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Prevention project of the chronicity of cognitive-behavioral complicationsof mild head traumatic brain injury

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The project aimed to build a protocol for the early diagnosis of deficits cognitive and/or behavioral in patients with Minor Head Trauma (m-TBI) in hours following the event and testing it on a sample of patients attending the emergency room of the Buccheri La Ferla Hospital. This is with the aim of promoting early diagnosis and secondary prevention of under-diagnosed or later-onset symptoms by reducing the risk of a worsening of the quality of social, working and family life.

A) Project objectives

To implement the project it was decided to put into practice a series of project actions aimed at early diagnosis and intensive rehabilitation of the deficits found through:

1) recruitment of the patient diagnosed with Minor Head Trauma (mild trauma cerebral: no diagnosis of ischemic or hemorrhagic lesions; possible state of loss of consciousness less than 30 minutes; post traumatic amnesia no later than 24 hours after occurrence of trauma; focal neurological deficit that may or may not be transient) at the Emergency Department of the Buccheri La Ferla Hospital within the first 48 hours from the onset and administration of a battery of tests for evaluation neuropsychological and/or behavioral of the patient;
2) taking care of the patient who needed rehabilitation;
3) quarterly follow-ups to monitor cognitive-behavioral functioning of the patient.

B) Objectives achieved

The project developed through different phases and actions:

- recruitment of the staff involved (4 neuropsychologists, a nurse and a doctor):

- organization and drafting of the executive project;
- holding strategic meetings with emergency room staff to determine the most suitable methods for patient recruitment;
- creation of the team and working group;
- development of the evaluation protocol;
- patient recruitment at the emergency room within 24/48 hours of the event;
- organization of the hospital-territory network;
- taken charge of neuropsychological rehabilitation treatment for patients with results below standard in the tests carried out;
- follow-up of patients;
- reporting.

C) Methodology

The evaluation of cognitive-behavioral deficits, as can be seen from the project executive, was carried out by the team of neuropsychologists through the administration of a battery of cognitive tests in association with a general screening test for the presence of any psychiatric symptoms at the OBI emergency room.

After administering the battery, the neuropsychologists evaluated it based on the scores the possibility of starting a cognitive rehabilitation process using tools already in use at the U.O. of Rehabilitation of the Buccheri La Ferla Hospital and commonly used for this purpose scope. Each intervention focused on the rehabilitation of the resulting cognitive functions deficit for each subject who wanted to adhere to the proposal.

A patient database in Excel format has also been set up for data recording of the enlisted subjects well guarded, through the use of passwords, to protect privacy.

An informed consent form and a guide explaining the risks of the drug have been prepared minor head trauma to be retained upon discharge from the emergency room.

All the work carried out was constantly coordinated through working group meetings and monitoring of the progress of the project between the staff and the scientific manager.

Distribution of the sample:

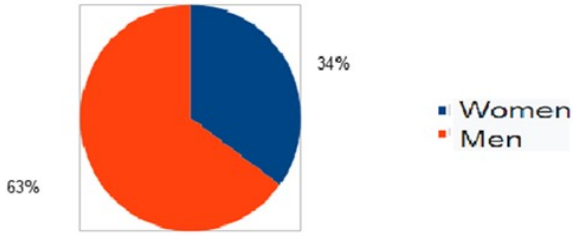

Figure n. 1: Distribution of the sample by gender (percentage values)

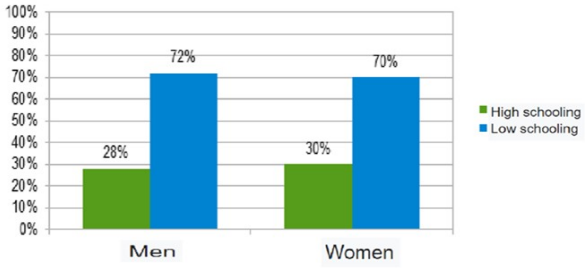

Figure n. 2: Level of education of the sample divided by gender(percentage values)

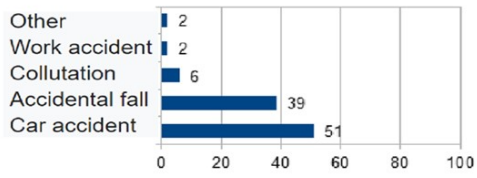

Figure 3: Subdivision of the sample (N49) by cause of minor head injury (percentages)

D) Results

After the first preparatory phase of the project and after having established the recruitment methods of patients, coordinating the work of neuropsychologists and emergency room doctors, are 49 patients were recruited from October 2018 to October 2019 (32 men and 17 women) who, having signed the informed consent, have agreed to become our champion research project.

