Stroke Treatment from Onset to Rehabilitation

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A B S T R A C T

This symposium acknowledged considerable variation across European in-hospital stroke services in their level of expertise, facilities available for rapid neuroimaging, and access to treatment interventions for acute stroke patients. Stroke neurologists face the dilemma of deciding whether to dispatch acute stroke patients to a highly specialised comprehensive stroke centre, or to the nearest available centre. In Catalonia, all stroke centres are connected by telemedicine networks, and emergency services have received training in the Rapid Arterial Occlusion Evaluation (RACE) scale that predicts large vessel occlusion (LVO). These initiatives were precursors to the ongoing t**RA**nsfer to the **C**losest local stroke centre vs. direct transfer to **E**ndovascular stroke **C**entre of **A**cute stroke patients with suspected LVO in the Catalan **T**erritory (RACECAT) trial. This study is expected to provide evidence-based guidance for the most appropriate hospitalization of acute stroke patents. The relative contributions of intravenous thrombolysis (IVT) and mechanical thrombectomy (MT), as single or combined treatment interventions, in acute stroke patients, have not been fully elucidated. The rationale for the SWIFT DIRECT study is presented. This will investigate IVT as a bridging concept plus MT, versus direct MT. Strong evidence demonstrating continuous cardiac monitoring with insertable cardiac monitors (ICMs) is superior to standard monitoring for the detection of AF is presented. Current guidance for short-term standard monitoring may lead to substantial numbers of patients with AF remaining undiagnosed. The use of the Reveal LINQ™ ICM and the FocusOn™ service provided by Medtronic is described. Finally, the role and clinical investigation of intrathecal baclofen for the treatment of post-stroke spasticity is discussed.

Key words: acute stroke, IVT, mechanical thrombectomy, RACECAT, SWIFT DIRECT, insertable cardiac monitors, intrathecal baclofen.

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INTRODUCTION

This recent symposium, held at the European Stroke Organisation Conference (ESOC) May 2017 meeting in Prague, and moderated by Professor Urs Fischer, presented important new initiatives and interventions that are making significant advances in the quality of care administered to stroke patients throughout the stages of their patient journey. The scope of this symposium was to cover the whole chain of survival from the acute stage of stroke, through aetiology, treatments, and rehabilitation. Improved outcomes are resulting from faster and more accurate initial assessment, faster diagnosis-led hospitalization and treatment decisions, and from supportive post-stroke rehabilitation interventions and treatment.

THE ANGELS INITIATIVE

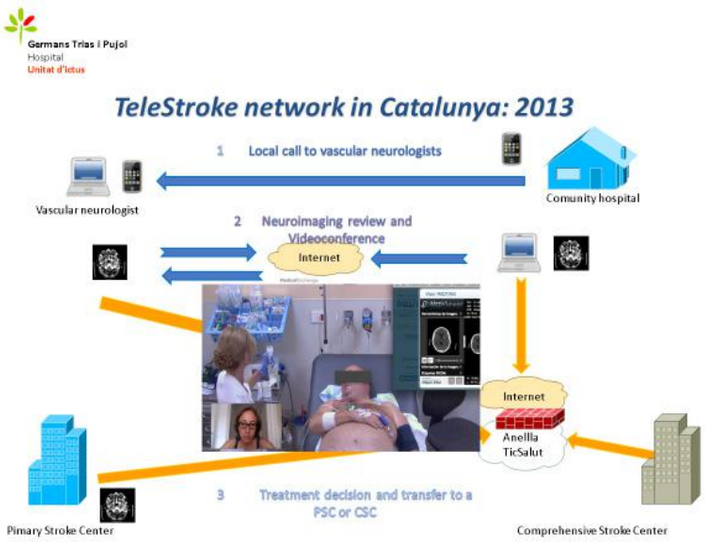
Professor Fischer, on behalf of ESOC, thanked Medtronic following their announcement of support for the Angels Initiative through a newly created partnership with Boehringer Ingelheim. The Angels non-promotional organization aims to create a community of at least 2,500 stroke centres and stroke-ready hospitals throughout Europe. The overall goal of the Angels Initiative is to improve the quality of care for stroke patients, through the implementation of evidence-based interventions and treatment solutions.
This symposium featured four individual presentations and a summary of each is included in this publication.

REGIONAL PRE-HOSPITAL ORGANISATION: THE CATALAN MODEL. PROFESSOR ANTONIO DÁVALOS, BARCELONA, SPAIN.

Time is of the essence when treating a patient who has suffered a stroke; however, there are important unanswered questions that arise during the acute phase. In particular, should patients go directly to specialised stroke centres for thrombectomy, if large vessel occlusion is suspected, or should the patient be transferred to a smaller hospital for initial thrombolysis with IV tissue plasminogen activator (tPA) before referral to specialised centre?

