Fondation Ophtalmologique Adolphe de Rothschild

INTERET DE L'ASPIRATION DISTALE PREMIERE DANS LA RECANALISATION PAR THROMBECTOMIE DANS L'INFARCTUS CEREBRAL

Endovascular revascularization with contact aspiration versus stent retriever in ischemic stroke with large vessel occlusion, the ASTER TRIAL: A Randomized Clinical Trial.

ASTER

PROTOCOLE DE RECHERCHE EN SOINS COURANTS

Code de la recherche: MPN_2015_22 Version n°1.1 du 24/07/2015

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The study protocol and the form of consent were approved by the CPP (Comité de Protection des Personnes) Ile de France VI, ID 2015-A00830-49,

1. Scientific Rationale - Introduction

Mechanical thrombectomy (TM) has now been validated by 4 published randomized studies (Cf. MR CLEAN, 2014 ESCAPE, 2015, SWIFT PRIME, 2015, EXTEND IA, 2015). These studies have shown for the first time that mechanical thrombectomy is the reference treatment for cerebral infarction related to proximal cerebral occlusion and results in -35% of severe cerebral infarction disability and decreased mortality. All of these studies used stent retriever thrombectomy devices to achieve 58-72% recanalization (MR CLEAN, 2014 ESCAPE, 2015) .This "recanalization" criterion is of major importance because it largely determines the functional prognosis of patients following cerebral infarction (Khatri, 2014).
These results are exciting but we can do even better. Indeed, already new strategies of thrombectomy are available with a particular attraction for ADAPT (A Direct Aspiration first Pass Technic). This technique involves starting the thrombectomy procedure by direct aspiration of the thrombus, using a dedicated suction catheter. This technique provides a high level of endovascular navigability and allows high recanalization rates (> 90%), with low morbidity (Turk A, 2014 and Kowoll 2015).Indeed, if recanalization is not obtained with the aspiration catheter, the operator can deploy a stent retriever through the suction catheter, combining the interest of both techniques.

We first performed a comparative observational study between these two strategies among 244 patients in two centers (FOR, and Hôpital Foch) for cerebral infarction related to a proximal occlusion. This is, to date, the largest series of patients with ADAPT as a first line strategy. The complete recanalization rate was 84% with ADAPT versus 68% with a stent retriever (P = 0.006) (Unpublished data, Oral presentation at the European Stroke Organization, April 2015).
Our study aims to evaluate in a rigorous way whether the first-line aspiration during thrombectomy in the acute phase of cerebral infarction is of interest to patients in terms of immediate surgical success and prognosis for the patient. The aim is to determine the best thrombectomy strategy to reduce the stroke patient's disability. Indeed, recanalization of the occluded artery is the major prognostic factor associated with patient disability. Currently, stroke affects 1 patient every 4 minutes in France, with each year, approximately 130,000 new patients (prevalence estimated at nearly 800,000 patients, of which 500,000 will have sequelae).
In 2004, cerebral infarction was the most costly pathology for the health care system in terms of average annual expenditure per patient and the total reimbursement per long-term condition (ALD). With endovascular therapy (mechanical thrombectomy), there are twice as many patients who can live independently after this type of stroke. A retrospective preliminary study suggests that the ADAPT thrombectomy system has a better cost-effectiveness ratio (Turk, AS, 2014).

2. Objectives of the research

2.1. Primary objective:

- To demonstrate the superiority of a first-line aspiration strategy (ADAPT) during cerebral thrombectomy, compared with first-line stent retriever use in cerebral infarction related to proximal occlusion

2.2. Secondary objectives:

- To compare, between these two strategies of thrombectomy:
  • the degree of recanalization at the end of the first treatment strategy

• the procedural delays
• the rate of intraoperative complications: perforation, dissection, subarachnoid hemorrhage, the presence of erratic cerebral embolisms
• complications at the groin puncture
• the incidence rate of 24-hour cerebral hemorrhage• 3-month disability of patients
• the proportion of deaths at 3 months, related to cerebral infarction

- To compare the interest of the two strategies in subgroups of patients: according to the occlusion site (average cerebral, internal carotid, tandem), depending on the length of the clot evaluated on the initial imaging.

