PERFEQTOS

Performance feedback on quality of care in hospitals performing thrombectomy for ischemic stroke, a cluster-randomized trial (PERFEQTOS)

STUDY PROTOCOL

Version 2.0 – August, 2020

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Steering committee
Members of the Executive Committee and all local Principal Investigators

Amendments

Version 1.0 - 08-11-2019

Version 2.0 – 06-08-2020
Summary of the main changes:

- Composition of Executive Committee and local Principal Investigators (page 2-3)
- Stepped-wedge design and procedure of randomization (chapter 3, page 10)
- Sample size calculation based on 13 hospitals instead of 17 hospitals (chapter 4, page 11)
- Description of the quality indicators dashboard (chapter 5, page 12)

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

AVG	General Data Protection Regulation (in Dutch: Algemene Verordering Gegevensbescherming)
CT	Computed tomography
DASA	Dutch Acute Stroke Audit
DICA	Dutch Institute of Clinical Auditing
EVT	Endovascular treatment
GDPR	General Data Protection Regulation
IVT	Intravenous thrombolytics
METC	Medical research ethics committee (MREC); in Dutch: medisch ethische toetsing commissie (METC)
MRDM	Medical Research Data Managment
mRS	modified Rankin Scale
NIHSS	National Institute of Health Stroke Scale
PIP	Performance Improvement Plan
QIT	Quality Improvement Teams
UAVG	Act General Data Protection Regulation (in Dutch: Uitvoeringswet Algemene Verordering gegevensbescherming)
WGBO	Act on the Medical Treatment Contract (in Dutch: Wet op de geneeskundige behandelingsovereenkomst)
WMO	Medical Research Involving Human Subjects Act (in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen

SUMMARY

Background: The treatment effect of endovascular thrombectomy (EVT) for ischemic stroke on functional outcome is highly time-dependent. Therefore, process indicators such as door-to-groin time are considered measurements of quality of stroke care. Although provision of performance feedback to healthcare professionals based on data from quality registries is common practice in many fields of medicine, observational studies of its effect on quality of care have shown mixed results. We propose an interventional study about the effect of performance feedback on quality of care for ischemic stroke.

Objective: The overall aim of this study is to assess whether performance feedback to healthcare providers in individual hospitals providing EVT for ischemic stroke, resulting in action plans and targets based on this feedback, improves door-to-groin time and thereby quality of care.

Setting: Thirteen hospitals in The Netherlands providing endovascular treatment (EVT) for ischemic stroke, participating in the Dutch Acute Stroke Audit (DASA) from the Dutch Institute of Clinical Auditing (DICA), will participate in this study.

Study design: This is a stepped-wedge cluster randomized trial. The study will be initiated with a period of 6 months in which no hospitals receive the intervention. Subsequently, every six months three to four hospitals are randomized to cross over from the control to the intervention group. This process continues until all hospitals are crossed over to receive the feedback intervention.

Intervention group: These hospitals will receive performance feedback consisting of three-monthly reports with patient characteristics, structure, process and outcome indicators on patients with ischemic stroke treated with EVT. Hospitals can compare their present performance with their own performance in the past and with other hospitals in The Netherlands. The performance feedback is provided to local Quality Improvement Teams (QIT), including at least a neurologist, interventional (neuro)radiologist, neurology resident, and a stroke nurse. The QIT uses the performance feedback report to define their own target(s) on (a) specific indicator(s) and to develop a performance improvement plan (PIP). The impact of this improvement plan is evaluated in the next three-monthly performance reports.

Control group: These hospitals receive no structured performance feedback and are not yet required to have a QIT and PIP.

Primary outcome: Door-to-groin time.

Secondary outcomes: Door-to-needle time, post-EVT recanalization grade (eTICI), post- EVT neurological deficit (NIHSS after 24 hours), functional outcome measured at 3 months (modified Rankin Scale (mRS)), adjusted for prognostic factors at baseline.

Statistical analysis: The effect of intervention will be analyzed in multilevel regression models that accommodates the cluster design of the study and adjust for center and patient characteristics as well as time since start of the trial.

