

The changing world of innovative stroke treatment



Dr Sanjeev Nayak is a Consultant Interventional Neuroradiologist at the University Hospitals of North Midlands, who is one of the first and forefront pioneers of Mechanical Thrombectomy in acute ischemic stroke in the United Kingdom.

Dr Sanjeev Nayak speaks to Oruen for this expert interview.

Dr Nayak earned his Membership of Royal College of Physicians (MRCP) and Fellowship of the Royal College of Radiologists (FRCR) after graduating from India. He undertook further higher dual certification in Diagnostic and Interventional Neuroradiology in Europe under the European Union of Medical Specialists (UEMS) and completed an additional fellowship in Stroke Intervention from Austria. He brought back the skills he acquired in Europe and helped set up the first UK 24/7 Mechanical Thrombectomy service at the Royal Stoke University Hospital, Stoke-on-Trent which became one of the leading centres for minimally invasive stroke thrombectomy in the United Kingdom.

The mechanical thrombectomy service for stroke developed by Dr Nayak in the UK has saved the lives of many patients who would have otherwise died or sustained permanent neurological deficits. In addition to the lives saved, this service has resulted in cost savings to the NHS that runs into millions of pounds, by preventing or minimising stroke disabilities.

Dr Nayak has authored national QIPP and Thrombectomy documents with NICE and other UK national authorities. He has a passion for clinical research and has also been involved in numerous thrombectomy device developments. This has led him to win the prestigious The Sun Newspapers "Who Cares Wins" award for "Ground-breaking Pioneer and Discovery" following a nomination made by one of his patients.

Dr Nayak has been recognized by his peers and his patients for his outstanding achievement in establishing the service which has expanded under his leadership to cover a wide region including Midlands, Shropshire, Cheshire and Wolverhampton. Having been nominated for 19 national awards in various categories of BMJ and HSJ awards (2012-2019), he also won the prestigious "Windrush70 Award for Clinical Excellence" in 2018 following which he was invited to 10, Downing Street, to meet the Prime Minister. Dr Nayak was hailed by the NHS in 2018 as one of "health and care's top 70 stars" (voted no 2 in the entire NHS) for his efforts to get Mechanical Thrombectomy in stroke widely adopted.

Dr Nayak has also founded various national training courses and is strongly involved in medical education. He has developed courses through numerous new innovative teaching modules and has a strong belief for evidence-based practice with a motto of "saving lives through excellence" and "achieving excellence through education".

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Q1. Can you please outline the current problems and challenges in the treatment of acute ischemic stroke in the UK?

I would like to focus more towards acute ischaemic stroke, and thrombectomy. There are currently a number of issues in providing thrombectomy services.

The 1st issue to note is the service of variations, some services are available 24/7, while others are there from 9-5. This makes a variation for the patients as well. So, if some patients are "lucky enough" to get a stroke during a certain time of the day, they are treated, while others are not. So that is a service variation. Only 3 to 4 centres in the UK offer a 24/7 service for thrombectomy, and the rest either have no service, or they provide a patchy service between 9-1 or 9-5.

The 2nd issue is manpower. We don't have enough nurses, doctors and radiographers to do these procedures. When I say the manpower it's not just one speciality, but an entire group of people in the stroke thrombectomy pathway. So, we need more of these people. When you look at some hospitals, they don't have the equipment necessary for providing this service for thrombectomy. You need an angiography suite, and CT/MRI scanners. You have the availability of them in patchy times, or you don't have the staff to manage the equipment, or you don't have staff to run the service on a regular basis.

The 3rd and quite important point is the geographic location of the patients. Now some places have a very good network arrangement, where patients get transported to the nearest thrombectomy centre within a specified time period. If you look at stroke, it is very time critical. For every second or minute you lose, you lose millions of neurons. So, if the treatment is delayed by a large time, the patient will have a very poor outcome. Because of the transportation issues, the patients don't have access to go to the nearest thrombectomy centre. This can sometimes be a couple of hours, and sometimes can be as close as 15 minutes. So, if some centres are more than a few hours away then the patients from those regions can have a bad clinical outcome. You thus need to have quicker transportation and transfer arrangements in place.

Another issue is transfer of patients within hospitals. If a patient comes to a district general hospital for them to be moved to a thrombectomy centre, there is no urgency because once they are in the hospital it's considered to be a safe place. That transfer in itself can take hours once in a hospital. That's why it's important to have a "critical code transfer"; where inter-hospital transfer is done within a critical timeframe of 8 minutes.

One of the other most important factors I would say is, though the Department of Health has

provided funding for thrombectomy, those are only for the procedure and the time the patient stays in the hospital- it's basically the patient pathway. There is no proper pot of funds to fund the other aspects. Paying extra nurses, recruiting extra anaesthetists or extra doctors, or providing a pot for extra equipment such as an angiography suite. Until all of these issues are addressed as a whole, you won't be able to solve to current problems associated with stroke thrombectomy.