- To carry out a cost / effectiveness evaluation of the two strategies

3. Population selection

3.1. Inclusion Criteria

- Age> 18 years
- Cerebral infarction of the anterior circulation (carotid termination in T or L, ACM1 or ACM2)
- Occlusion of the anterior circulation proved by imaging (angioCT or MRI)
- With or without prior intravenous thrombolysis
- Access to recanalization by endovascular treatment within 6 hours of symptom onset

3.2. Criteria for non-inclusion

- Absence of indication or contraindication to thrombectomy - Association with a cerebral infarction of the posterior circulation - Occlusion of the cervical carotid.
- Allergy to radiographic contrast products
- Patient dependent before stroke (modified Rankin score> 3)
- Known pregnancy, breastfeeding
- Person with legal protection
- Non-affiliation to a social security scheme
- Opposition of the patient or (in case of urgent inclusion) of his / her relatives

3.3. Secondary exclusion criterion

- No access for catheterization

4. Research Methodology

4.1. Design of the study

- Prospective, randomized, multicenter trial, controlled in two parallel groups
- Centralized 1: 1 randomization, stratified on the center, and on prior IV thrombolysis
- The assessment of the primary endpoint will be made by two independent neuroradiologists who will be unaware of the thrombectomy strategy.
- The protocol provides for the enrollment of patients in an emergency situation (L. 1122-1-1 and L.1122-1-2)

4.2. Organization of the study

Description of the endovascular strategies

According to the recommendations of the French Neurovascular Society , the medical strategy of management of acute proximal occlusions within 6 hours involves the following medical measures:

- hospitalization of the patient in a neurovascular unit

- treatment by IV thrombolysis if the patient is eligible
- initiation of medical products, acts, and methods to prevent or treat the worsening or recurrence of cerebral ischemia
- the initiation of products, acts, and methods to prevent or treat general complications related to decubitus or the neurological state of the patient.

Currently, an increasing number of operators begin the thrombectomy procedure by frontline contact aspiration. This strategy makes it possible either to recanalize the occluded artery, or otherwise to mount a stent retriever (synergistic technique) through the suction catheter in case of failure of the aspiration. However, the effectiveness of this strategy has never been proved.
The common practice is therefore variable according to the operator, who can choose to use either aspiration (ADAPT technique) or the stent retriever. In case of failure or operational difficulty, operators can switch from one strategy to another.

In the ASTER study, thrombectomy is planned for all patients included. Randomization will determine whether aspiration is used in the initial therapeutic strategy. Patients randomized to the ADAPT group will therefore undergo a first distal aspiration. Patients in the "stent retriever" group will not have this initial aspiration. The first aspiration thrombectomy procedure (ADAPT) or stent retriever procedure will be performed according to the recommendations of good practice (a maximum of 3 passes, if necessary, before concluding that the technique has failed, and use of a proximal occlusion balloon in the retriever stent arm).
The choice of adjuvant techniques will be left to the operator's discretion. This information will be collected in the FIU. In the event of failure, the rescue procedure is left to the operator's choice, with the aim of guaranteeing the patient the best chances of recanalization, and according to the usual practice of the center.

The type of device used during thrombectomy will be the one routinely used in the center. The centers participating in the study are thus centers that routinely practice both types of technique. All devices used will be CE marked for this indication. The thrombectomy will be carried out by operators who meet the qualifications required for the accreditation of NRI exercise by HAS 2013, having experience in both techniques. Concurrent treatments for the use of these stents and the option of anesthesia (conscious sedation or general anesthesia) are the usual prescriptions for the routine management of these patients.

