DOI: 10.17650/1683-3295-2022-24-3-32-36

ФУНКЦИОНАЛЬНЫЕ ИСХОДЫ ХИРУРГИЧЕСКОГО ЛЕЧЕНИЯ ПАЦИЕНТОВ С ЧЕРЕПНО-МОЗГОВОЙ ТРАВМОЙ ЧЕРЕЗ 6 МЕСЯЦЕВ ПОСЛЕ ОПЕРАЦИИ: КАРИБСКОЕ ОДНОЦЕНТРОВОЕ ПИЛОТНОЕ ИССЛЕДОВАНИЕ

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Введение. В статье представлено первое одноцентровое проспективное исследование, оценивающие функциональные исходы после хирургии черепно-мозговой травмы. Исследование проводилось в Доминиканской Республике.
Цель. Определить функциональный статус пациентов, получивших хирургическое лечение, относительный риск неблагоприятного прогноза и связь между функциональным статусом и прогностическими переменными, разработанными Международной миссией по прогнозированию и анализу клинических исследований черепно-мозговых травм (International Mission for Prognosis and Analysis of Clinical Trials in Traumatic Brain Injury, IMPACT) через 6 мес после травмы.
Материалы и методы. Проспективное динамическое исследование включало когорту из 22 пациентов, получивших хирургическое лечение по поводу черепно-мозговой травмы в Травматологической больнице доктора Нея Ариаса Лоры (Dr. Ney Arias Lora Traumatology Hospital) в Доминиканской Республике. Для определения функционального исхода мы использовали IMPACT-калькулятор (реакция зрачков, гемоглобин, гипоксия, возраст, двигательный ответ, очаги на компьютерной томографии, гипотензия и т. д.) перед операцией и расширенную шкалу исходов Глазго (Extended Glasgow Outcome Scale) через 6 мес после операции. Для статистической обработки данных использовалась SPSS database (версия 15.0, Чикаго, США). Применялись мера центральной тенденции и критерий Фишера. Статистически значимым приняли $p \leq 0{,}05$ с 95 % доверительным интервалом.
Результаты. Прогностические переменные, связанные с неблагоприятным прогнозом: двигательный ответ ($p = 0{,}01$), гипоксия и гипотензия ($p = 0{,}05$). Отклонения в двигательном ответе были связаны с повышенной смертностью (относительный риск – 10; 95 % ДИ = 3–22). Нормальная реакция сгибания наблюдалась у всех пациентов, показавших хорошее восстановление ($p = 0{,}04$).
Заключение. В результате 67 % пациентов показали хороший функциональный исход (умеренная инвалидность и хорошее восстановление). Смертность составила 23 %. Предоперационный двигательный ответ – хороший прогностический фактор исхода хирургического лечения черепно-мозговых травм.

Ключевые слова: хирургия черепно-мозговых травм, травматическое повреждение головного мозга, функциональный статус, расширенная шкала исходов Глазго, Международная миссия по прогнозированию и анализу клинических исследований, IMPACT

Для цитирования: Encarnacion M.J., Baez I.P., Paulino J. и др. Функциональные исходы хирургического лечения пациентов с черепно-мозговой травмой через 6 месяцев: карибское одноцентровое пилотное исследование. Нейрохирургия 2022; 24(3):32–6. (На англ.) DOI: 10.17650/1683-3295-2022-24-3-32-36

Functional outcome at 6 months of surgical traumatic brain injury: A single Caribbean Center pilot study