In Catalonia, in 2004, hospitals receiving stoke patients were initially identified as primary stroke centres or community hospitals. Of the 35 community hospitals, 12 had telemedicine links to primary stroke centres. Subsequently, in 2011, nine centres were designated as primary, and six centres (with mechanical thrombectomy experience) as comprehensive stroke centres (CSCs). Each CSC now has responsibility for community hospitals and in some case primary centres. Professor Dávalos discussed how three CSCs in Catalonia have developed a system of acute stroke care. From 2013, at any time, two of the three CSC teams are on call to cover the responsibilities of all three CSCs. One team manages endovascular thrombectomy (EVT) in its own centre plus all the telestroke management from feeder community hospitals. The second CSC manages EVT in its own centre plus EVT in the third centre; this involves the neurointerventional team moving between CSCs and avoids moving patients.

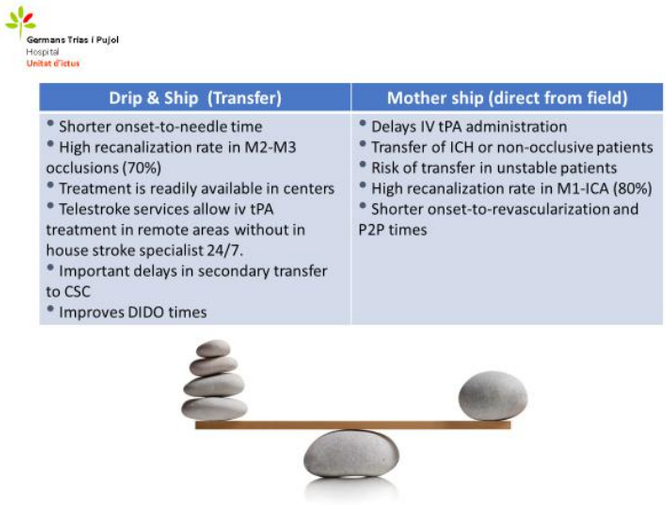
All community hospitals, primary stroke centres, and comprehensive stroke centres in Catalonia are now connected by telemedicine networks. Vascular neurologists at CSCs are available on a 24-hour basis to receive calls from community hospitals and to review neuroimaging by video conference, leading to more streamlined treatment and patient transfer decisions. Currently around 300 patients a year are evaluated in Catalonia in this way. In 2016, approximately a third of these patients received IV tPA, and over a half were transferred to primary or comprehensive stroke centres for EVT assessment. As a result of these telemedicine networks (shown in schematic form below), the use of IV tPA in community hospitals in Catalonia has increased.



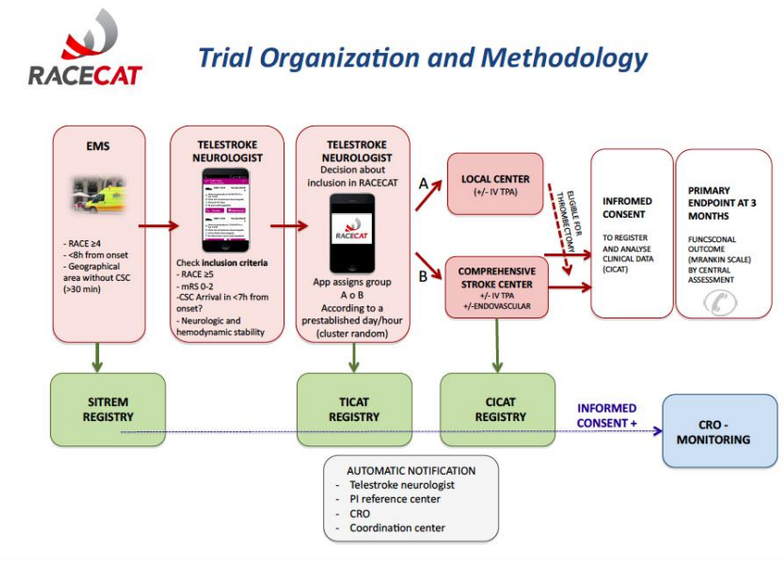
In 2012, SONIIA, a government mandated prospective registry was established with the aim of continuously monitoring the quality of all reperfusion therapies administered to patients with acute ischaemic stroke in publicly financed Catalonian hospitals. SONIIA provides information on the number of patients treated and records how successful treatments are. This registry has illustrated a steady increase in both IV tPA use and EVT in recent years. Importantly, SONIIA allows for benchmarking, and can provide information on outcomes achieved and relative performance comparisons (e.g. onset of treatment time) between individual centres.

