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Analysis of door-to-needle time for thrombolysis in acute ischaemic stroke using statistical process control charts

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ABSTRACT

Background Thrombolysis should be administered as soon as possible to suitable patients with acute ischaemic stroke. We introduced a new protocol for patients who had a stroke to achieve reduced door-to-needle times for the best possible outcome. Since then, we have closely monitored each patient who had a stroke. Our goal was to assess whether statistical process control charts could be useful in detecting deviations in door-to-needle times when using four well-known rules applied by Western Electric (WE rules 1–4).

Methods We analysed retrospectively door-to-needle times of together 200 acute ischaemic stroke patients before and after the implementation of our new stroke protocol. In addition, 25 patients at the time of reorganisation (transition period) were analysed. Statistical process control chart rules WE 1–WE 4 were applied to detect door-to-needle deviations and to monitor process uniformity.

Results Before the implementation of the protocol, median door-to-needle time was 53 min and after the implementation 20 min. Statistical process control chart rules were triggered only once in 100 patients before the reorganisation but seven times in 25 patients during the transition period. None of the rules WE 1–4 were activated after the reorganisation, indicating the stability of the reorganised acute ischaemic stroke process.

Conclusions The use of statistical process control charts demonstrated a significant reduction in door-to-needle times during the reorganisation. Further, it showed that the acute ischaemic stroke process with a 20 min door-to-needle time is very stable.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Statistical process control (SPC) charts have been used in medicine to investigate the stability of processes. However, SPC charts have very rarely been used to analyse the meticulous process of acute ischaemic stroke (AIS) when the door-to-needle time of thrombolytic therapy is very short.

WHAT THIS STUDY ADDS

⇒ SPC charts were an excellent tool to reveal changes in the AIS process and the homogeneity of the revised process.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ SPC charts, which are an easy way to present complex statistical analyses of processes, can be used in a high-quality, time-dependent AIS process in the emergency department.

BACKGROUND

When a patient suffers an acute ischaemic stroke (AIS), thrombolysis with tissue plasminogen activator (tPA), intravenous alteplase, will be given as soon as possible, if appropriate.[1–3] Patients mostly receive tPA within 4.5 hours after the onset of symptoms and with an in-hospital door-to-needle time (DNT) of 60 min or less.[1]

For patients with AIS, a median DNT of 20 min is feasible when neurologists organise the diagnostic pathway in a tertiary hospital.[4] However, even recently concerns have been raised as to why in most hospitals the implementation of an evidence-based stroke protocol has not been successful.[5]

In Finland, emergency medicine was recognised as one of the medical specialties in 2013.[6] Shortly thereafter, the chief neurologist of our hospital, Kanta-Häme Central Hospital (K-HCH), proposed a reorganisation of the AIS process. K-HCH is a tertiary hospital situated 80 km from Tampere University Hospital. K-HCH serves as a primary stroke centre for patients presenting with acute stroke symptoms.

We implemented a new treatment protocol for patients who had a stroke in our emergency department (ED), mainly led by emergency physicians (EPs).[7] CT, CT angiography and CT perfusion are used for stroke imaging. Availability of MRI is limited mainly to office hours imaging if needed. Thrombolysis is delivered in the CT room. Prior to thrombolysis, the patient's background, symptoms and their temporal relationship to the onset of stroke are considered. Additionally, the National Institutes of Health Stroke

Scale (NIHSS) score and any contraindications to thrombolysis are evaluated. Furthermore, any potential delay in the immediate radiologist's report is noted, as is the time stamp for door-in-door out for patients who require thrombectomy. All data, including DNT, were collected in conjunction with manual thrombolysis forms and electronic patient records.

We were able to show that it is possible to achieve a median DNT of 20 min with clinical results at least comparable to those in a system led by experienced neurologists.[8] Other studies on AIS protocols have reported findings similar to ours.[9–11]

In quality research, the outcome of time-dependent variables can be evaluated by calculating not only means or medians but also the upper and lower control limits (UCL and LCL) of the process.[12] Statistical process control (SPC) charts are used in a wide variety of processes.[13–15] SPC charts are also known as Shewhart charts according to their inventor, Walter Shewhart, who was working for Bell Labs in the 1920s. Charts can be used as a SPC tool to monitor whether a manufacturing or business process is in a state of control. Thus, the variation and its divergences are presented in visible form for a single employee. Using SPC charts, the process can be systematically analysed and, if necessary, deviations can be addressed to correct the process, thereby improving the quality of the process.

Although AIS patients can be treated safely and without delay, it is not certain whether the quality of the process remains constant.[16] The aim of the present study is to assess retrospectively whether interpreting SPC charts could be useful in identifying possible DNT deviations in the AIS treatment process in the ED.