1. INTRODUCTION AND RATIONALE

Endovascular therapy for ischemic stroke

Each year, more than 20,000 ischemic stroke patients are admitted in Dutch hospitals and 8,500 patients die because of stroke. (1) The outlook on treatment of ischemic stroke has improved drastically by the introduction of endovascular treatment (EVT). With EVT, the interventional neuro-radiologist advances a catheter through an artery in the groin up to the blocked intracranial artery to remove the blood clot. A meta-analysis of randomized trials showed that EVT strongly improves three-month functional outcome with an absolute risk reduction in terms of death or permanent disability of 19.5%. (2, 3) However, the effect of EVT is highly time dependent. Every hour delay from start symptoms to the initiation of EVT results in death or permanent disability in 1 out of every 19 patients.(4) Having the right infrastructure and an efficient process of care is of utmost importance to be able to treat every patient as fast as possible and to achieve optimal outcomes.

Performance feedback

We hypothesize that giving feedback to healthcare providers on the performance of their own hospital improves processes of care and leads to better outcomes. Providing performance feedback regarding process indicators to health care professionals is already quite common in healthcare. (5, 6) Many medical registries give performance feedback to the healthcare provider on a continuous basis, but there is no empirical evidence indicating how this feedback is best provided.(5) Research on the effectiveness of feedback on quality of care showed mixed results. The feedback intervention effects are very heterogeneous and no operationalization factors are identified to support the design and delivery of effective audit and feedback interventions. Understanding this variability has been limited in part by lack of explicit design of the feedback interventions (7-10) and the absence of quantitative evaluation of effectiveness.

2. OBJECTIVES

The overall aim of this study is to assess whether performance feedback to healthcare providers in individual hospitals providing EVT for ischemic stroke, resulting in action plans and targets based on this feedback, improves door-to-groin time and thereby quality of care.

3. STUDY DESIGN

Study design

We will conduct a stepped-wedge cluster randomized trial. This is a special form of a randomized experiment in which an intervention at group level (here: group of hospitals) is introduced step by step (figure 1). The design can be used when randomization at individual level is not possible and when it is desirable for ethical, logistical or financial reasons that the intervention is introduced in steps. (11)
The study will be initiated with a period of 6 months in which no hospitals receive the intervention. Subsequently, every six months three to four hospitals are randomized to cross over from the control to the intervention group. This process continues until all hospitals have crossed over to receive the feedback intervention. Having all hospitals receiving feedback at the end of the study, in contrast to a usual cluster randomized trial where half will remain in the control group, increases the willingness of hospitals to participate because feedback is perceived to be useful.

The analysis of a stepped-wedge design offers two possibilities. First, a comparison can be made between the effects of all hospitals at the time of the experimental intervention and all hospitals at the time of the standard treatment. Secondly, it provides an opportunity to measure the effects of time of the intervention and investigate the effect of underlying temporal changes because of its longitudinal settings. (11)