Pre-hospital training in stroke has been a priority in Catalonia. Over 3,000 emergency dispatchers and technicians have received specialised training with

an emphasis on the 5-component Rapid Arterial oCclusion Evaluation (RACE) scale. This predicts large vessel occlusion (LVO) and identifies potential patient candidates for endovascular treatment on a 0 to 9-point scale. Currently, RACE evaluations are conducted in 80% of pre-hospital stroke assessments in Catalonia. In the light of these recent developments Professor Dávalos and colleagues have deliberated on whether they should develop and adopt a "drip and ship" or a "mothership" model approach to developing stroke treatment facilities. Potential advantages and disadvantages of the two treatment approaches can be listed as:



The recommendation from the 2016 ESO-Karolinska Stroke Update Conference was that in the absence of evidence, for patients considered eligible for intravenous thrombolysis (IVT) in the field, if estimated transfer time to the nearest primary stroke centre is considerably shorter than time to a comprehensive stroke centre (approximately more than 20-45 minutes), the drip and ship model should be considered. Rather than adopting this recommendation as the basis for a primary model, the Catalonia Stroke Programme decided on further investigation, and to conduct a study to clarify which model should be implemented to best effect. The RACECAT trial has been designed to compare the t**RA**nsfer to the **C**losest local stroke centre vs. direct transfer to **E**ndovascular stroke **C**entre of **A**cute stroke patients with suspected large vessel occlusion in the Catalan **T**erritory. This is an ongoing controlled trial where patients with acute stroke and suspected LVO (RACE scale score >4) are adjudicated to one of the two stroke circuits. The primary outcome variable is the modified Rankin Scale score at 90 days. In this study, the vascular neurologist is in control of all ambulances on a 24-hour basis, and is connected to the emergency medical services by video conference in real time. An overview of the organization and methodology of the study is shown in the following diagram.



The RACECAT trial started in March 2012 and to date (early June 2017) has enrolled 100 patients. The study aims to complete enrolment of a planned population of 1,774 in March 2020. Professor Dávalos summarised by noting that Drip and Ship compared with Mothership patient transfer results in longer times from stroke onset to both imaging and groin puncture for revascularization. A further concern is that advantages of direct transfer to a comprehensive stroke centre may be counterbalanced by delay in conducting successful pharmacological thrombolysis, particularly in distal occlusions. He stressed that the impact of stroke patient transfer models has not been analysed in trials; however, the RACECAT trial may provide insights and guidance for health authorities, and stroke neurologists, to develop the most appropriate systems of hospitalization and care for acute stroke patients in other regions.

SWIFT DIRECT: IN HOSPITAL STROKE TREATMENT PROFESSOR JAN GRALLA, BERN SWITZERLAND

The question of whether acute stroke patients should go directly to the angiography suite, or whether bridging thrombolysis should be administered is also challenging for in-hospital management of acute stroke. Professor Gralla is principal investigator on the Swift Direct study and he felt this study is likely to have considerable impact on the future in-hospital patient management in comprehensive stroke centres (CSCs).

Professor Gralla stressed that IV thrombolysis is effective and has been the gold standard treatment since 1995. Pooled analysis of intravenous alteplase vs. control studies (ECASS, ATLANTIS, NINDS, EPITHET and IST-3 trials) confirms the effectiveness of IV thrombolysis when administered within the time window of 4.5 hours. Notably, patients with low NIHSS scores are likely to receive greatest benefit with IV tPA compared with patients with high NIHSS scores. Therefore, the size of the thrombus does make a difference. Referring to a study conducted by Riedell et al (2014), Professor Gralla explained that the thrombus size in the MCA determines the likelihood of successful recanalization with IV tPA, If the thrombus is below 8 mm (small thrombus burden) there is a high chance of successful revascularization.

Professor Gralla pointed out that IV thrombolysis (IVT) and mechanical thrombectomy (MT) in LVO are complementary treatments: one is very effective in the distal vessels, and the other in proximal vessels. Meta-analysis data from RCTs investigating IVT vs. IVT and MT after large vessel ischaemic stroke show the combined treatment is highly effective. The number needed to treat (NNT) with endovascular thrombectomy to reduce disability by at least one level on the Modified Rankin Scale (mRS) for one patient was 2.6. Hence, the current prevailing contention is that treatment for distal vessel occlusion should be IVT only, and for proximal vessel occlusion IVT plus MT.

Professor Gralla reviewed the role of IVT in the treatment of large vessel occlusion and listed the arguments for and against its use in LVO.