There is some progress being made, but it is very slow, it will take a longer time because of these various issues I've mentioned.

Can you tell us about your experience in setting up a 24/7 thrombectomy service? What were the challenges and how did you overcome them?

We at the University Hospital of North Midlands were the first in the UK to set up a 24/7 service for thrombectomy in late 2009/early 2010. I want to reiterate that this was a time period before the class 1 evidence for thrombectomy came in place through randomised clinical trials. The evidence only came in 2015 following which NICE provided guidelines for Mechanical Thrombectomy in stroke in 2016. The Department of Health rolled thrombectomy out to the rest of the NHS in 2017.

We started our journey way back in 2009/10 because we saw the benefits of thrombectomy straight away in those days. We were one of the first in the UK to pioneer this service. One of the reasons was because we saw a lot of patients in our hospitals dying from large vessel strokes. We felt we were in a helpless position seeing patients dying or having severe disabilities from large strokes and not having treatment which is as effective as thrombectomy. In those days, these patients only received intravenous thrombolysis, and we know from the evidence that it only works for 20% of patients. For patients with large vessel strokes, the outcome is poor so we wanted to do something very different and radical which can change patients' lives, and also save them from disability. We set up a working group of people from different specialities that came together from stroke, anaesthesia, the emergency department and radiology- we all got together and agreed that we have to do something radical and innovative. So, we set up a pathway of treating the large vessel stroke cases on a case-by-case basis, and one of the most important things was we involved the stroke patients as patient champions. We initially absorbed the funding from our own department budget. We initiated our new treatment pathway on a case-by-case basis and we had the advantage of having patients who had the treatment sitting on our panel as a stroke champions which helped us in developing a business case. Following achieving good clinical outcomes, we presented the clinical and financial cost saving data to the commissioners who were impressed with what

they saw, and the stroke champions who were on our panel also promoted this. As a result, we were able to obtain funding for this early through specialised commissioning. It was important to run a consistent 24/7 service and we had some shortfalls due to lack of staffing, etc. To overcome this we used the staffing that was available through our major trauma service contract. We had the staff to perform interventional radiology procedures for major trauma, so we used the same staff to provide the service for thrombectomy. We provided additional incentives to people who were interested in providing this service such as extra payments, time in lieu and other various incentives were provided. Based on that we started off with case-by-case basis and eventually we provided a consistent 24/7 rota for thrombectomy.

Based on the good clinical benefits shown by our service, our regional hospitals were also interested in obtaining these benefits for their patient population. The second step was to provide a 24/7 thrombectomy service to our region which caters to a population of 3 million. We then started treating patients from our regional hospitals through a pathway that we developed through our heart and stroke research network. A rota was formed with the regional hospitals to provide this service. We set up an image link network through teleradiology to obtain images of patients' CT scans from the regional district hospitals which we evaluated at our tertiary centre. We wrote clear protocols for our in-hospital and out-of-region patients. For example, patients coming from out of the region had a drip and ship method, where they received intravenous thrombolysis in their hospital and then were sent to our hospital for thrombectomy. Based on that we developed a regional network for thrombectomy, and we engaged very fast and quickly with the ambulance service to discuss transfer arrangements, and the critical code for the patients who were identified as requiring thrombectomy. Overall, we put all of these things together and managed to develop a 24/7 service way back in 2010. It has all worked very well and we continue to provide that same service today. With changing times, we have made improvements to our door to needle time and also incorporated Artificial Intelligence (AI) to improve our patient selection, patient journey and patient outcomes.

How can the national problem of implementing a 24/7 thrombectomy service be resolved?

Well, I would say this is a million-dollar question! Around the time of 2016 to 2018, I was invited to speak at the National Congress on providing a 24/7 service. At that time there was only our centre along with one other centre which was in London that were providing this service. Two years later it was still the same as in 2020, so nothing has changed over the last couple of

years. However, I now believe there are two other centres which provide a 24/7 thrombectomy service and things are slowly improving. I still feel there is a lot of work to be done. One of the most important factors we feel from our experience, is the willingness and the motivation from everyone to provide this service. There should be buy in from all parties. There should be passionate and motivational team leaders to lead a like-minded team which will then help achieve success. When we started, we had no funding but still managed to go forwards, but that required a lot of motivation. I would say start slowly first, with a 9-5 service, then you can expand the service delivery time to maybe 8pm, and then 24hrs, instead of going straight into the latter which might cause a significant burden on the service itself. Another recommendation is to have a network approach - if you don't have enough people or teams to provide this service in your hospital then try to work with a nearby hospital to share the work, where these patients can be treated and have similar pathways with the ambulance transfers too. Also, it's important to highlight that everyone mentions there are not enough doctors or nurses. We need train more of them, appoint more Neuroradiologists, anaesthetists, radiographers and more stroke physicians (all the individuals in the thrombectomy pathway) and we will also need external funding to help train and recruit these individuals. Also, we need a separate pot for the funding for the equipment. You need to have appropriate funds to secure an angiographic theatre and other equipment and for these we require funding.

