm detector elements to image an entire organ, including the brain, in a single rotation. It can show the brain's dynamic blood flow and real-time function, which is crucial for stroke patients and enables rapid and accurate diagnosis when time is critical.

With whole brain perfusion and digital angiography, the Aquilion ONE gathers the information clinicians need to evaluate the penumbra, the region impacted by the stroke. With a

single axial rotation, a non-contrast examination of the brain can be performed in one second. If no hemorrhage is found, a single injection of contrast material can be administered and the entire brain is imaged intermittently over 60 seconds. This single exam takes less than one minute and produces data showing individual arterial or venous phase to look at digital subtraction angiography with full blood flow information. It also shows whole brain volumetric perfusion.

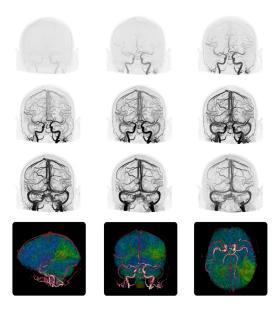
By pairing whole brain imaging with the Singular Value Decomposition Plus (SVD+) delay-insensitive perfusion algorithm, the Aquilion ONE produces the most advanced CT perfusion imaging in the industry. SVD+ uses a novel technique to account for delays between the arterial input function and the tissue curve, correct for noise and perform

calculations with fast computation times. The SVD+ algorithm is unique in that it shifts the artery curve so that it always begins just prior to the contrast arriving in the tissue curve. It also uses a unique pre-conditioning technique that stabilizes the algorithm, minimizes noise and ensures accurate, delay-insensitive calculations of mean transit time. As a result, the Aquilion ONE produces new maps providing more information clinicians can use to accurately and quickly diagnose neurological conditions.

Beyond brain imaging, the Aquilion ONE features a full suite of dose reduction technologies that limit radiation dose to the lowest possible amounts while maintaining the highest clinically appropriate image quality needed for diagnosis.

The utilization of the Aquilion ONE and its ability to perform whole brain perfusion studies resulted in tremendous benefits for the SCC and its patients starting in year one and has continued to realize cost savings and improved patient outcomes. For ICD-9-CM code 434.91 (Unspecified Cerebral Artery Occlusion with Cerebral Infarction) the SCC saw more than a full-day reduction in hospital stay, had more patients discharged to home and saw quarterly cost savings exceeding \$230,000.

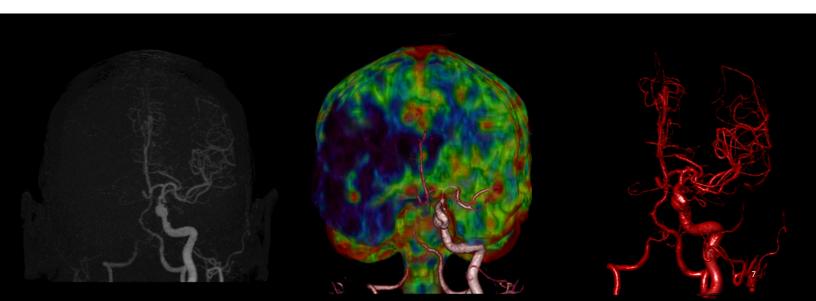
ICD-9-CM codes 435.9 (Unspecified Transient Cerebral Ischemia) and 434.11 (Cerebral Embolism with Cerebral Infarction) also saw improvements in these areas. Both had an increase in patients discharged to home and substantial cost savings. Overall, for just these three ICD-9-CM codes, the SCC achieved an approximate annualized savings of more than \$2 million in 2012, totaling a cost savings of more than \$5.4 million in the five years since installing the Aquilion ONE.



BRINGING THESE BENEFITS TO OTHER HEALTHCARE FACILITIES

The SCC is an impressive example of how an exceptional multidisciplinary team with comprehensive education and community outreach can use innovative imaging technology to improve financial performance as the federal government implements new, shared-risk, delivery models of patient care. Healthcare facilities with dedicated stroke programs can experience the significant cost savings achieved through reduced length of stay, reduction in outpatient services, reduced complications, and lower recurrence of readmission.

Make no mistake, effectively managing episode-based care requires more than just superior imaging technology. It demands multidisciplinary cooperation and collaboration, and Toshiba Medical's offering of a multidimensional knowledge base, dynamic customer interaction, and a robust support system of training and education will help healthcare organizations provide efficient and effective service, and prosper within today's healthcare environment.



ACUTE STROKE STUDY

Kaleida Health's Stroke Care Center

Kaleida Health's Stroke Care Center at the Gates Vascular Institute completed a three-phase, non-controlled study analyzing the patient and fiscal benefits of using Toshiba Medical's Aquilion™ ONE CT system for diagnosing acute stroke.



Inpatient data sets from July to September 2007, prior to the Aquilion ONE installation, were compared with data sets from July to September 2009 (phase one), July to September 2010 (phase two), and from July to September 2011 and July to September 2012 (phase three), which utilized the Aquilion ONE, and concerned the top three discharging ICD-9-CM codes. Full data sets and study methodology available.

19% reduction in patients discharging to **rehab**(ICD-9-CM 434.91: Unspecified Cerebral Artery Occlusion with Cerebral Infarction)