

Review Article

India needs to act fast against the stroke epidemic: a tactical and radical change needed

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ABSTRACT

In India stroke is the 4th leading cause of mortality and 5th leading cause of disability. The mean age of onset of stroke in India is lower than in western countries, and even the incidence in the young population is high in India. When we performed the review of literature, we found there are two different sets of countries in the world. Historically, one set of countries has adopted the best national policies with an aim to reduce mortality, morbidity, and disability in patients. Then there is another set of countries like India, which has fought this epidemic in a fragmented manner and so is still looking at a huge stroke burden. To understand this divide, we studied the history and present format of the fight and then compared it to that of India. Finally, we can outline areas that require improvement. This article suggests a tactical and radical change in the fight against stroke. India needs to ACT FAST to prevent the damage because of stroke. To write this review, we wanted to understand the historical background of stroke, so we conducted an extensive review of articles with keywords, studied the way trials on tissue plasminogen were done, how CT scan discovery made the difference, and since then, how developed countries have made progress. Then we studied the present Indian situation and the actual root cause of high mortality and disability in Indian stroke patients. We then reviewed how developed countries plugged their gaps.

Keywords: Stroke, Disability, Time is brain, Interventional radiologist, Stroke ready hospital, Stroke unit, tPA, Thrombectomy

INTRODUCTION

Stroke as a disease has come a long way, from being called as Struck down by violence in Greek to a disease due to ischemic cascade, to a disease due to impaired cerebral blood flow, and now called a Brain attack.¹ Stroke was always put into a category of a disease that cannot be treated as there was brain tissue death and hence was always called apoplexy.² It got a mention in medical books for the first time in the 5th century by the father of medicine, Hippocrates, and it took 2500 years to understand the whole process, and finally, we are at a juncture where we can boast that we can try and cure the disease.² The human brain is made of billions of cells, a

spongy organ protected by a bony skull and washed by protective CSF, with a special set of functions. The brain initiates and controls the movement of each body part, provides intelligence, understands the senses, and acts as a controller of behavior. So, when there is a stroke where the oxygen supply to a part is reduced or stopped, it causes deterioration of all the above functions. Around 2500 years back until the 17th century, there was a theory of spirits causing the disease or divine punishment, and also due to an imbalance in the mixture of blood, yellow bile, black bile, and phlegm.² Then the knowledge of ischemia and hemorrhage came in, and stroke was classified into two types. Since until the 1970s there was very little research regarding the treatment part, the

mainstay of management was prevention.² So, till now, this disease has retained its ranking of being one of the top reasons for disability in humans and the second leading cause of death.³ Then came the breakthrough in the form of two landmark discoveries. Firstly, the world got its CT scan investigation in 1970, which revolutionized the management of stroke.^{4,5} Secondly, the use of tissue plasminogen activator-tPA injection in the treatment of ischemic stroke from 1995.^{6,7} For the last 28 years, western countries like the USA and European countries have helped their citizens achieve a disability-free life after stroke and have drastically reduced the stroke burden.³