METHODS

We were interested in whether SPC charts could identify early changes in DNT when a new treatment protocol for AIS patients was implemented. The second aim was to evaluate the stability of our process before and after the reorganisation. To determine if the process was under control, we used four well-known rules applied by Western Electric (WE).[12]

Rule number 1 (WE 1) consists of one point more than 3 SD from the mean, WE 2 two (or more) out of three consecutive points fall beyond the 2 SD and on the same side of the central line, WE 3 four (or more) out of five consecutive points fall beyond the 1 SD and on the same side of the central line and WE 4 eight (or more) consecutive points fall on the same side of the central line. UCL and LCL represent the normal, acceptable variation based on SD, from −3 to 3 SD from the mean. Any point outside the limits indicates a special cause for variation and should be investigated for better control.[12]

In our stroke process, the groups before and after the implementation of the new treatment protocol consisted of consecutive tPA-treated AIS patients, 100 before and 100 right after the reorganisation. Between them was the transition period, when the EP-led process was rehearsed and implemented in our ED.[7] In this study, we first ascertained whether the SPC chart rules could detect any deviations during the period before the reorganisation. Second, we analysed if the learning process in the treatment of 25 consecutive patients was noted by the SPC chart rules during the transition period. Finally, we used these rules to monitor the stability of our process after the reorganisation.

The inclusion criteria for this study were a patient with unprecedented symptoms of AIS ≤4.5 hours, evident clinical findings of AIS and a head CT without any haemorrhagic findings before the initiation of thrombolytic therapy. Exclusion criteria for the study included basilar thrombosis, unconsciousness and patients whose symptoms varied during the stay in the ED. In this publication, we used the Strengthening the Reporting of Observational Studies in Epidemiology cohort reporting guidelines.[17]

Analysis

The distribution of DNT values was positively skewed. In order to normalise these values, we used the natural logarithmic transformation. Adjusted means were calculated using this transformed distribution and control limits for the SPC chart were assessed. Finally, these control limits and the means were back-transformed. In addition to evaluating the SPC charts, we also conducted well-known statistical analyses of the material. The median DNT and the range of the distribution before and after the reorganisation were calculated. The non-parametric independent-samples Mann-Whitney test was used to reveal statistical differences. Median differences in DNT and NIHSS between the before and after groups were calculated by using independent samples Hodges-Lehmann estimate. We performed statistical analyses with SPSS Statistics V.29 (IBM, Released 2022. IBM SPSS Statistics for Windows). A $p<0.05$ was considered significant.

Table 1 Demographics of AIS patients undergone thrombolytic therapy

	Before, n=100	After, n=100	P value
Gender, female (%)	53 (53)	43 (43)	N.S.
Age, median; range	70 (38–97)	72 (30–96)	N.S.
DNT, median; range	53 (20–131)	20 (8–60)	<0.001
NIHSS, median (range)	7 (1–22)	6 (1–24)	N.S.

Results before and after the reorganisation are presented. Results of the transition period are omitted.
AIS, acute ischaemic stroke; DNT, door-to-needle time; NIHSS, National Institute of Health Stroke Scale; N.S, not significant.