Population of the study
Patients hospitalized for suspicion of ischemic infarction secondary to an occlusion of the anterior circulation within 6 hours from stroke onset.
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Information and non-opposition to patient participation
After verification of the inclusion and non-inclusion criteria, the principal investigator or one of his / her collaborators (registered on the delegation of authority log) will explain to the patient the objectives and conduct of the study, using an information form and will seek non-opposition from the patient.
Most patients eligible for this research will not be in a state of consciousness allowing comprehension of this information; moreover, the inclusion will be carried out in an emergency context. If the state of consciousness of the patient does not allow this, and in view of the therapeutic urgency, the non-opposition of a relative (trusted person if it is present) will be sought so as not to delay the management of the patient. Otherwise, the physician will include the patient according to the inclusion protocol in emergency situations. Once the patient has regained a sufficient state of consciousness, his / her objection to further research and processing of the information collected will be sought.
The patient can leave the study at any time on request. Patients not complying with the protocol and patients lost to follow-up will not be excluded from the study.

Randomization Procedure
After checking the inclusion and non-inclusion criteria and the patient's non-opposition, the randomization

will be done by computer server, the system automatically assigning the strategy group and the inclusion number. The inclusion will be effective after randomization. The patient will then be permanently assigned to the strategy in question.

4.3. Evaluation criteria

Main Assessment Criterion

Comparison between the two thrombectomy strategies (randomization groups with first aspiration [ADAPT] or with stent retriever) of the percentage of patients with complete recanalization (final score TICI 2b-3, annex) at the end of angiography.

The assessment of the primary endpoint will be made by an independent evaluator blinded to the endovascular procedure.

Secondary Criteria for Assessment

Comparison between the two strategies of thrombectomy (randomization groups with first aspiration [ADAPT] or with stent retriever: of

- The percentage of patients with complete recanalization (TICI score 2b-3) at the end of the first treatment strategy implemented
- the time between femoral puncture and the time of access to the clot
- the recanalization time (time between femoral puncture and the obtaining of a final score TICI 2b-3)
- the occurrence of peri-operative complications: peri-procedural perforation, dissection
- the presence of erratic cerebral emboli
- the occurrence of complications at the puncture site
- the NIHSS (National Institute of Health Stroke Score) score
- the proportion of patients with a gain of 4 NIHSS points at 24h
- Modified Rankin score (appendix) at 3 months (favorable if mRS ≤ 2)
- the occurrence of intracranial hemorrhage (parenchymatous or subarachnoid) on cerebral imaging (CT or MRI according to the habits of the center) at 24 h (+/- 12 h) according to the ECASS2 classification
- the occurrence of symptomatic intracranial hemorrhage within the first 24 hours
- the occurrence of death within 3 months.

The medium-term evaluation will be carried out at 3 months +/- 15 days. It can be done by telephone if a follow-up visit is not planned as part of the care or if the patient cannot move. In all cases, the assessment will be made by a person not directly involved in the patient's care.

No specific radiological examination is required in the study. Examinations will be carried out according to the habits of the centers in the current management of this pathology. The imaging data (initial MRI or scanner, thrombectomy procedure, MRI or control scanner) will be evaluated centrally after the patient leaves the hospital, by independent experts, in the absence of treatment and clinical data.

4.4. Study Withdrawal

The patient can leave the study at any time on request. Patients who refuse to participate in the study will be treated as usual. The included patients will not be able to participate simultaneously in another trial.

Research termination may be decided by the sponsor, in particular in the case of complications (after opinion of the Independent Safety Committee) or in the case of non-inclusion.

4.5. Project feasibility

The investigating centers have a recruitment of patients admitted for thrombectomy superior to the recruitment necessary for the study (data of activity on 2014).
All investigating centers perform thrombectomy in more than 40 patients per year and have experience in both thrombectomy strategies (ADAPT and Stent retriever).
The two principal investigating centers are:
Dr. Michel PIOTIN, MD, PhD, Adolphe de Rothschild Ophthalmological Foundation, Paris
Dr. Bertrand LAPERGUE, MD, PhD, FOCH Hospital, Suresnes

The list of other investigating centers is being developed.