Pro-IVT in LVO arguments	Arguments against ITV for LVO
• rtPA: Can be started fast / earlier than EVT • rtPA: Low infrastructural requirements rtPA: May facilitate recanalization • rtPA: May improve reperfusion of small vessels.	• rtPA: May delay EVT (procedure takes approximately30 mins) • rtPA: Poor recanalization rates in large vessel occlusion • rtPA: Narrow time window with decreasing efficacy • rtPA: May increases risk of hemorrhage • rtPA: May cause life-threatening complications • rtPA: May produce thrombus dislocation • rtPA: May limit dual antiplatelet medication (stenting) • rtPA: Impact on health care costs ($3,000).

rtPA = recombinant tissue plasminogen activator

Professor Gralla questioned what evidence was available to support mechanical thrombectomy (MT) intervention in IVT-eligible patients with large vessel occlusions. There is an increasing number of emerging publications that are focused on the use of MT alone vs MT plus IVT.in proximal vessel occlusions. This reflects the current high level of interest.in quantifying any potential benefits that the combined treatment may provide. Two publications were identified as relevant to the discussion here. Weber et al (2017) compared outcomes in patients with acute stroke treated with MT with and without bridging IVT. This study found no significant differences, at three months, in patients with LVO treated with and without bridging IVT. A retrospective matched-pairs analysis of direct mechanical intervention versus combined intravenous and mechanical intervention, in patients eligible for IVT who had suffered large artery anterior stroke, was performed by Professor Gralla's research team (Broeg-Morvay et al., 2016). This study revealed no notable differences in mRS scores between treatments at three months. In addition, IVT on top of MT may increase bleeding rates. Hence, in these studies, IVT did not appear to provide additional benefit.

Professor Gralla reviewed the Drip and Ship and Mothership approaches to hospitalization and treatment in the context of designing a new study. Following the ambulance call, there are two ways to treat patients with acute stroke:

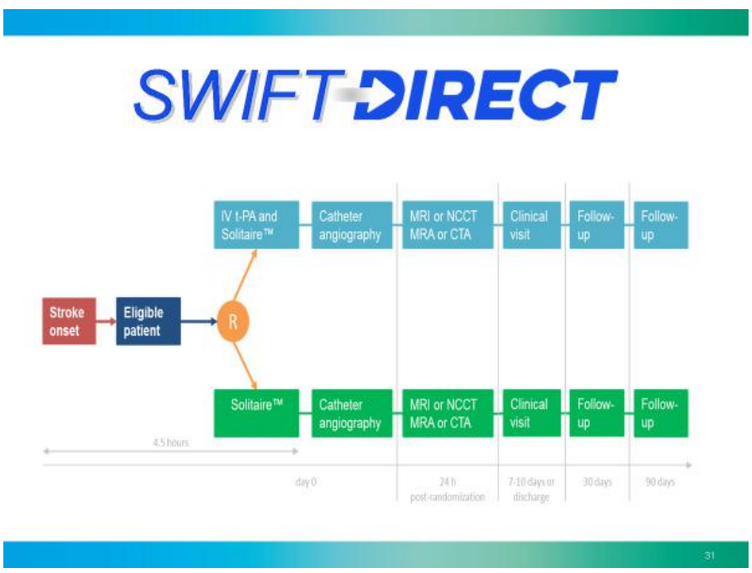
- Direct patient to a stroke unit and receiving IVT followed by transfer to a stroke centre for MT if revascularization has not been achieved (Drip and ship);

- Patient goes directly to a stroke centre and the decision taken to conduct IVT followed by MT (current gold standard based on RCTs) i.e. the Mothership paradigm.

However, an important question within the mothership paradigm is to ascertain whether there is any evidence of recanalization following IVT. Professor Gralla and colleagues have examined rates of relevant canalization associated with bridging IVT in mothership patients.

Canalization rates of 4-10% were observed in internal carotid artery (ICA) and middle cerebral artery (MCA) indicating that the effect of IVT in this time window within the work flow is not extensive.

A definitive RCT comparing mothership patients who will receive direct mechanical thrombectomy (MT) vs. IVT and MT is needed. And a key question, posed by Professor Gralla was: Is the future for mothership patients IVT for peripheral occlusions, and endovascular thrombectomy (EVT) only for LVO. This question will be addressed by the SWIFT Direct study i.e. Solitaire™ With the Intention For Thrombectomy Plus Intravenous t-PA Versus DIRECT Solitaire™ Stent-retriever Thrombectomy in Acute Anterior Circulation Stroke. SWIFT Direct will be conducted in European countries and Canada and will recruit 400 mothership patients eligible for IVT with proximal vessel occlusions (M1-MCA and ICA) including tandem occlusions. All patients will be randomized on a 1:1 basis to their allocated treatment, and this will be administered within a 4.5 hour time window at comprehensive stoke centres. The study will investigate IVT as a bridging concept plus MT versus direct MT, and only stent retriever thrombectomy will be performed. A non-inferiority design will be utilised and the primary outcome will be mRS assessment at 90 days. Recruitment will be from 30 high volume centres (>80-100 patients/ year), with well established fast in-hospital workflows. An outline of the design of the SWIFT Direct study is shown in the diagram presented below.



The study is planned to commence in July 2017 and should be complete in July 2020.