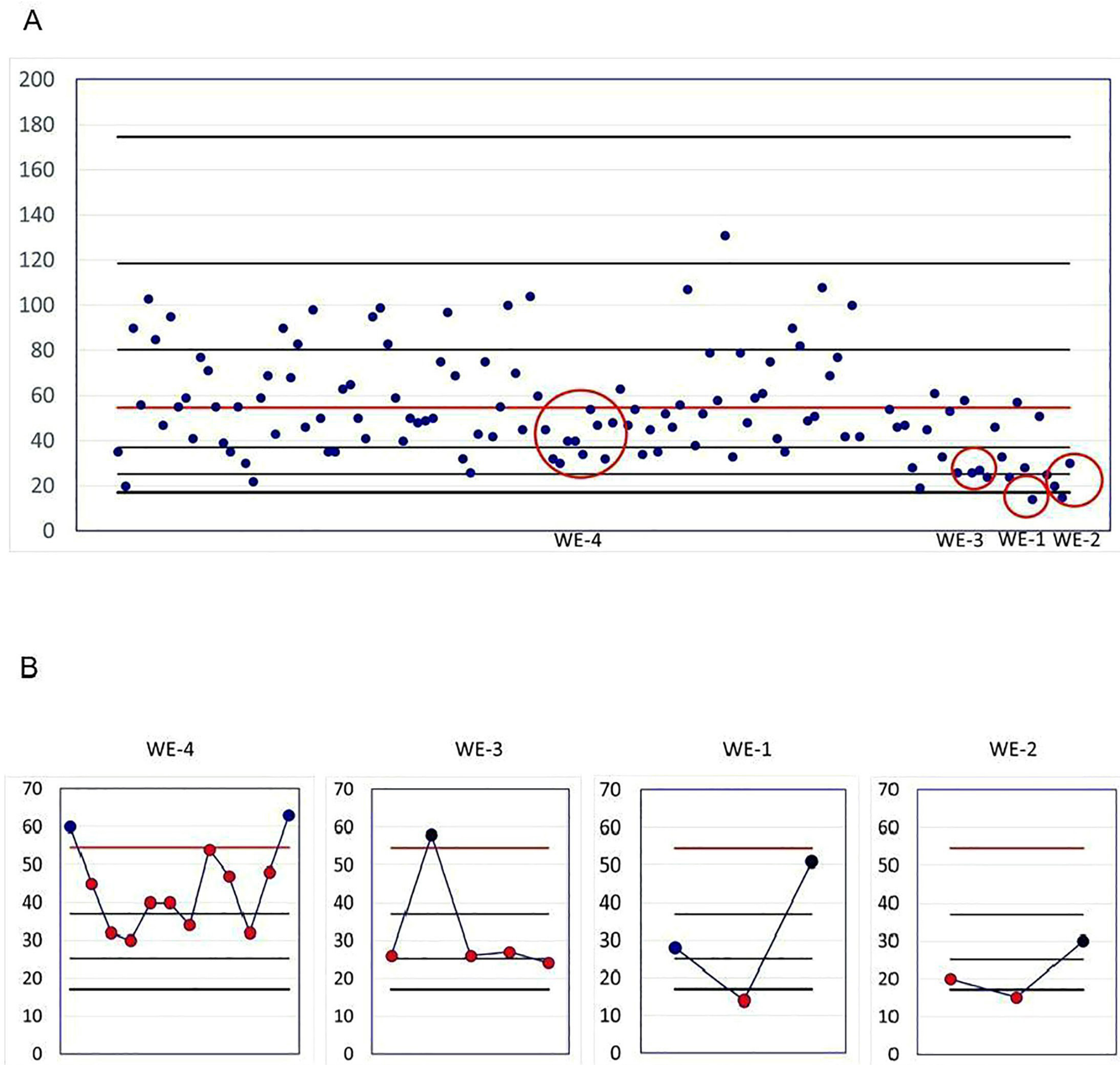

Figure 1 SPC chart showing DNTs (minutes) before the reorganisation of the AIS process and during the transition period (A). Examples of WE rules are presented in order of appearance (B). AIS, acute ischaemic stroke; DNT, door-to-needle time; SPC, statistical process control; WE, Western Electric.

RESULTS

Our study included 225 patients, 100 patients before the reorganisation from 2009 to 2012, 25 patients during the transition period and 100 patients after the reorganisation from 2013 to 2015. Their demographic data are compiled in table 1. The difference in median NIHSSs before and after the reorganisation was 0 (95% CI −1 to +2). The variation in DNT before the reorganisation added to the results of the transition period is presented in figure 1A. WE rules appearing in the data are presented in figure 1B. Before the reorganisation, only WE rule 4 was realised. In the transition period, WE rules 1–3 were triggered multiple times, WE rules 1 and 2 twice and WE rule 3 thrice.

DNT before and after the reorganisation—specifically, during the transition period—is presented in figure 2. DNT after the reorganisation was significantly lower than before it. After the transition period, none of the WE rules were realised. Median DNT before the reorganisation was 53 min and after the reorganisation 20 min. The difference in median DNTs was 32 (95% CI 28 to 37) min. Adjusted mean was 54.5 and 20.2 min, respectively. UCL was before and after the reorganisation 174.7 and 71.9 min, while LCL was 17.0 and 5.7 min, respectively.

DISCUSSION

The main result of this study was the ability of SPC charts to indicate the evident change in the DNT of AIS patients. Further, when the process was under control after the transition period, not a single WE rule was realised in the SPC charts.

To the best of our knowledge, this is one of the first studies to examine stroke protocol with the evaluation