4.6. Duration of participation and duration of study
Total duration of study: 27 months
Inclusion period -: - 24 months
Duration of participation per patient: 3 months maximum

4.7. Schedule of Events

	Inclusion (<6h)	Post thrombectomy	24hr follow-up	90d follow-up
Information	✓		✓	✓
Non-opposition	✓		✓	✓
Randomization	✓			
Clinical examination	✓			✓
mRS score	✓			✓
NIH Stroke Scale	✓		✓	
Radiological data	✓	✓	✓	
Medications		✓		
Complications/Adverse Events		✓	✓	✓

5. Data Management and Statistics

5.1. Data collection
All data of the patients meeting the inclusion criteria will be collected anonymously. Patients will be identified by a patient number corresponding to a center number, an inclusion number in the center (chronological order) and the patient's initials (first letter of last and first name).
A nominative list of the patients enrolled in the study, with the corresponding patient number , will be kept in each center, stored in the investigator binder, and will be destroyed 15 years after the end of the study.

The clinical variables from the patient record will be reported on an electronic case report form (eCRF) by the principal investigator, one of his collaborators or a clinical study technician.
The imaging files will be anonymized, stored on a CD-ROM and collected for a centralized evaluation.

5.2. Data analysis
All the statistical analyses will be performed independently, by a statistician, blinded to the allocated arm, of the Biostatistics Department of the CHRU of Lille under the responsibility of Professor A. Duhamel.
The software used will be SAS version 9.3 or later (SAS Institute Inc, Cary, NC, USA). All statistical tests

will be performed with a 2-tailed alpha risk of 5%. No interim analysis will be performed. A detailed statistical analysis plan will be written and finalized prior to the database lock.
Baseline characteristics will be described for each arm. Quantitative variables will be presented using mean and standard deviation in cases of Gaussian distribution, or using the median and the interquartile range (i.e. 25th and 75th percentiles) otherwise. The normality of the distributions will be assessed graphically by histograms and using the Shapiro-Wilk test. Qualitative variables will be presented as the frequencies and percentages of each modality.
Analyses will be conducted in intention to treat and per-protocol samples (deviations from the protocol will be defined in the detailed statistical analysis plan).

Primary objective
The complete recanalization rate at the end of the thrombectomy procedure will be compared between the two arms using a Chi-Square test. The effect size for the ADAPT strategy (experimental arm) will be calculated in terms of absolute and relative rate difference (experimental arm vs. control) with their 95% confidence intervals. A stratified analysis on the center will be carried out to assess the center effect; the Breslow-Day test will be used to test the interaction between the center and the treatment effect.

Secondary Objectives
The quantitative secondary endpoints will be compared between the two arms using the Student's t test or the Mann-Whitney U test in cases of a non-Gaussian distribution. The qualitative secondary endpoints will be compared between the two arms using the Chi-square test or the Fisher’s exact test (in case of expected frequencies <5).

5.3. Sample size calculation
The main objective is to show, in patients with cerebral infarction of the anterior circulation, the superiority of first distal aspiration (ADAPT, experimental arm) to increase the complete recanalization rate at the end of the thrombectomy procedure in comparison with the use of first-line stent retriever approach (control arm).
According to the literature, the complete recanalization rate after the use of a first-line stent retriever is estimated between 58% and 72% (MR CLEAN, 2014 ESCAPE, 2015). A retrospective study conducted at Foch and the Rothschild Foundation hospital found a complete recanalization rate of 70% with the use of first-line stent retriever (± the use of rescue thrombectomy) and a complete recanalization rate of 85% with the use of the ADAPT strategy ((± the rescue thrombectomy) (unpublished data). In terms of effect size, this study showed an increase in the recanalization success rate by 21% with the ADAPT strategy. To demonstrate this effect size, with a two-sided test, an alpha risk of 5% and a power of 90%, 161 patients per arm (322 patients in total) are required.

6. Regulatory information

6.1. Distinction research and care
All the medical products, procedures and additional examinations required for the study are prescribed / performed within the framework of the usual care of the patients. No further follow-up visits are required for the study. The only difference with the routine practice is that the choice of an initial aspiration at the beginning of the thrombectomy procedure is conditioned by the randomization and not by the habits of the center and / or the operator.

6.2. Safety evaluation
Description of Safety Assessment Parameters

Within the framework of a trial evaluating routine care, all medical acts or strategies which are the subject of this study are part of usual practice and are used in accordance with their indications. Any potential adverse events are those associated with the patient's usual care (care-related).