1960-1995 ERA OF TREATMENT OF STROKE: VAST STROKE BURDEN

Before 1970, if we consider the management of stroke, it revolved around prevention rather than treatment modalities. Since we had no lead in pathophysiology except it being because of blockage of arteries or hemorrhage, doctors tried prevention and rehabilitation. In 1942, internist Howard Rusk left his practice and, for the first time in history, began comprehensive rehabilitation during World War II, which later became the reason for help for those who suffered from stroke.⁸ Until then, stroke was considered a disease of disability where millions waited in bed to die as there was no help. Rehabilitation techniques helped millions to get back to work and do their daily chores with minimal dependence. But there was no help in treatment, and so thousands died because of stroke.⁸ Until this time, one thing was understood: in stroke, blockage of an artery happened because of atherosclerosis and atherothrombosis.⁹ But there was no way to know whether the patient who came in with a stroke had a blockage or a hemorrhage. The revolution happened with the advent of the CT scan machine and its utility in medicine when, for the first time, a live brain was scanned on 1st October 1971.⁵ During the same time, one more research was going on; antiplatelets were studied for their effect in preventing cardiac and cerebral ischemia. With positive results, the era of antiplatelets like aspirin, dipyridamole, ticlopidine, and clopidogrel started.¹⁰⁻¹² Along with medical ways of prevention, carotid endarterectomy also provided good results.^{1,3} As the research progressed with speed, three more things came up which were given to patients of stroke. The first thing that came up was hemodilution, where the viscosity was lowered, and the blood was diluted.^{14,15} Then the theory of ischemia and its role in neuronal damage came in. This ischemic cascade theory led to the use of neuroprotective therapies.¹⁶ So, for years, patients were given antiplatelet drugs, volume in the form of crystalloids, colloids, and also medicine as neuroprotection. While this was going on in various corners of the world, tissue plasminogen activator tPA was tested upon. In 1980, Desire Collen discovered tPA, and soon it was researched as a blood clot-dissolving drug, and animal trials were completed with good results.^{17,18} This led to the landmark national institutes of

neurologic disease and stroke (NINDS) tissue-type plasminogen activator (tPA) stroke trial.^{19,20} This trial led to FDA approval of its use in ischemic stroke in 1995, which led to the rise of an era of disability freedom for stroke patients.²¹ The era of endovascular therapies in stroke got a boost when thrombus retrieval devices were tested-the MERCI retriever in 1999 and got FDA approval in 2004.^{22,23} So, with this, stroke patients now had IV thrombolysis by tPA and, if not responsive or partially responsive, then mechanical means to retrieve the thrombus. And so, the chances of timely recanalization increased, and so did the chances of less disability. In the last 30 to 20 years, there has been the development of 2nd generation and 3rd generation devices, which are increasing the safety and also helping many operators do recanalization of middle-caliber arteries.²²

1996 TILL NOW: LESS MORTALITY-LESS DISABILITY

As the FDA approval was there and the details sank in, neurologists got a shot in the arm in the treatment of stroke patients. Now they had a needed weapon, which over the period has proven the reason for less death and lesser disability in stroke patients. Soon, certain things became sacrosanct for a hospital, which were called "stroke ready". It was seen that stroke treatment had a few important principles. Stroke is a brain attack due to the stoppage of blood circulation to part of the brain, which can be an ischemic stroke or a hemorrhagic stroke. Just like a heart attack, blockage of an artery was considered the main reason for ischemic stroke.^{24,25} Time is brain-brain is neurons, cells, and synapses, and without them, the functions of the brain are impossible. Once a stroke starts, it is observed that millions of cells, neurons, fibers, and synapses die every minute.²⁶ So, the time we waste in transporting, diagnosing, investigating, and discussing the course of treatment, the affected brain tends to lose cells, neurons, fibers, and synapses, leading to permanent disabilities in the patient. Time lost is brain lost-so it is very clear that we have no time to lose in the case of stroke because once the cellular damage increases, there is a ripple effect in the surrounding brain. The core and penumbra parts of the brain post-stroke explain the ischemic cascades and the effects. There are many pathways that lead to cellular death, like excitotoxicity, oxidative stress, and apoptotic-like pathways.²⁷ The golden hour-once the various data of the NINDS study was evaluated, it was decided that to try and dissolve the clot or to remove the clot from the brain vasculature post-stroke, there is a golden hour. It was seen that the effect of tPA was best in the early minutes of the stroke, and by the end of 4.5 hours, the effect reduced drastically. So, with this time-dependent success, it is advocated that intravenous tPA gives optimal success when given within 4.5 hours of the onset of the stroke, and the door-to-needle time should be less than 1 hour.²⁸ ACT FAST is the tool developed for the first time in the United Kingdom to evaluate patient diagnosis of stroke. This was designed to improve the recognition and subsequent

response in patients with stroke.²⁹ So, it was universally accepted that success in the treatment of stroke is strictly time-dependent, and to reduce the mortality and disability burden, there needs to be some mechanism so that patients get effective treatment everywhere.