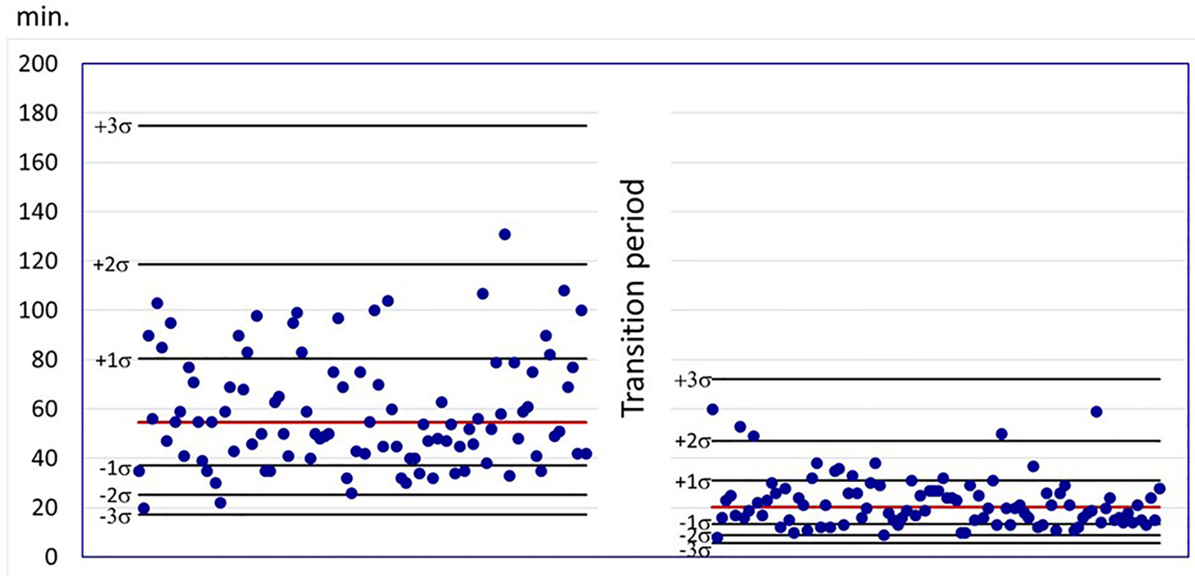

Figure 2 SPC chart showing DNTs (minutes) before and after the reorganisation of the AIS process. AIS, acute ischaemic stroke; DNT, door-to-needle time; SPC, statistical process control.

of DNT using SPC charts. We carried out a search in PubMed without time restrictions (search terms [Title/Abstract]: "stroke" AND "statistical process control" AND ["thrombolys*" OR "needle"]), which yielded only one publication. In Norway, Ajmi *et al*[10] implemented a revised stroke protocol by simulation-based training sessions. Fu *et al*[11] introduced theory-based resource integration for patients who had a stroke. Our results are in accordance with the evident reduction in DNT. Besides conventional statistics, these authors also demonstrated improvement in DNT with SPC charts, which was an illustrative way to present the results.[10 11] Also, Kamal *et al*[18] visualised DNT performance and picture to puncture performance over time in patients who had a stroke with simple charts. The advantage of the SPC chart is to identify unforeseen and intermittent causes and ultimately improves the whole stroke process.

This methodology has been used in other fields of medicine. We found one study with SPC on the door-to-balloon time in patients with ST-elevation myocardial infarction.[19] These results are not entirely comparable to those of our own project, but properly designed protocols and the SPC charts provided a statistically robust mechanism to assess the evident decrease in treatment delays after the process reorganisation and provided a visually clear presentation of the magnitude of the change in individual measurements.

SPC charts have been used especially in paediatric processes. Trau *et al*[20] implemented a new protocol for the pharmacological treatment of status epilepticus in the paediatric ED as a quality improvement initiative. They presented before-and-after SPC charts with treatment times of first and second-line antiepileptics. SPC charts showed decreased medical treatment times after the implementation of the new protocol. In another study, a four-part safety airway programme was launched to decrease the number of severe tracheal intubation-associated adverse events in tertiary and community paediatric EDs and urgent care settings.[21] Adverse events were reduced, which was clearly illustrated by SPC charts.

Reorganising established processes may be very difficult. We have noticed that when treating AIS patients and aiming to achieve reduced delays, the staff involved in the whole stroke process should understand the importance of rapid and targeted action. Following the reorganisation, each patient who has undergone thrombolysis is analysed every 6 months using the WE rules by a specialist and reported to the ED board. All outlier DNTs are meticulously examined, and any apparent discrepancies are rectified. Good results can be achieved through training, constant maintenance of situational awareness and close communication with neurologists.[7 8 22 23]

CONCLUSION

This is one of the first studies to report the use of SPC to analyse changes in the treatment process of AIS patients in the ED. The SPC charts showed a significant reduction in the DNT together with a great reduction in the variation in the DNTs of individual patients. To conclude, after the reorganisation, the treatment process of AIS patients was of better quality and more predictable than before, as was clearly visually demonstrated in the SPC charts. Our ED will continue to analyse the process to achieve the best possible result for AIS patients.

Contributors The study is based on an original idea of AP. MG and AP gathered the material. VH and TK made important interpretations of the data. MH performed the statistical analyses. MG, VH, MH, TK and AP drafted the manuscript. All authors read and approved the final manuscript. AP is responsible for the overall content as guarantor.

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Competing interests No, there are no competing interests.

Patient consent for publication Not applicable.

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