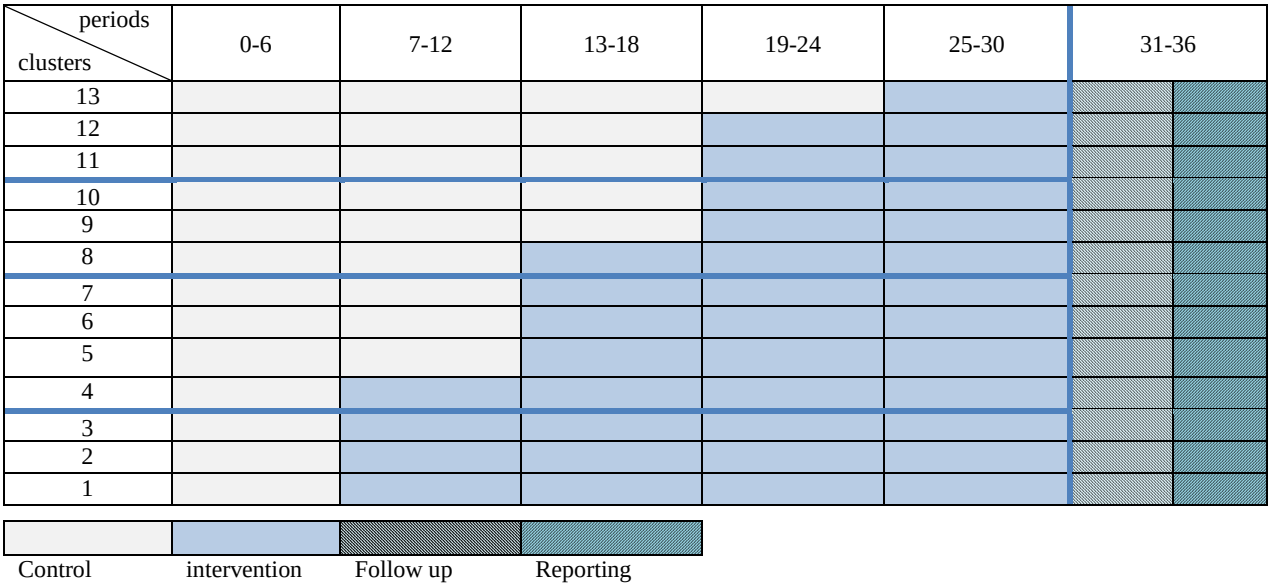

Figure 1. Stepped-wedge intervention allocation and study flow.

Randomization, blinding and treatment allocation

Hospitals are randomized to cross over from the control to the intervention group. Randomization will be done by picking balls from a bowl containing small pieces of paper with hospital names by the Study Coordinator in presence of the Principal Investigator and an independent observer.

4. STUDY POPULATION

Population base
EVT is provided in intervention hospitals specialized in EVT in The Netherlands. 13 out of 17 EVT hospitals approved to participate in the study. We will collect data of patients with an ischemic stroke who were registered in DASA as treated with EVT.

Figure 2 Participating hospitals

Power calculation
We assumed 13 EVT centers to be randomized in four clusters per time step with a mean of 30 patients per center and a mean door-to-groin time of 77 minutes (standard deviation: 46 minutes) and ICC 0.37 (estimates obtained from the MR CLEAN Registry data). Assuming a significance level of 5%, this would result in 88% power to detect a clinically relevant reduction in the mean door-to-groin time of 10 minutes.

5. INTERVENTION

Quality indicators dashboard

Hospitals in the intervention arm will receive three-monthly feedback through reports with quality indicators, based on the DASA data collected in their own hospital. These indicators are defined with the Donabedian framework including indicators of structure, process, and outcome.(12) Furthermore, the case-mix of the treated cohort will be summarized with relevant patient characteristics at baseline.

Patient characteristics:

- Age
- Time from onset to presentation in the hospital (onset-to-door-time) stratified for directly referred and transferred patients
- NIHSS at presentation in the hospital
- Location of the proximal intracranial occlusion

Structure indicators:

- Total number of patients treated with EVT (volume)
- Number of direct and transferred patients treated with EVT

Process indicators: (stratified for directly referred and transferred patients)

- Time from presentation in the hospital to IVT (door-to-needle time)
- Time from presentation in the hospital to initiation of EVT (door-to-groin time)

Outcome indicators:

- Post-EVT recanalization grade (eTICI score)
- Neurological deficit after EVT at 24 hours (NIHSS)
- Functional outcome measured with the modified Rankin Scale (mRS) at three months

These quality indicators will be presented through an interactive dashboard. The indicators for the participating hospital will be compared with the average results of other hospitals for the same time period and with their own results of before the trial.

Quality Improvement Team

Every three months, the healthcare providers of all hospitals in the intervention arm will receive feedback through the dashboard. Each hospital will install a local Quality Improvement Team. This team minimally consists of a neurologist, an interventional (neuro)radiologist, a resident in neurology, and a stroke nurse. It can be expanded with representatives of other relevant disciplines.

Performance Improvement Plan

The members of the local Quality Improvement Team analyze the three-monthly feedback and use this feedback to set targets on (a) specific indicator(s) to improve the quality of care and to develop Performance Improvement Plans to achieve these targets. The impact of this improvement plan is evaluated in the next three-monthly performance report.

Workshops

We will arrange workshops with all the hospitals in the intervention arm every six months. The best performing hospitals and best improving hospitals will share their way of working and executed quality improvement plan.

6. OUTCOME

Primary outcome
Time from presentation in the hospital to initiation of EVT (door-to-groin time).