To summarise, you need to have passion and motivation, but also you need to have funding for providing the manpower and equipment to deliver the service - these are probably the first steps in solving this problem.

For Thrombectomy to be successfully adopted there should be measures in place, one of them is to have time critical measures which include pre-hospital notification, a rapid transfer from emergency department to CT scan and to intervention (a stream line pathway for that). There should also be a well-functioning ambulance service with critical transfer code and air ambulance for air transfer - these are the time critical measures which are required for a successful adoption as well.

What is the role of AI in stroke imaging and treatment? Has AI made any difference to your thrombectomy practice?

I see artificial intelligence as the future in the fast-moving world of diagnostic and therapeutic stroke management. Using AI will help stroke victims when 'Time Is Brain' and this will help stroke patients by providing positive insight to the treating clinicians by accelerating stroke diagnosis. This ensures accurate therapeutic intervention in the shortest possible time

after the onset of stroke. AI is used more and more in clinical practise. Artificial Intelligence, especially in stroke, uses a machine learning algorithm. It basically reads the pattern of thousands of stroke scans, and is then able to diagnose what kind of stroke a patient is having. For stroke we mainly use AI to diagnose brain vessel occlusion through CT angiogram and CT perfusion for brain physiology analysis. Once the scan is done you will automatically get the result on your phone or email therefore, it's very quick. To give you a real-time example, if you are in a district hospital and its midnight and you require a scan and report, you may not have availability of a reporting radiologist at that time. Sometimes a scan report may take hours to be available and these delays can negatively affect the patient outcomes. AI algorithm will give you an answer within a matter of minutes. It means you save all that time and allows you to make a decision on the patient to be transferred to the nearest centre offering thrombectomy - especially useful in a district general hospital setting where there is a lack of manpower or radiologists reporting these scans. Also, another important aspect of AI, in patients who have stroke of unknown symptom onset or wake up strokes (patients who have just woken up from a stroke), thrombectomy can be offered after 24hrs after the DAWN and DEFUSE trial results. Previously such patients were not treated, but because of AI's CT perfusion images you can actually see how much of the brain is still salvageable. So those patients who were not previously treated can now be treated and benefit from AI, which widens your treatment horizon by applying this new technology. Taking all this into consideration, AI is probably the future of stroke treatment. We have been using AI in stroke for many years and we are seeing better streamlined pathways for the patients by reducing treatment delays which then translates to better clinical outcomes.

Has the COVID pandemic affected the way strokes are treated? What is your experience in providing a hyperacute stroke service during COVID pandemic?

COVID has certainly affected the way strokes have been treated. The most alarming fact we saw during COVID was that there was a reduction in 39.5% of admissions of patients admitted with stroke during the COVID period when compared to 2019. There could be multiple factors; perhaps patients were too scared to come to the hospital or whether being at home with self-isolation provided some beneficial way that the strokes were reduced but overall there were a reduction in strokes during this time.

Also, what we saw during the COVID period was patients coming in with more serious strokes. Although we did not see any change in the rate of thrombolysis or the patients being offered thrombectomy, we certainly saw that there were more serious stroke patients who died due to the severity of their strokes. COVID is not just a

respiratory illness; it also causes blood clots as we all know now. It can clots to the lungs also known as pulmonary embolism, clots to other organs of the body and to the brain causing strokes. So we have to be aware of COVID - it's not just about treating strokes but it's trying to prevent these complications happening in the first place. We are still learning from it and hoping that with a lot of awareness and preventive measures we can probably reduce the events of strokes from this deadly disease.

What is your view on the emerging market with newer stroke devices? What would you be looking at when evaluating these new devices?

This is an interesting question. Just like how you have a number of mobile phones in the market, the stroke Thrombectomy market is also saturated similarly with a number of devices. The devices which are used in thrombectomy include a stentriever which is a mesh made of nitinol, or a tube like catheter which is used for thrombosuction. There are a number of these devices in market, however, initially the evidence showed that using a stentriever for thrombectomy was more effective, but over a period of time we are seeing the data shifting. It shows that whether you use thrombosuction or stentriever you can get good outcomes. The most important factor was what they call a 'first pass effect' - this is when you either use suction or you use a stentriever - but within the first pass if you can get the clot out you will achieve a good clinical outcome. The concern however about the number of devices is there is no regulatory factors for these devices, anybody can use any device if it's got a CE mark. We don't have data for each of these devices, so I think it's important we have some form of regulations even though it's not yet in place, perhaps some form of national registry for these devices, so that you can monitor the clinical outcomes and the success rate for such devices. If you're a physician you should be guided by the devices which are associated with the best possible clinical outcomes, and not the ones being promoted by industry. A National registry/regulation can possibly stop or prevent those devices which are not working that well when compared to others and should promote the ones that work well.