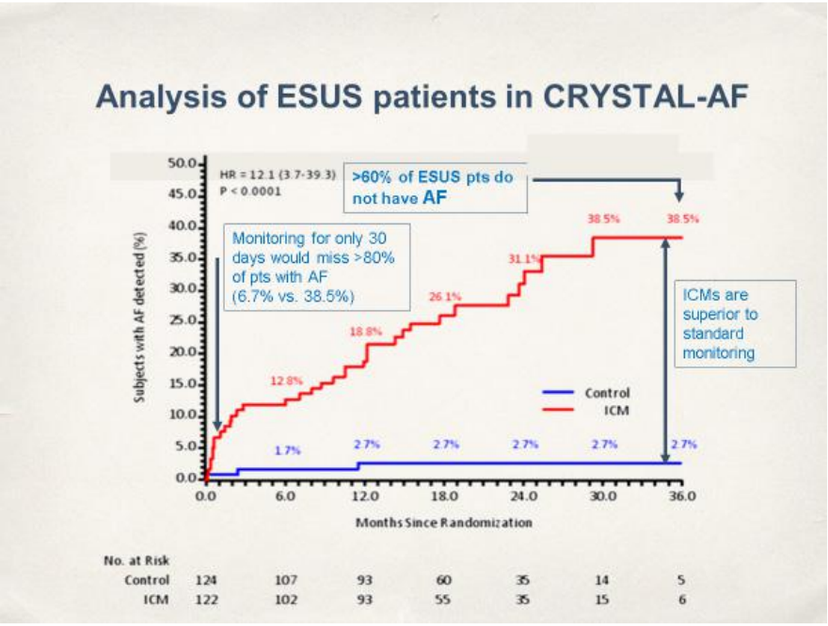
AF DETECTION USING INSERTABLE CARDIAC MONITORS: A CALL FOR NEUROLOGISTS. PROFESSOR KRASSEN NEDELTCHEV, AARAU, SWITZERLAND.

Professor Fischer introduced this presentation with a question: How thoroughly should we as stroke neurologists investigate our patients for atrial fibrillation (AF)?

Professor Nedeltchev acknowledged the complexity of stroke pathophysiology and etiology. Ischaemic stroke may result from several causes including large and small artery disease and a large sector of patients are classified as cryptogenic with stroke of unknown origin. Within the pool of patients with AF-related cardioembolic stroke, only one third is correctly classified at the time of stroke or TIA. The reason for this is that in more than two thirds of these patients, AF is occult, and remains undetected on the EKG at the time of stroke. To develop strategies for stroke prevention in cryptogenic stroke and embolic stroke of undetermined source (ESUS), Professor Nedeltchev outlined two approaches:

- Stroke neurologists can look harder and longer for AF and possible causes of stroke using non-invasive cardiac monitors, insertable cardiac monitors (ICMs), and identification of carotid or aortic plaques.
- All patients with stroke of unknown origin should receive anticoagulation on the assumption that these patients have undetected paroxysmal AF.

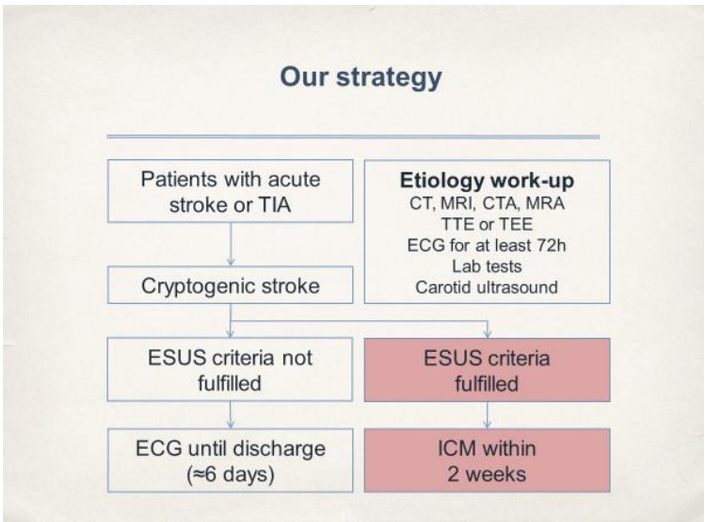
Cryptogenic stroke accounts for approximately 25-30% of all strokes; however, embolic stroke of undetermined source (ESUS) is a more recent and stringent classification and accounts for around 18% of all strokes. Professor Nedeltchev provided a summary analysis of cardiac monitoring in those patients who met ESUS criteria in the CRYSTAL-AF trial. In these patients, continuous cardiac monitoring with ICMs was superior to standard monitoring for the detection of AF. If monitoring of these patients had been restricted to one month - the duration of monitoring recommended by the American Heart Association – approximately 80% of patients with AF would have been missed.