An Independent Oversight Committee (ISC) will be established to ensure the balance of complication rates

between each strategy. Data will be blinded to the randomization group (group A and group B).
The CSI will meet on a regular basis throughout the study, on its own initiative or at the request of the proponent. It will include Professor Emmanuel Touze, CHU of Caen, Professor Mikael Mazighi, CHU Lariboisière, and Doctor Olivier Detante, CHU Grenoble.

Managing unwanted events

These are events that may occur during the study period. Monitoring these adverse effects is part of the routine practice within each center.
The events observed in the study will be recorded as they occur in the clinical research file, in order to be presented to the CSI.

The declaration of serious adverse events related to medical devices and administration of medicines must follow the usual reporting circuit provided by the regulations in force in healthcare institutions, with a copy to the study sponsor (by fax to the clinical research unit on 01 48 03 64 30).

6.3. Access to data and privacy

During and after the trial, the data collected and transmitted to the sponsor by the investigators (or any other collaborators in the research) will be codified. In no case, the names of the persons concerned, their address or any other information enabling a direct identification, will be visible.

6.4. Quality control and quality assurance

The conduct of the trial in the investigating centers and the management of the subjects will be done in accordance with the Helsinki Declaration and the current Good Clinical Practices.
The investigators of each center undertake to receive representatives of the sponsor for quality control and compliance visits, as appropriate.

Instructions for data collection

All information required by the protocol must be recorded on the electronic clinical research file. These data must be collected and recorded as they are obtained and explicitly recorded in the clinical research file . Any missing data should be coded.

The investigator is responsible for the accuracy, quality and relevance of all data entered.

Quality control

The investigator shall make the documents and individual data strictly necessary for the monitoring, quality control and audit of this research available to the persons responsible for quality control and duly mandated by the sponsor for this purpose.
The person (s) mandated by the sponsor will visit each center on a regular basis once the trial has been set up, one or several times during the course of the research, according to the rhythm of the inclusions and at the end of the trial. During these visits, the following elements will be reviewed:
- protection and safety of persons,
- compliance with the research protocol, the procedures defined therein and the regulatory texts in force,
- quality of data collected in the observation booklet: accuracy, missing data, consistency of data with source documents (medical records, appointment books, originals of laboratory results, etc.)
- management of possible products and biological sampling.

Any visit will give rise to a written monitoring report.

Audit

An audit can be carried out at any time by persons mandated by the sponsor and independent of the researchers. Its objective is to ensure the quality of thetrial , the validity of its results and the respect of the law and the current regulations. The persons who direct and supervise the research agree to comply with the requirements of the sponsor and of the competent authority with respect to a research audit or inspection. The audit can be applied at all stages ofthe trial, from the development of the protocol to the publication of the results and the classification of the data used or produced during the research.

6.5. Legal and ethical considerations

The Rothschild Ophthalmological Foundation will be the sponsor of this research in routine care, and its clinical research unit (URC) will be responsible for regulatory missions.

Before starting the trial, each investigator will provide the sponsor's representative with a copy of his / her dated and signed personal CV with his / her registration number to the physician's order or RPPS number.

Request for Committee for the Protection of Persons (CPP) approval

This research will be submitted to the Paris Ile de France VI CPP, without which it cannot begin. This will be notified in the information form.

Substantial amendment to the protocol

The Coordinator will inform the proponent of any proposed amendments to the protocol. Substantial changes will be submitted by the proponent to the PPC for opinion.

CNIL declaration

This research is subject to the law n ° 78-17 of 6 January 1978 relating to data processing, computer files and freedoms. Therefore, the management of directly or indirectly identifying data collected in this research is subject to the referral to the National Commission of Informatics and Liberties (CNIL).

Information note

A written document, submitted to the committee for the protection of persons, will be explained and given to patients. As part of research to evaluate routine care, individuals have the ability to oppose their participation in research. This is stated in the information form. The information given to the persons and their absence of opposition must be notified and dated in their medical file. In case of opposition, the patient will benefit from the strategy proposed to him. Upon completion of this research, the researcher may be informed of its overall results in accordance with the terms and conditions specified in the research document. Information relating to the rights of persons participating in this research (right of access and rectification, right to object to the transmission of data subject to professional secrecy which may be used in the course of this research) shall be incorporated into the information note for the patient.