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Background. This is the first prospective study that evaluates the functional outcome after a surgical procedure secondary to a traumatic brain injury, in a single center, in Dominican Republic.
Aim. To determine the functional status of surgically treated patients 6 months post-trauma, the relative risk of poor prognosis and association of functional status with the predictive variables of the International Mission for Prognosis and Analysis of Clinical Trials in traumatic brain injury.
Materials and methods. A prospective, longitudinal study was conducted in a cohort of 22 patients surgically treated for a traumatic intracranial injury at Dr. Ney Arias Lora Traumatology Hospital in Dominican Republic. We applied the International Mission for Prognosis and Analysis of Clinical Trials calculator, (pupillary response, hemoglobin, hypoxia, age, motor response, computed tomography lesion, hypotension, etc.) prior to surgery and the Extended Glasgow Outcome Scale 6 month after surgery to determine the functional outcome. The International Mission for Prognosis and Analysis of Clinical Trials form was modified by adding preoperative glucocorticosteroids and rehabilitation therapy. The SPSS database (15.0 version, Chicago Il.) was used. Central tendency measures and Fisher's test were applied. Thus, $p \leq 0.05$ with a 95 % confidence interval was considered statistically significant.
Results. The predictive variables associated with a poor prognosis were motor response ($p = 0.01$), hypoxia and hypotension ($p = 0.05$). Alterations in motor response was associated with increased morbidity and mortality (RR: 10; 95 % CI: 3–22). Normal flexion was found in all patients with good recovery ($p = 0.04$).
Conclusion. As a result, 67 % of patients had a good functional result (moderate disability and good recovery). Mortality was 23 %. Preoperative motor response is a powerful prognostic factor in traumatic brain injury.

Keywords: surgical traumatic brain injury, TBI, functional status, Extended Glasgow Outcome Scale, International Mission for Prognosis and Analysis of Clinical Trials, IMPACT

For citation: Encarnacion M.J., Baez I.P., Paulino J. et al. Functional outcome at 6 months of surgical traumatic brain injury: A single Caribbean Center pilot study. Neyrokhirurgiya = Russian Journal of Neurosurgery 2022;24(3):32–6. DOI: 10.17650/1683-3295-2022-24-3-32-36

BACKGROUND

Adjuvant therapy in current neurosurgery has turned the management patterns of various pathologies, allowing better outcomes. Developing technologies such as robotic surgery, dendritic cell vaccines for certain brain tumors, gene therapy, and radiosurgery are some of these promising evolving techniques. Despite this, surgical brain-spine trauma still depends entirely on the surgeon's technical skills. According to World Health Organization there are 1.35 million death each year due to road traffic injuries. J. Jr Bruns and W.A. Hauser [1] define traumatic brain injury as a critical socio-economic and public health problem, being the leading cause of mortality and disability in young patients. In 2018 there was a total of 2168 death due to traffic accidents in Dominican Republic, equivalent to a rate of 21 cases per 100,000 habitants, a big increase compared to previous years [2]. This data corroborates with J.A. Langlois and R.W. Sattin [(Wang, Wang et al. 2017) 3] and G.R. Boto et al. [4], who say that each year the number of disabled and killed people by motor vehicle accidents will increase, and trauma will surpass their congeners (cardiovascular and cerebrovascular disease) as the number one cause of death worldwide.

MATERIALS AND METHODS

This is a prospective, observational pilot study conducted in a cohort of 22 patients who were surgically treated for a traumatic intracranial injury at Dr. Ney Arias Lora Traumatology Hospital in Dominican Republic between January 1st and July 30th 2018. We applied in traumatic brain injury (TBI) the International Mission for Prognosis and Analysis of Clinical Trials (IMPACT) calculator (pupillary response, hemoglobin, hypoxia, age, motor response, computed tomography (CT) lesion, hypotension, etc.) previous to surgery and the Extended Glasgow Outcome Scale (GOS-E) 6 month after surgery to determine the functional outcome. Our team modified the IMPACT form by adding the Glasgow level, pre-surgical time and rehabilitation therapy.

Patients over the age of 14 years old who were surgically treated for a TBI were included. Cases with incomplete medical records were excluded. Those with multiple surgeries due to politrauma, during their hospital stay, and those that could not be contacted by phone were excluded as well.

The original primary outcome was to determine the functional status of this surgically treated patients 6 months after trauma (a composite of death, vegetative state, or severe disability) as evaluated on the GOS-E and to establish the association of functional status with the predictive variables of the IMPACT in TBI. Second, to determine the relative risk of worse prognosis according to those variables.