A particularly striking figure to emerge from this analysis is that more than 60% of ESUS patients did not have AF. In an ESUS trial, these patients would receive anticoagulation that may not be beneficial, and may expose the patient to risks associated with antithrombotic therapy. These observations suggest that longer-term and improved continuous cardiac monitoring to identify whether AF is evident, or not present, is preferable to administering anticoagulation on the assumption that patients have undetected paroxysmal AF.

Professor Nedeltchev gave an overview of published studies that have used insertable cardiac monitors. The overall picture that emerges is that the vast majority of patients with AF are diagnosed beyond two months of cardiac monitoring. Professor Nedeltchev felt the use of non-invasive monitoring would lead to a sizeable proportion of patients with AF going undetected. The "simulation study" (Choe et al., 2015) was based on a sub-group of patients from the CRYSTAL-AF study who received insertable cardiac monitors (ICMs) within two weeks of having stroke onset. This allowed alternative intermittent monitoring strategies to be simulated. Notably, when compared with continuous monitoring with ICMs, all the simulated intermittent monitoring strategies showed a very low sensitivity (not more than 20%).

Given these concerns, Professor Nedeltchev presented the strategy that has now been adopted in his unit.

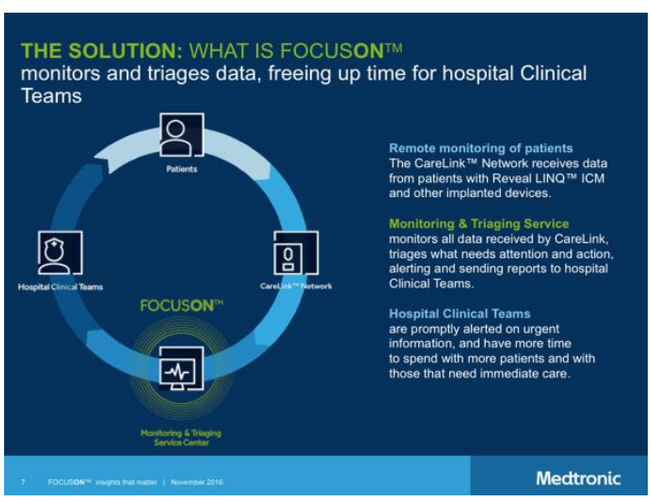


Where ESUS criteria are fulfilled an ICM is inserted within two weeks of stroke onset.

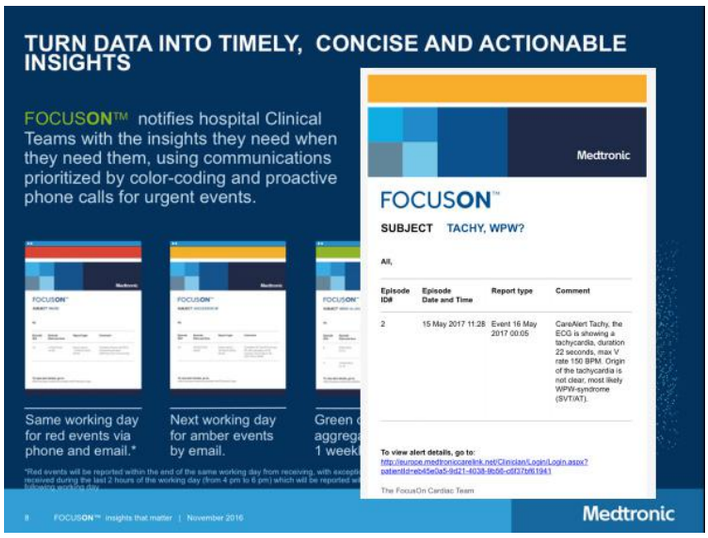
Whether a cardiologist or neurologist should conduct ICM insertion is potentially a subject of debate. Professor Nedeltchev did not have a definitive answer, but stressed the importance of "ABCD" principles in establishing good doctor-patient relations ships.

- A = Adherence: Take your time to inform your patients and ensure they fully understand the available medical information relevant to their condition and its treatment.
- B = Behaviour: Physicians should treat their patients decently and create a good interpersonal relationship.
- C = Continuity of care: This is known to improve patients' outcomes.
- D = Delays. Avoiding delays increases patients' satisfaction and improves clinical outcomes.

In line with principles C and D above, implantation of Medtronic's Reveal LINQ™ is undertaken personally by Professor Nedeltchev on his unit. He stressed the importance of adequate local anaesthesia, particularly for the region at the distal end of the ICM. Incision is conducted with the instrument provided by Medtronic. This may require a forceful approach in some patients, but thereafter implantation is straightforward. Professor Nedeltchev acknowledged the important back-up support from the FocusOn™ service provided by partnership with Medtronic. All EKGs recorded by Reveal LINQ are reviewed by a certified monitoring centre and reports will then be sent to the managing physician. This company has had experience of interpreting over 2 million EKGs since 1977, and currently deals with over 70,000 EKGs a year. Around 1,500 patients from 20 centres based in 11 countries have been enrolled into FocusOn™ so far. Key aspects of the FocusOn™ initiative are shown below.