STROKE READY SYSTEM: BEST COORDINATED STRIKE ON THE DISEASE

When we talk of the management of stroke patients, it is essential to understand that it is a time-dependent response, requiring coordinated efforts of a multi-specialty team, emergency response department, ICU, neurosurgical and CATH labs for neurointerventions, and a dedicated radio imaging department, rehabilitation center, and ambulance system. Any country has diverse geographical areas, and so the idea was to save as many as possible, and thus, three types of centers were proposed and activated throughout the western world, especially the USA.³⁰ Acute stroke care unit uses the ACT FAST tool and rapidly assesses the patient; if critical, it stabilizes the patient, performs a diagnostic scan, is equipped for intravenous thrombolysis, and starts the transfer to the higher center. Peripheral stroke unit has a dedicated stroke team, all diagnostic facilities, ICU care, and a rehabilitation department. Comprehensive Stroke Unit or thrombectomy-capable stroke centers (TSC) is the most advanced neurology center with all facilities of a multispecialty hospital with the availability of neurosurgical and neurointerventionist teams. To standardize the whole practice, criteria were set for certification as stroke units, and the essential features of the whole checklist were as follows. The concept of a stroke team requires a dedicated team with an emergency specialist, neurologist, neurointerventionist, neurosurgeon, critical care specialist, radiologist, neurology nursing staff, and physiotherapist. In an acute stroke care unit, a dedicated physician was needed. Since door-to-needle time was the most important concept, the ready availability of the above specialists helped reduce the time lost.³¹ The radio imaging department was critical because, before 1970, every effort to treat stroke patients failed drastically because there was no way to see the live patient's brain by any means. So, a treating doctor never knew whether he was dealing with an ischemic stroke or a hemorrhagic stroke. On 1st October 1971, the world got its first CT scan machine through the efforts of Godfrey N. Hounsfield, and live brain scanning became a reality.⁵ This helped researchers and treating doctors to identify ischemic stroke from hemorrhagic stroke. With time, the availability of CT angiography, MRI brain (Conventional MRI, MRI DWI, MR Angiography), and ultrasonography (carotid Doppler) made the management of stroke more successful.^{32,33} The decision to give IV tPA, thrombectomy, carotid endarterectomy, and later carotid stenting became easier and effective. Patient transport services are crucial because the whole concept and success of stroke management are strictly time-dependent. Door-to-needle is the time that is easily controllable as the patient is in the hospital where the

logistics are protocol-based. But the golden hour of 4.5 hours can be attained only if the patient is transferred immediately to the nearby stroke unit. This required trained ambulance units, be it road or air, and also public awareness of calling them timely and allowing the smooth passage of this unit while on the road. As time passed, the training involved teaching the ambulance staff and doctor with ACT FAST tools, stabilizing techniques while on the way, and informing the stroke unit about the condition of the patient. This helped reduce the alarm-to-door time.^{34,35} An expert group of the neuro team was essential. Until before 1996, physicians and neurologists used to treat stroke patients as the treatment required hemodilution by giving crystalloids or colloids, adjusting the ventilator settings to increase CO₂ levels, prescribing neuroprotective medicines to decrease damage due to ischemic cascade, antiplatelet drugs, and finally working for prevention. It involved vascular surgeons and neurosurgeons who did carotid endarterectomy and craniotomy to decompress the brain, respectively. After the approval of intravenous tPA and mechanical thrombectomy, the need for neurointerventions/interventional radiologists came in. In the last three decades, the world has seen growth in the number of dedicated interventional radiologists.^{37,38}