We had the hospital ethical committee approval for this project and formal consent from patient's family. SPSS database (15.0, Chicago Il.) was used. Central tendency measures and Fisher's test were applied. Thus, $p \leq 0.05$ with a 95 % confidence interval was considered statistically

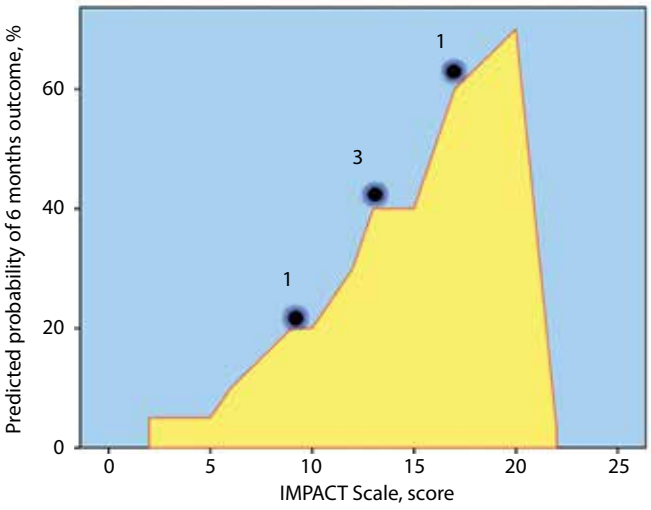
significant and as a trend those data with p between 0.06 and 0.1.

RESULTS

All patients were males, 63 % of them (14 cases) were under 30 years old. The level of consciousness according to the Glasgow Scale was heterogeneous, with a slight predominance of severe trauma – glucocorticosteroids (GCS) < 8/15, within which were most of the deceased; 58 % (13) were above 9/15.

For a better understanding, outcome scores were dichotomized as favorable outcome (good recovery/moderate disability) or unfavorable outcome (dead/vegetative/severe disability). The Figure shows the results: 67 % of cases had a favorable outcome; 23 % (5) of patients died, 3 of them in the acute/subacute hospital setting. We found no association between age and pupillary reactivity compared to functional prognosis, unlike the relationship between hypoxia and survival, as 80 % of the deceased patients were in the group with hypoxia data ($p = 0.009$), and all patients with good functional outcome were not associated with this variable.

Normal motor response (obey verbal command, localize to stimuli, normal flexion to stimuli) was associated to a favorable outcome ($p = 0.05$). When dichotomized to alive or death, motor response was statistically significant ($p = 0.01$; RR: 10; 95 % CI: 3–22). Normal flexion was found in all patients with good high recovery (Table 1). When analyzed from a survival perspective, the absence of hypoxia was significantly associated with survival ($p = 0.009$), Hypotension and Glasgow Coma Scale were not related to it (Table 2).



Mortality (predicted probability, IMPACT score)

DISCUSSION

Optimizing procedures and protocols, in the interest of saving lives and ensuring a better functional result, is vital in medicine, searching of predictive variables has been and will remain the north in modern neurosurgery, not only in the context of trauma, but all neuropathological entities. A. Marmarou et al. [5] and collaborators found that the pupil response was strongly associated with a worse prognosis, unlike our data, where we found no relationship ($p = 0.3$).

Age is the variable that has presented greater attention in traumatic brain injury, along with pupillary reactivity, it has been highlighted as an important variable associated with prognosis, S.C. Choi and T.Y. Barnes [6], S.C. Choi et al. [7] in a population of 523 patients found that patients with ages above a 50 years old threshold had a higher probability of a worse prognosis. These data are similar to those of T.R. Hodelin et al. [8], who in 2011 conducted a research in Cuba with 110 patients where they found that patients over 60 years old had a worse outcome. In our investigation, the age did not influence the functional outcome ($p = 0.4$), probably because most of the patients (20) were under 50 years old and the distribution in relation to the severity of the trauma was homogeneous.