The group of patients evaluated has an average age of 46.7 years; specifically the average age of male sample is 43.66 years and female sample is 53.35 years.

Furthermore the sample of the research project has a low level of education (average 8.73); specifically the average education of the male sample is 8.81 and that of the female sample is 8.82.

The causes of minor head trauma were: road accidents (25 cases), accidents domestic (15 cases), fight (3 cases), accident at work (2 cases), other (4 cases). 41% of patients enrolled at T0 (first evaluation carried out in the emergency room) have presented scores below the norm for some of the cognitive functions assessed. Between 30% of patients with cognitive impairment accepted the proposal to carry out treatment neuropsychological rehabilitation, carrying out an hour of therapy weekly with one of the neuropsychologists who are members of the research project team.

During the months of intervention, compared to the total sample, a percentage of drop out at the different follow up phases. 20% of patients independently decided not to consider it necessary to carry out subsequent neuropsychological evaluations, stating that they do not present cognitive disorders or do not want to go to hospital due to the health emergency COVID-19.

More generally, the analysis of the protocols of the patients evaluated highlighted the presence of deficits of executive functions (measured by the Frontal Assessment Battery test), of memory a short and long-term of the auditory-verbal type (m. deferred prose), of divided attention (Trial B), understanding (Token test), abstraction, cognitive estimates. More generally the analysis of the protocols of the patients evaluated highlighted the presence of:

- deficits in executive functions (measured by the Frontal Assessment Battery test) in 34.7% of patients evaluated;
- auditory-verbal short and long-term memory deficits (m. Prose deferred), divided attention (Trial B) and understanding (Token test) in 31% of cases;
- lack of abstraction in 14% of cases;
- and 29% of the patients evaluated obtained poor results in the "estimates" sub-test cognitive".

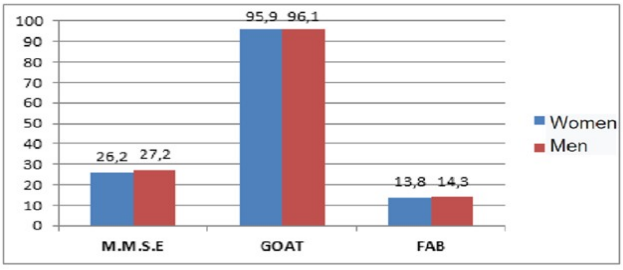

Figure 4: Test results divided by gender, average values (MMSE; GOAT; FAB)

Differences were also found in the extent of the deficits measured between subjects with a level of high and low education. Patients with low educ tion more frequently present deficits concerning the

cognitive functions of memory, understanding and praxis skills.

None of the enrolled patients showed behavioral deficits.

The project was suspended for two months (March -May 2020) due to the emergency Covid-19 healthcare. In recent months many patients should have undergone follow-up at a year from the event. At the time of resumption of project activities, one was proposed follow-up neuropsychological evaluation to patients, but they refused to perform the follow up for fear of going to hospital.

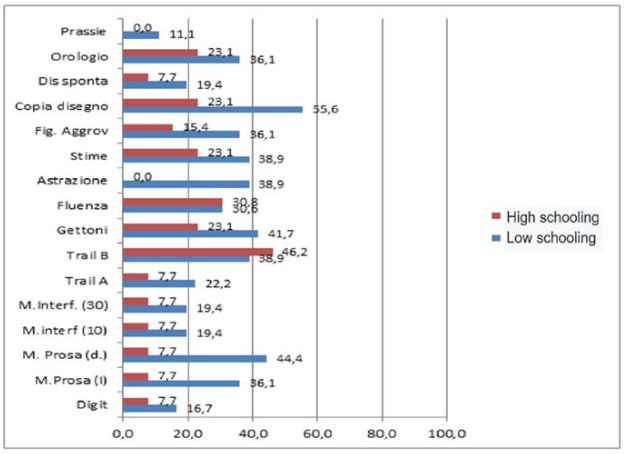

Figure 5: Presence of cognitive deficits in ENB-2 sub-tests in subjects with low education (1 - 10)and with high schooling (11-17), percentage values

Executive project

Introduction

The project was aimed at patients who attended the Buccheri La Ferla emergency room with history of minor head trauma (m-TBI: Mild Traumatic Brain Injury), subjected to negative clinical evaluation and/or possible CT scan and which therefore tested negative for lesions ischemic or hemorrhagic and who presented a state of loss of consciousness less than 24 hours.

Objective: early diagnosis and management of the patient with cognitive deficits to the secondary and tertiary prevention of outcomes from m-TBI.