LAST 50 YEARS IN STROKE IN A NUTSHELL

As the research gave positive results and as the trials yielded positive results, the FDA was fast enough to provide the needed approval for both IV tPA and mechanical thrombectomy. Over this period, three things are considered the mainstay of management. The role of time in treating ischemia and reducing disability is critical. The availability and ability to quickly do the scanning and categorize the stroke into ischemia and hemorrhage are vital. The development of catheters and devices to perform endovascular therapies and the availability of interventional radiologists are essential. With these three pillars established and guidelines and certification in place, these countries and healthcare systems overcame a few roadblocks to success. Time is the foundation of stroke management, where alarm-to-door and door-to-needle times need to be strictly followed. So, policymakers and medical associations prepared a roadmap for outlining the areas that can lead to delays and then systematically removing those areas. Attitude plays a significant role in this whole management pathway. Timely availability of transport, radiologists, and stroke teams is essential for success. Along with this, patients and their relatives need to understand the importance of an immediate call to ambulance services. The attitude of physicians needs to change, where they refer such patients directly to hospitals that are stroke-ready. Availability is critical, realizing that there is a need for separate stroke units. So, the availability of different types of stroke units, diagnostic scans, cath labs with retrieval devices, and tPA is essential. Finance is another factor, as for any treatment success, the consent of relatives is crucial. When

therapies are costly, finance becomes a roadblock, and consents are not forthcoming. In such cases, making therapies affordable, fully covered in insurance, or adding them to national policies is helpful. We have come a long way from stroke being an untreatable disease to stroke causing disability for life, and now, if timely action is taken, the patient can recover fully.

GLOBAL BURDEN OF STROKE

It is a known fact that stroke is the leading cause of mortality and morbidity across the globe. Initially, it was considered a disease of developed countries, but now we are seeing a rise in developing and low-income group countries as they have an epidemiological shift from infectious to non-communicable diseases. In stroke, there are two things that every epidemiologist should take into consideration. First, mortality-this parameter is less dependent on the availability of stroke units or intervention facilities but more on the suddenness of the disease, the area affected in the brain, and the availability of equipped critical care units at the point of origin. Survival and intervention at a later stage are only possible if the patient is stabilized and made to reach a comprehensive stroke unit. The second point is disability due to stroke, which is definitely dependent on well-equipped stroke units and upgraded rehabilitation centers across the country. In stroke, the research picked up from the 1990s and has become fast-paced with more and more development in interventional devices, including catheters, stents, suction devices, and balloons. With the availability of medicine and devices, the countries that could increase expertise in interventional radiologists, increase well-equipped stroke units, and establish hospitals with equipped intensive care units or emergency departments have substantially decreased mortality and disability-adjusted life-years (DALYs). The data published by the global burden of diseases, injuries, and risk factors study (GBD) helps us understand the position of the world and India.³⁹ The global mortality rate decreased by 36% from 1990 to 2016, and over the same period, the global DALY rate declined by 34%. In 2016, stroke was the second largest cause of death globally, with 5.5 million deaths after ischemic heart disease. The Indian mortality rate decreased by 23% from 1990 to 2016, and over the same period, the global DALY rate declined by merely 2.3%. India has a 68.6 percent incidence of stroke, 70.9 percent stroke deaths, and 77.7 disability-adjusted life years (DALYs) lost. The real reasons behind this big difference in India and global data are multifaceted. The unavailability of health centers in rural and urban areas that can immediately stabilize critical patients is a significant issue, with overall statistics showing a mere 2.3 ICU beds available per 1 lakh population. In contrast, in the USA, Germany, and Europe, where there has been a fall in mortality in stroke, the numbers are almost 14, 47, and 15, respectively, per 1 lakh population.^{40,41} There is a lack of ICU beds in rural areas and public hospitals.⁴¹ So, when a stroke patient is brought to an ill-equipped center, the chance of survival