The FocusOn™ service is built around a team of skilled cardiac data technicians, nurses and cardiologist, who classify transmitted patient data based on their clinical relevance. FocusOn™ reviews all EKGs, on a daily basis, for any that are suspicious for AF or other disturbances, and provides colour-coded alerts for the hospital clinical team managing the patient with the suspicious EKG. A red alert is reported by phone and e-mail within 24 hours and signifies AF or a life-threatening condition; amber alerts are e-mailed on the next working day, and green alerts are e-mailed on a weekly basis. Examples of these alerts are shown below.

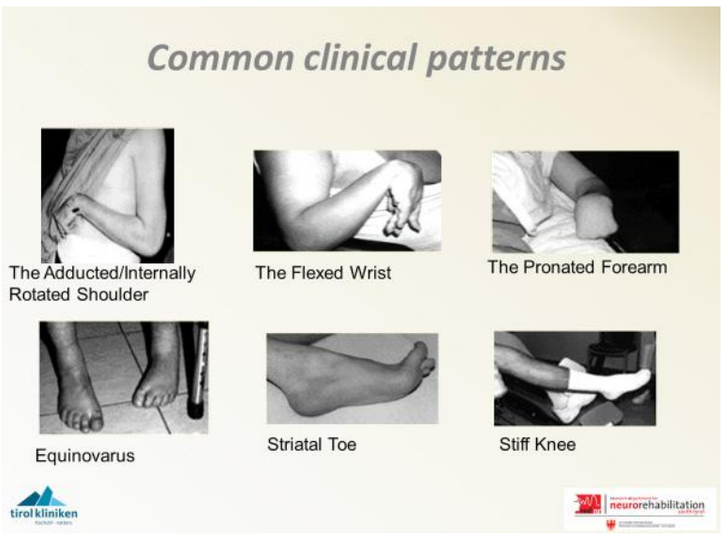


Hence, the FocusOn™ service provides time-saving, succinct, and prompt communications to healthcare professionals and identifies urgent cases that need the managing physician's immediate attention.

STROKE AND SPASTICITY: PROFESSOR LEOPOLD SALTUARI, INNSBRUCK, AUSTRIA.

Professor Saltuari began with a classical definition of spasticity: "A motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks resulting from hyperexcitability of the stretch reflex as one component of the upper motor neuron syndrome." However, in clinical discussions of spasticity, most physicians are referring to Upper Motor Neurone Syndrome (UMNS). Professor Saltuari stressed that a patient with spasticity is predominantly a paretic patient; he differentiated between phasic spasticity characterized by hyperexcitability of reflexes and clonus, and tonic spasticity defined by extensor and flexor spasms, Babinski sign, and dysynergistic patterns. The neurophysiology of UMNS is complex and Professor Saltuari highlighted the importance of disruption of descending control of spinal pathways and structural and/or functional re-organisation at the cerebral and spinal level.

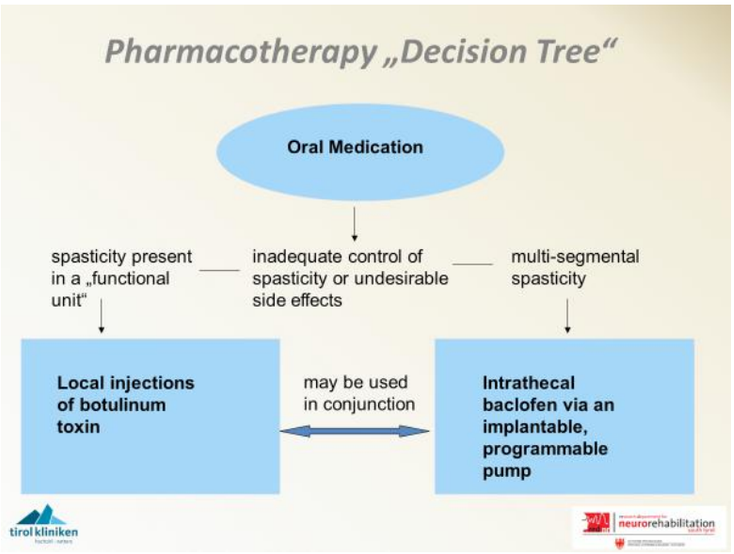
Professor Saltuari illustrated the common clinical features that are associated with spasticity.



In stroke patients, spasticity in the lower limbs often manifests as extension pattern, pes equinovarus and striatal toe. Collectively, these pathological patterns represent a major challenge to the restoration of mobility in stroke patients.