Specific objectives

- Neuropsychological evaluation of the patient diagnosed with m-TBI within 48 hours from the event at the OBI (short intensive observation) of the emergency room.
- Quarterly follow-ups to monitor cognitive and behavioral condition of the patient for the next 12 months after the trauma.
- Rehabilitation of the patient in whom a cognitive deficit has been detected and monitoring of the general clinical condition in collaboration with the nurse and doctor of the team of the U.O. of Rehabilitation over the 12 months following the event.
- Extended care of the patient in the event of other physical complications e behavioral.

Inclusion/Exclusion Criteria

INCLUSION:

Patients affected by non-concussive TBI-m.

Pts affected by TBI-m with short loss of consciousness less than 24 hours

Patients from 16 to 79 years

EXCLUSION:

Patients affected by dementia full-blown

Patients suffering from known neurodegenerative diseases

Patients suffering from known intellectual disabilities

Patients with psychiatric pathology

Methodology

To achieve the general objectives of the project, a team of 4 was set up neuropsychologists, a profes-

sional nurse and a doctor who worked at the specific m-TBI clinic guaranteeing daily availability from Monday to Saturday to allow the evaluation of the patient diagnosed with m-TBI within 48 hours of diagnosis.

Based on the availability and availability of the professionals involved, the evaluation was possible often even on the same day as the patient is admitted.

The patient suffering from m-TBI was sent from the ED to the U.O. of Rehabilitation where he came from an initial screening of the main cognitive functions was carried out or assessed at the emergency room Same rescue if not transportable or if not discharged within the 24/48h period.

In relation to the outcome of the evaluation, the patient was taken care of by the medical team professionals to undertake a weekly rehabilitation program or one postponed to the next three-month follow-up, with clarifications regarding the monitoring of any symptoms that may take over due to m-TBI. The patients who have agreed to undertake the path of cognitive rehabilitation they went weekly (one-hour therapy) to the U.O. Of Rehabilitation and treatment lasted an average of three months for each patient.

Instruments

- Informed consent.
- Small information guide for the patient on TBI-m and list of possible symptoms they may arise at a later time.
- Screening tools for in-depth behavioral disorders (if considered necessary): Symptom Checklist-90-Revised,SCL90R (Prunas A. and Derogatis LR, 2011).
- Tools for neuropsychological screening 15-79:
- Questionnaire for collecting medical history data (created ad hoc);
- Mini Mental State Examination, MMSE (Measso G., Cavarzeran F., Zappalà G. Et to the. 1993)
- Short neuropsychological exam 2, ENB2 (Mondini, Mapelli, Vestri, Arcara and Bisiacchi, 2011)
- Galveston Orientation and Amnesia Test, GOAT (Levin et al. 1979; Crovitz, 1987; Mac-Millan et al. 1996)
- Frontal Assessment Battery, FAB (Apollonius I, et al. 2005

Timeline

The two-year project took place as follows:

I year: patient recruitment, cognitive assessment and possible rehabilitation; start quarterly follow-up.

II year: quarterly follow-ups for monitoring and reporting.

Project phases

1. Patient accepted and diagnosed by the ED and under observation at the OBI;
2. within 48 hours patient recruitment and sending to the rehabilitation department or to the emergency department for first cognitive assessment (T0);
3. a) if cognitive deficits are found, referral to a neuropsychologist (other than the evaluator) for treatment cognitive rehabilitation (therapy one hour a week) at the U.O. of Rehabilitation;
4. b) re-evaluation of the improvement at 3 months (T1), at six months (T2), at nine (T3) and at 12 months (T4);
5. a) if no deficit is found, the patient is sent back to the next follow-up check three months with

testological re-evaluation (T1), at six months (T2), at nine (T3) and at 12 months (T4). In during the first meeting the patient was informed of the possible onset of signs and symptoms of m-TBI and therefore please contact the rehabilitation unit, even before the three months for possible revaluation.

6. b) if during subsequent follow-ups cognitive deficits were found, the patient was referred to a rehabilitation program at the U.O. of Rehabilitation.
7. Statistical processing of the results.

E) Attachments:

a) informed consent;

b) small information guide for the patient on m-TBI from the point of view of the possible symptoms that may arise at a later time;

c) medical history sheet.

Annex a): Informed consent

INFORMED CONSENT FOR RESEARCH PURPOSES

The undersigned Dr. Giorgio Mandalà, Scientific Director of the study and of the Unit Rehabilitation of the Buccheri La Ferla Hospital in Palermo, as research coordinator of the Health Department of the Sicily Region provides the following information in accordance with current legislation.