Secondary outcomes
- Time from presentation in the hospital to IVT (door-to-needle time)
- Post-EVT recanalization grade (eTICI score)
- Neurological deficit after EVT (NIHSS at 24 hours)
- 3-month functional outcome (mRS)
- Completeness of data delivered to DASA

7. DATA COLLECTON AND PROCESSING

Data are routinely collected in the Dutch Acute Stroke Audit (DASA), in which structure, process and outcome measures of all stroke patients are registered. The DASA is facilitated by the Dutch Institute for Clinical Auditing (DICA), an independent organization, founded by medical specialists, that facilitates national audits for numerous medical professions. The National Health Care Institute ('Zorginstituut Nederland') utilizes DICA to fulfil the role given by the government of maintaining the quality and affordability of health care in the Netherlands as well as provide transparency in quality of care to the public. Funding for the audit is ensured by 'Zorgverzekeraars Nederland' (i.e. the umbrella organization of nine health insurers in the Netherlands). Hospitals are free to decide who carries out the data registration (for instance (research) nurses, data managers or neurologists), but the final responsibility rests with the neurologist. Medical Research Data Management (MRDM), a Trusted Third Party, is involved to pseudonymize the data to comply with privacy legislation. Hospitals have three ways to provide the collected data to this data processor. First, an online survey through a secured web environment is available for hospitals to record the data. Second, hospitals can distribute the data in batches, i.e. data files in which large amounts of data can be transferred directly to the data processor. Third, to minimize registration burden, some hospitals took initiative to implement data linkage, i.e. extracting the data from their individual electronic patient health record to be automatically forwarded to MRDM.(13)

Participating hospitals will sign a written agreement that allows MRDM to send pseudonymized data about the patients treated in their hospital to Erasmus MC for the purpose of this study. These data are encrypted by MRDM and sent to the study coordinator in Erasmus MC. The study coordinator will convert this data into averages and percentages on an aggregated (hospital) level. This aggregated data will be summarized in a performance feedback report in a dashboard format. All hospitals that are randomized to the intervention arm of the trial will receive an updated performance feedback report every three months.

8. STATISTICAL ANALYSIS

Descriptive statistics:
Median (and interquartile range) or percentage of case-mix and indicators of quality of care will be presented per hospital. The results of each hospital will be compared with other hospitals, before and after implementation of the intervention. The summary statistics of each cluster (hospital) will be compared using Pearson's chi-square statistic and a non-parametric Kruskal Wallis test.

Missing variables:
Multiple imputation will be used in cases of missing data on baseline patient characteristics. This will be done with multivariate normal models. Missing process measures and outcomes will not be imputed.

Analysis of intervention effect on outcomes:
We will use (generalized) linear mixed models for analyzing the effect of performance feedback intervention on the primary and secondary outcomes. Adjusting for the systematically different observation periods and for clustering in the data will be accomplished by fitting an appropriate model with the fixed effects for intervention yes/no, calendar time (month) to account for autonomous time trends, and baseline patients' characteristics, and random effect for cluster.(14) In this model we can estimate the variance of outcome at the cluster level (inter cluster variation) and individual level (intra cluster variation) to estimate the total performance feedback effect. The increase in the variance due to the clustering will be given by variance inflation factor.

9. ETHICAL CONSIDERATIONS

All patients will receive usual care according to national and local guidelines and current insights.

Ethical statement
This study does not fall within the scope of the Dutch Medical Scientific Research with People Act (WMO). The research protocol has been submitted to the Medical Ethical Authorization Committee of Erasmus MC for confirmation.

Privacy
Clinical information about patients is processed in the context of the clinical audits. Both the Act on the Medical Treatment Contract (WGBO) and the General Data Protection Regulation (AVG) and the Dutch Implementation Act General Data Protection Regulation (UAVG) apply to this processing. The processor (MRDM), on behalf of the healthcare providers, processes this data in such a way that DICA receives only pseudonymized data from patients. Pseudonymized, in accordance with the General Data Protection Regulation (GDPR), means that personal data have been processed in such a way that they can no longer be linked to a specific person without additional data being used. These additional data are stored separately and technical and organizational measures are taken to ensure that personal data are not linked to an (identifiable) person.

Patient recruitment and informed consent
We use data collected routinely for quality purposes. The data are collected with a waiver of patient consent as is common in clinical audits.

10. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

Data collection and storage
The pseudonymized data from DASA are stored on the Erasmus MC's secure server, which is only available to the study coordinator and principal investigator.

Publication policy
After the last follow-up has been completed, the database is locked and made available for scientific research. The research team will then write a scientific paper about the feasibility and effectiveness of performance feedback to individual hospitals providing EVT for ischemic stroke.
The main paper will be published in an international scientific journal in the field of acute stroke care and presented at international congresses for stroke specialists.

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