Measurement of spasticity relies on rating scales. The Modified Ashworth Scale is used for assessing tonic spasticity and categorises increases in muscle tone on a scale of 0-5, and reflex scales are used to assess phasic spasticity. Professor Saltuari described the effects of a 50 µg intrathecal injection of baclofen directly into the spinal fluid of patients with spasticity. After 30 minutes, the H/M ratio of the soleus H-reflex was reduced by approximately 50%, indicating reduced phasic activity. At two hours, Ashworth rating scores for the knee were also reduced by around 50% indicating reduced tonic activity. Altered reflexes in the brain stem were also observed. Interpreting these observations, Professor Saltuari, explained that intrathecal baclofen takes around 2 hours to reach the brain stem which generates the tonic spasticity response, whereas, phasic activity occurs at the spinal level.

Prevalence estimates of post-stroke spasticity (PSS) are highly variable with reported rates ranging from 4% to 42.6%, and disabling spasticity ranging from 2% to 13%. After three months' post-stroke, spasticity is evident in 17% to 42.6% of patients (Wissel, 2013). Professor Saltuari stressed that PSS can be very painful, and outlined a treatment algorithm for PSS. Typically, this involves physiotherapy and treatment with oral antispastic agents (baclofen, dantrolene, tizanidine). Side effects with oral treatment are common and this affects patient cooperation and compliance. Oral baclofen shows poor penetration across the blood-brain barrier, so high doses are required to reduce spasticity, but at the cost of poor tolerability and loss of patient cooperation. Focal treatment with botulinum toxin can be very effective for focal or multifocal problems due to spasticity. However, if these treatments do not achieve the desired therapeutic goals, Professor Saltuari emphasized that intrathecal baclofen should be considered before resorting to orthopaedic surgery, and this may help both low-capacity and high-capacity PSS patients.



Intrathecal baclofen avoids the problem of blood-brain barrier penetration and a dose in the order of 500 times smaller than an effective oral dose may be used.

In stroke patients, spasticity can give some positive contributions; notably: maintainence of muscle tone, helping the patient to stand against gravity, and trunk stabilisation. Sometimes the use of antispasmodic drug treatment can have a negative impact on these factors. To ilustrate this point, Professor Saltuari provided video footage of a young female patient with painful left-sided spastic hemiplegia. Physiotherapy, oral drug treatment, and botulinum neurotoxin had been unsuccessful. When intrathecal baclofen was administered, an improvement in spasticity was observed but the patient showed a mild weakness of the affected limb resulting in a reduction of the standing phase. For this reason, Professor Saltuari outlined the importance of pre-operative intrathecal baclofen evaluation of high level patients. Lumbar puncture and administration of intrathecal 50 or 100 µg baclofen, followed by assessments for reduction of spasticity and motor control will be very helpful in deciding the optimal dose. Following a convincing positive evaluation, and patient consent, pump implantation by the neurosurgeon can then proceed.

Professor Saltuari provided video footage of a young male patient with intracerebral haematoma of the upper brain stem with a "locked in" or caged pattern of spasticity hampering his motor control. Intrathecal administration of 400 µg baclofen (a large dose) led to a remarkable reduction in spasticity with loss of his caged posture, illustrating spasticity can be treated effectively with intrathecal baclofen.

A small-scale study conducted by Professor Saltuari and co-workers produced outcomes that justified the conduct of a prospective, randomized controlled trial of intrathecal baclofen versus conventional therapy in the management of severe post-stroke spasticity (the SISTERS trial). This study has now been conducted and publication of results will be forthcoming.

CONCLUSIONS

Rapid hospitalization of acute stroke patients, CT scanning, and provision of treatment likely to provide the best outcomes for individual patients, continue to be major challenges for healthcare professionals. Decisions on routing the patient to the most appropriate hospital stroke centre, and on whether IVT or mechanical thrombectomy (or both) are in the best interests of the patient can be difficult to judge. However, important well-controlled, randomized, clinical trials are being conducted. It is anticipated that these studies will high quality evidence to help stroke neurologists make these decisions quickly, and on a more informed basis. Accordingly, results from the ongoing RACECAT and SWIFT DIRECT studies are eagerly awaited.

Implantable cardiac monitors, particularly Medtronic's Reveal LINQ™ backed by the FocusOn™ EKG evaluation and reporting service, are improving the detection of AF. Continuous cardiac monitoring to identify whether AF is present, or not present, is preferable to administering anticoagulation on the assumption that patients have undetected paroxysmal AF. Finally, intrathecal baclofen therapy should be considered as treatment option for stroke patient with disabling spasticity which is not adequately managed by other treatments such as physiotherapy, oral drug treatment, and botulinum neurotoxin.

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