Our results showed a trend towards worse prognosis in patients who had hypoxia ($p = 0.1$). N.G. Baldwin et al. [9] and cols, based on income information, analyzed 828 patients from the Traumatic Coma Data Bank by selecting a combination of variables to predict early survival mortality. The elderly, low GCS scores and the presence of pupil alteration, hypotension and hypoxia were associated with mortality. The probability of death was calculated for each subject, so that if it was greater than 0.5, mortality was predicted. Predictions were correct in 91.2 % of patients. D.K. Menon and C. Zahed [10] also noted that hypoxia was associated with unfavorable evolution and poor functional outcome.

Table 1. *Outcome related variables*

Variable	Outcome		*p*-value
	Favorable (good recovery/moderate disability)	Unfavorable (dead/vegetative/severe disability)	
Glasgow Outcome Scale	>8/15	≤8/15	0.07
Motor response (normal flexion versus abnormal flexion)	Normal flexion	Abnormal flexion or extension	0.05
Hypoxia	No	Yes	0.05
Hipotension	No	Yes	0.05

Table 2. *Survival associated variables*

Variable	Alive	Death	*p*-value
Motor response (other than normal flexion)	2	4	0.01
Hypoxia	2	4	0.009

The most important database at the global level in relation to prognostic factors and functional outcome is the IMPACT, contains a total of 9205 patients with traumatic brain injury moderate and severe, treated in the last 20 years in 8 clinical trials and 3 observational studies. It was developed by the Institute of Health of the United States of America, and of the same there have been numerous scientific papers in relation to the variables and the prognosis of traumatic brain injury; A. Marmarou et al. [5] examined these variables and found a strong association between the motor response and functional outcome 6 months after the trauma (OR: 1.74–7.48), establishing that the lower the score on this line of the Glasgow Coma Scale, the worse was the prognosis of the patient ($p = 0.0001$), these data are consistent with those of our research, where we show that the patients who had a lower score in motor function had a worse functional outcome than those who presented with a flexion normal (RR: 10; 95 % CI: 3–22). All patients with good high and low recovery had normal flexion ($p = 0.04$).

CONCLUSION

As a result, 67 % of patients had a good functional result (moderate disability and good recovery), mortality was 23 %.

Only the motor response, as a predictive variable, had a significant association in relation to the functional result ($p = 0.04$), patients with normal flexion had a good high recovery and the relative risk of a worse functional outcome in patients with motor component disorder is 10 times higher than those had normal flexion.

Limits. It is very likely that the differences between the variables "age/pupil reactivity" and the functional result have been affected by the small number of subjects studied, in a larger, representative population study, these variables may be directly related to the patient's prognosis. Prospective research is needed, with a control group in which functional outcomes can be measured in patients operated *versus* patients treated conservatively. As a retrospective study, this paper is subjected to multiple bias, mainly inter-observer variations of Glasgow score and subjectivity in relation to the presence or not of hypoxia and hypotension in some cases.

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Конфликт интересов. Авторы заявляют об отсутствии конфликта интересов.
Conflict of interest. The authors declare no conflict of interest.

Финансирование. Работы выполнялись без внешнего финансирования.
Funding. The work was performed without external funding.

Соблюдение прав пациентов и правил биоэтики. Протокол исследования одобрен комитетом по этике Больницы ортопедии и травматологии доктора Ней Ариас Лора (Доминиканская Республика). Семьи всех пациентов подписали информированное согласие на участие в исследовании.
Compliance with patient rights and principles of bioethics. The study protocol was approved by the ethical committee of the Dr. Ney Arias Lora Traumatology Hospital (Dominican Republic). The families of all patients gave written informed consent to participate in the study.

Статья поступила: 10.02.2022. **Принята к публикации:** 25.05.2022.
Article submitted: 10.02.2022. **Accepted for publication:** 25.05.2022.