6.6. Final Research Report

The final research report will be co-authored by the co-investigators and the biostatistician for this research. This report will be submitted to each of the investigators for opinion. Once consensus has been reached, the final version must be endorsed by the signature of each investigator and sent to the sponsor as soon as possible after the actual completion of the research. A report drawn up in accordance with the competent authority's reference plan shall be transmitted to the competent authority and to the CPP within one year after the end of the search (ie last visit of follow up of the last patient enrolled). This period will be extended to 90 days in the event of premature termination of the trial.

6.7. Data processing and document retention

The data will be collected by the investigator on an electronic clinical research file. In accordance with the applicable laws and regulations, in particular articles L.1121-3 and R.5121-13 of the Public Health Code, persons with direct access to data, (for example, investigators, persons responsible for quality control and all persons required to collaborate in the tests) shall take all necessary precautions to ensure the

confidentiality of information relating to experimental treatments, tests, persons who lend themselves to it, in particular as regards their identity and the results obtained. The data collected by these persons during the quality control or audits are then made anonymous.

Documents and data relating to this research will be archived at the end of the trial by the investigator and the sponsor for a period of 15 years after the end of the study. This indexed archive includes:
- Copies of the mandatory CPP notice
- The successive versions of the protocol (identified by the version number and version date),
- Correspondence letters with the sponsor,
- The paper version of the completed and validated observation booklet of each subject included, authenticated (dated and signed) by the investigator
- All appendices specific to the study,
- The final report of the study from the statistical analysis and the quality control of the study (with copy to the sponsor).
- Possible audit certificates carried out during the research
- The database which gave rise to the statistical analysis must also be archived by the analyst (paper or computer).

6.8. Insurance and Scientific Commitment

Insofar as research is well qualified as routine care research by the requested CPP, which means no additional risk associated with the study, the insurance will be that of the institution responsible for care (Article L. 1142-2).

Each investigator will undertake to comply with the obligations of the law and conduct the research according to the B.P.C., in accordance with the terms of the Helsinki Declaration in force. To do so, a copy of the scientific commitment dated and signed by the principal investigator of the participating center will be given to the proponent's representative.

6.9. Rules for Publication

Persons who have actually participated in the development of the protocol, its conduct and the drafting of the results will be signatories to the publications.
The Rothschild Ophthalmological Foundation will be mentioned as the sponsor of this research.
Financial support will be mentioned.

7. Références bibliographiques

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8. Annexes

Classification TICI (Thrombolysis in Cerebral Infarction)

Score	Revised TICI
0	No perfusion or anterograde flow beyond site of occlusion
1	Penetration but not perfusion. Contrast penetration exists past the initial obstruction but with minimal filling of the normal territory
2	Incomplete perfusion wherein the contrast passes the occlusion and opacifies the distal arterial bed but rate of entry or clearance from the bed is slower or incomplete when compared with non-involved territories
2A	Some perfusion with distal branch filling of <50% of territory visualized
2B	Substantial perfusion with distal branch filling of ≥50% of territory visualized
2C	Near-complete perfusion except for slow flow in a few distal cortical vessels or presence of small distal cortical emboli
3	Complete perfusion with normal filling of all distal branches

Score de Rankin modifié (mRS)

0	Aucun symptôme	No symptoms.
1	Pas d'incapacité en dehors des symptômes : activités et autonomie conservées	No significant disability. Able to carry out all usual activities, despite some symptoms.
2	Handicap faible : incapacité d'assurer les activités habituelles mais autonomie	Slight disability. Able to look after own affairs without assistance, but unable to carry out all previous activities.
3	Handicap modérée : besoin d'aide mais marche possible sans assistance	Moderate disability. Requires some help, but able to walk unassisted.
4	Handicap modérément sévère : marche et gestes quotidiens impossibles sans aide	Moderately severe disability. Unable to attend to own bodily needs without assistance, and unable to walk unassisted.
5	Handicap majeur : alitement permanent, incontinence et soins de nursing permanent	Severe disability. Requires constant nursing care and attention, bedridden, incontinent.
6	Décès	Dead.