The research for which consent is required has the purpose of diagnosis and rehabilitation of cognitive disorders in patients suffering from minor head trauma assessed at onset;

The research will last two years in which four (4) evaluations will be carried out with quarterly for the purpose of monitoring the patient in the twelve months following the trauma;

The research involves the following: the enrollment of patients within 48 hours following the trauma and the evaluation through a battery of neuropsychological and possibly psychological tests in order to identify any cognitive impairment. The research does not involve any type of invasive maneuver the administration of drugs.

Consent to the research is freely left to the will of those who have chosen and are able to participate be withdrawn at any time;

The professional Doctor undertakes to respond to any requests or doubts that may arise even after the conclusion of the study, as well as to provide additional information possibly requested by the participants;

In compliance with the provisions of the legislation on privacy, the data will be guaranteed and protected right to confidentiality, non-recognition and anonymity of research participants;

The data collected will be used and disseminated in a strictly anonymous form and exclusively for the scientific purposes previously illustrated; the data will be kept at the Rehabilitation Unit of the Buccheri La Ferla Hospital in Palermo;

At the end of the research, the professional will report the results of the study to the participants and others subjects possibly involved;

The research results will be presented in aggregate form so that the information provided are not attributable to individual participants;

After an extensive explanatory conversation on the above, which took place on ../../...., the assisted

person/guardian is invited to carefully read the contents of this document form before signing it.

The Professional (signature)

Annex b): Guide on head trauma

Head trauma guide

Dear Mr/Ms,

We would like to bring to your attention some possible symptoms that may occur close to the traumatic event or in the months following the event. Please read the list below carefully and contact your doctor as soon as possible first aid or our Rehabilitation Unit for a neurological and/or cognitive re-evaluation.

MAIN SYMPTOMS that can occur following minor head trauma:

- Short-term loss of consciousness (a few seconds or a few minutes); however, it's good
- point out that this symptom does not always occur;
- Mild mental confusion;
- Headache;
- Dizziness;
- Neck pain;
- Vision problems (diplopia, feeling of tired eyes, etc.);
- Tinnitus (ringing in the ears);
- Daytime sleepiness, unjustified tiredness and fatigue;
- Difficulty concentrating.

COGNITIVE SYMPTOMS:

- Decreased reflexes;
- Confusion and difficulty concentrating.
- Amnesia (memory loss), such that you are unable to remember events that occurred before (retrograde amnesia) or after the concussion (antegrade amnesia);

PHYSICAL SYMPTOMS:

- Headache;
- Vision disturbances, blurred or double vision;
- Perception of ringing in the ears (tinnitus);
- Nausea or vomiting;
- Dizziness;
- Sensitivity to noise or light;
- Changes in taste or smell;
- Loss of balance and coordination problems;
- Tiredness and lack of energy;
- Sleep disorders: insomnia or excessive drowsiness.

PSYCHOLOGICAL SYMPTOMS:

- Personality changes or psychological adjustment problems: irritability, distraction, inappropriate emotional responses (example: suddenly bursting out to laugh or cry);
- Mood disorders: nervousness, anxiety or depression.

If you notice any of these symptoms please book an appointment at our rehabilitation unit (tel. 091 479 413) for a cognitive reassessment or, in case of more obvious symptoms, contact the emergency room of our hospital or your doctor.

Annex c): Medical history sheet

HISTORY SHEET - MINOR HEAD TRAUMA

Name of examiner: _____

PRELIMINARY INTERVIEW (Explain the aims of this research and the investigation method, ask the patient (and/or the companion) to talk about the problems they have for a few minutes encountered. Write below the most important information that emerges from this first one interview)

HISTORY

PATIENT IDENTIFICATION

NAME AND SURNAME

Date of Birth (dd/mm/yy) AGE

Exam date (dd/mm/yy)

Date of accident (dd/mm/yy)

Gender Male ..... Female.....

Family Status Unmarried .....Widower ..... Married ..... Cohabiting ..... Divorced/separated…

Phone number

Number of years of schooling

Activities before the accident

Employment status at the time of the trauma

PRE - TRAUMATIC STATE

Informant The patient alone ..... Joint ..... Parents ..... Friend ....Guardian .....

Antecedent head trauma with sequelae(s).

Psychiatric pathology. Epilepsy.

Drug addiction.

Intellectual disability.

Neurodegenerative diseases.

Dementia pathology.

Type of accident

Fractures or other problems inherent to the accident

Site of the main lesion (hematoma or other)

No lesions identified

Front right

Front left

Bilateral frontal

Right posterior hemisphere

Left posterior hemisphere

Posterior fossa

Peri – ventricular

Diffuse lesion

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