without the availability of ICU, ventilators, diagnostic facilities, and expert manpower is less, and hence the burden of mortality because of stroke is high in India. Acute care stroke units are completely absent in rural areas and, in urban areas, are found more in private hospitals than public hospitals.⁴⁴ Availability of patient transport facilities with trained staff is essential to reduce mortality and morbidity. In India, the ambulances available per 100,000 population, both basic ambulances and advanced life support ambulances, connectivity of roads leading to ambulance travel time, ambulance response time from the time a call is made, and the trained staff in ambulances to assess and stabilize the patient are not up to the mark. Over two decades, emergency medical services were established but in a fragmented manner in various states, and there was no centralized control mechanism. So, the alarm-to-door time in stroke is maintained only in a few patients, approximately 40 hours in rural setups and 7 to 8 hours in urban setups. Only 25 percent of patients could reach a hospital in less than 6 hours.^{42,43} Once the patient reaches a stroke unit, the success of treatment depends on timely non-enhancing CT scan brain, CT angiography or MRI diffusion-weighted images, assessment by the stroke unit, and reperfusion by IV thrombolysis or mechanical thrombectomy. In India, radiological infrastructure is very poor in rural areas, and in urban areas, the round-the-clock availability of radiologists is a problem.⁴⁵ The 25% of patients who reach hospitals in less than 6 hours face failure due to the lack of a dedicated stroke team, unavailability of CT angiography or MRI brain DWI and angiography, lack of facilities for endovascular procedures, and lack of interventional radiologists.⁴⁵ Affordability is another concern, as all the above services like private ambulance services, medicines, imaging, mechanical thrombectomy, and rehabilitation are paid services in India. In India, insurance coverage is increasing, but endovascular therapy is still unaffordable. There are government policies like Ayushman Bharat and state policies, but they still do not cover endovascular therapies. Patients who are poor and go to government hospitals do not get stroke-ready units there and so have to undergo the same conservative treatment.⁴⁶ In the last decade, India has improved its healthcare facilities, whereby it has rolled out the Universal Healthcare program, Ayushman Bharat, which provided coverage to more than 50 crore people.⁴⁹ Under this scheme, the government is rebuilding the primary healthcare system equipped with basic healthcare facilities with expert manpower, empowering public and private healthcare to cater to poor and needy patients free of cost, and providing affordable medicines, devices, and stents.⁵⁰ Along with this, throughout the country, the ambulance transport network is being increased and brought under centralized emergency medical services.⁵¹ In the next few years, there is an urgent need to improve a few things to make it a robust stroke care unit. Multidisciplinary stroke teams, which are very low at present, i.e., 36%, and stroke units, which are also low, i.e., 32%, are the need of the hour.⁴⁵ We need to increase the seats in courses

offering neurology, neurosurgery, and neuro-intervention radiology. In stroke rehabilitation, untrained and half-trained physiotherapists are available, who cannot perform the job of occupational therapists, speech therapists, and cognitive rehabilitation. We need to increase this expert manpower to provide a quality of life to survivors.⁴³ Telemedicine is another area that acts as a blessing in stroke management. In a large country like India with difficult terrain and vast rural areas, it is highly ambitious to provide intravenous thrombolysis. But if we can learn from the USA and Germany, who have achieved more than 90% coverage through stroke telemedicine services, it could be beneficial.⁴⁷

The biggest roadblock is the attitude of patients and family physicians. It is seen that the general public is unaware of stroke symptoms or warning signs and so neglects them and hence does not ask for help in time.⁴⁸ Also, due to the century-long practice of family physicians, patients are sent for scans to radiological centers and then sent to hospitals for treatment, which leads to wastage of time. Again, because the concept of stroke-ready hospitals is just gaining ground, the majority of patients reach hospitals that are not stroke-ready and so are treated with conservative methods. This will require a systematic campaign involving the government, media, and medical fraternity.^{24,43}

CONCLUSION

Through this article, we wished to first highlight the point that many countries of the world have achieved success in stroke management through a systematic and multi-disciplinary approach that involved people, the medical fraternity, the government, and hospital administrators. As the research moved ahead and as experts were available, this approach yielded results in the form of reduced mortality and reduced disability. Even in disability-ridden patients, a good rehabilitation program helped patients regain confidence and strength to come back to society. This has helped reduce the overall stroke burden in those countries. India is the largest populous country where the stroke burden is high, and it actually adds substantially to the global burden as well. As healthcare is progressing in India in the right direction in the last decade, now is the time to make a national policy about stroke management. A mere national stroke registry and fragmented development will not help achieve the larger goal. This article outlines the problem areas in Indian stroke management as compared to the countries that are successful and, with that, tries to suggest various solutions to improve the overall program. If we move in the right direction with the right plan and guidelines, then our citizens will also have lesser mortality and fewer disability years.

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