NIHSS score: stroke severity assessment
http://www.google.fr/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwi84uzE0uDUAhUEXRoKHcu4AaMQFggjMAA&url=http%3A%2F%2Fwww.strokecenter.org%2Fwp-content%2Fuploads%2F2011%2F08%2FNIH_Stroke_Scale.pdf&usg=AFQjCNH0vj8ik0Rtu4Ssm3y2so1jawR7hA

Item	Intitulé	cotation	score	
1a	**vigilance**	**0** vigilance normale, réactions vives 1 trouble léger de la vigilance : obnubilation, éveil plus ou moins adapté aux stimulations environnantes **2** coma ; réactions adaptées aux stimulations nociceptives **3** coma grave : réponse stéréotypée ou aucune réponse motrice		
1b	**orientation** (mois, âge)	**0** deux réponses exactes 1 une seule bonne réponse **2** pas de bonne réponse		
1c	**commandes** (ouverture des yeux, ouverture du poing)	**0** deux ordres effectués 1 un seul ordre effectué **2** aucun ordre effectué		
2	**oculomotricité**	**0** oculomotricité normale 1 ophtalmoplégie partielle ou déviation réductible du regard **2** ophtalmoplégie horizontale complète ou déviation forcée du regard		
3	**champ visuel**	**0** champ visuel normal 1 quadranopsie latérale homonyme ou hémianopsie incomplète ou négligence visuelle unilatérale **2** hémianopsie latérale homonyme franche **3** cécité bilatérale ou coma (1a=3)		
4	**paralysie faciale**	**0** motricité faciale normale 1 asymétrie faciale modérée (paralysie faciale unilatérale incomplète) **2** paralysie faciale unilatérale centrale franche **3** paralysie faciale périphérique ou diplégie faciale		
5	**motricité membre supérieur**	**0** pas de déficit moteur proximal 1 affaissement dans les 10 secondes, mais sans atteindre le plan du lit. **2** effort contre la pesanteur, mais le membre chute dans les 10 secondes sur le plan du lit. **3** pas d'effort contre la pesanteur (le membre chute mais le patient peut réaliser une contraction musculaire avec ou sans mouvement du membre.) **4** absence de mouvement (coter 4 si le patient ne fait aucun mouvement volontaire) **X** cotation impossible (amputation, arthrodèse)	**Dt**	**G**
6	**motricité membre inférieur**	**0** pas de déficit moteur proximal 1 affaissement dans les 5 secondes, mais sans atteindre le plan du lit. **2** effort contre la pesanteur, mais le membre chute dans les 5 secondes sur le plan du lit. **3** pas d'effort contre la pesanteur (le membre chute mais le patient peut faire un mouvement tel qu'une flexion de hanche ou une adduction.) **4** absence de mouvement (le patient ne fait aucun mouvement volontaire) **X** cotation impossible (amputation, arthrodèse)	**Dt**	**G**
7	**ataxie**	**0** ataxie absente 1 ataxie présente pour 1 membre **2** ataxie présente pour 2 membres ou plus		
8	**sensibilité**	**0** sensibilité normale 1 hypoesthésie minime à modérée **2** hypoesthésie sévère ou anesthésie		
9	**langage**	**0** pas d'aphasie 1 aphasie discrète à modérée : communication informative **2** aphasie sévère **3** mutisme ; aphasie totale		
10	**dysarthrie**	**0** normal 1 dysarthrie discrète à modérée **2** dysarthrie sévère **X** cotation impossible		
11	**extinction, négligence**	**0** absence d'extinction et de négligence 1 extinction dans une seule modalité, visuelle ou sensitive, ou négligence partielle auditive, spatiale ou personnelle. **2** négligence sévère ou anosognosie ou extinction portant sur plus d'une modalité sensorielle		
		TOTAL		