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Cost-Effectiveness of Intracranial Pressure Monitoring in Pediatric Patients with Severe Traumatic Brain Injury: A Simulation Modeling Approach

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ABSTRACT

Objectives: To conduct an economic evaluation of intracranial pressure (ICP) monitoring on the basis of current evidence from pediatric patients with severe traumatic brain injury, through a statistical model. **Methods:** The statistical model is a decision tree, whose branches take into account the severity of the lesion, the hospitalization costs, and the quality-adjusted life-year for the first 6 months post-trauma. The inputs consist of probability distributions calculated from a sample of 33 surviving children with severe traumatic brain injury, divided into two groups: with ICP monitoring (monitoring group) and without ICP monitoring (control group). The uncertainty of the parameters from the sample was quantified through a probabilistic sensitivity analysis using the Monte-Carlo simulation method. The model overcomes the drawbacks of small sample sizes, unequal groups, and the ethical difficulty in randomly assigning patients to a control group (without monitoring). **Results:** The incremental cost in the monitoring group was Mex$3,934 (Mexican pesos), with an increase in quality-adjusted life-year of 0.05. The incremental cost-effectiveness ratio was Mex$81,062. The cost-effectiveness acceptability curve had a maximum at 54% of the cost-effective iterations. The incremental net health benefit for a willingness to pay equal to 1 time the per capita gross domestic product for Mexico was 0.03, and the incremental net monetary benefit was Mex$5,358. **Conclusions:** The results of the model suggest that ICP monitoring is cost-effective because there was a monetary gain in terms of the incremental net monetary benefit.

Keywords: brain injuries, cost-benefit analysis, decision support techniques, physiologic monitoring, probabilistic models, uncertainty.

Introduction

Severe traumatic brain injury (STBI) in children is a major cause of disability and mortality worldwide [1]. In Mexico in 2012, accidents ranked first in children aged 1 to 14 years, according to the National Institute of Statistics, Geography, and Informatics, half of which correspond to traumatic brain injury [2]. STBI is considered to be present in patients with a Glasgow Coma Scale (GCS) score from 3 to 8 points within the first 48 hours after the accident [3,4]. The health burden for children who suffer STBI is enormous because their physical and mental capacity may be greatly affected [5–7]. In addition, the associated care and rehabilitation procedures will have a financial impact on both their families and the State, and will translate into direct and indirect health costs. For example, in Germany, Sweden, and Spain, the average cost fluctuates between €7,600 and €9,000 per hospitalization, whereas the annual cost of care for the first 2 years after the injury has been estimated at more than €100,000 [8]. In the United States, the economic burden of care for patients with traumatic brain injury is substantial [9] given that the cost of hospitalization in 2006 and 2007 averaged US $21,460 ± $21,212 per patient [10]. Nevertheless, if the patient is a child, the cost will accumulate for the rest of his or her life [11]. Thus, the burden of annual hospitalization in children with this condition was more than US $1 billion in 2006 [12]. This amount did not include the cost of social service systems nor the value of the hourly work earnings that were not collected by relatives who cared for patients with post-traumatic sequelae [13,14]. To date there are no reports on the costs associated with STBI in children from Latin American countries, despite the health and economic impact of this condition.

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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The damage caused by the impact at the time of the trauma is known as the primary lesion. In addition, secondary injury results from changes in the extracellular environment, leading to increases in the intracranial pressure (ICP), which can limit the blood supply to the brain tissue and, in turn, produce a decrease in the cerebral perfusion pressure (CPP) [15]. Nowadays, ICP monitoring is a measurable parameter that can direct treatment toward the maintenance of an adequate CPP, and it is believed to have a positive influence on survival and quality of life [16].

Nevertheless, the use of ICP monitoring for its management is not fully accepted. In the "Guidelines for the management of severe brain injury" [1], the use of ICP monitoring is mentioned as a recommendation because there is insufficient evidence to establish its effectiveness or lack thereof in pediatric patients. Hence, globally there is controversy about its use, although there are numerous class II studies that endorse it [1,17].

Furthermore, the effectiveness and cost-effectiveness of ICP monitoring in children have not been investigated directly in the Latin American region. This study attempts to provide knowledge about the value of recommending ICP monitoring in pediatric patients with STBI in Mexico. This information could be useful in other Latin American countries under similar economic conditions with respect to health care.

Data collection of patients with STBI faces several challenges [18] because it is an extremely serious condition. Usually there is a lack of uniform criteria for the selection of variables [19], sample sizes are small, and groups to be compared are unequal because of the ethical difficulty in randomly assigning patients to a control group (without monitoring) [20,21] or because physicians may refuse to monitor or not to monitor some patients [22]. This produces samples affected by uncertainty, and so clinical studies have not provided a conclusive answer about the effectiveness and cost-effectiveness of ICP monitoring.

This study aimed to assess whether ICP monitoring is cost-effective, by using a statistical model, which is a simplified way to approximate a real situation, using formal math. The inputs for the model are the probability distributions of the related costs and quality-adjusted life-year (QALY) of Mexican children with STBI graded by severity using the GCS score. The use of probability distributions in a statistical model overcomes the uncertainty related to the size of a sample, adjusts for the inequality about the severity of the primary lesion, and permits evaluating the cost and effectivenes of ICP monitoring. The purpose of this approach is to produce evidence about the value of this technology under a standard care clinical environment to support decision making in the context of public hospitals.

Methods

The approach consisted of a trial-based economic evaluation using a statistical model. A prospectively collected sample of patients with STBI aged between 1 and 15 years with a previously normal psychomotor development and without concomitant chronic diseases was obtained.

Data Collection

The study was conducted in two hospitals and the data collection period was from November 2011 to June 2014. The study was submitted to the institutional review boards of both hospitals, which gave approval (R-2011-785067 and ICD-002-6-11, respectively). Authorization to enter the study was requested from the parents or legal guardians, who signed the written informed consent form if they were willing to participate.

The follow-up period was 6 months post-trauma. All patients were being treated either at the High Specialty Medical Unit of the Mexican Social Security Institute or at the Agustín O'Horán General Hospital of the Ministry of Health of Yucatán, both of which are public, third-level hospitals located in Mérida, Yucatán, Mexico. In the former, patients are affiliated government workers or their relatives, and in the latter patients are covered by the so-called Seguro Popular (Popular Insurance), or else they are people with no medical insurance. The intraparenchymal ICP probes and monitors were obtained through funding from the Teacher Improvement Program (*Programa de Mejoramiento para el Profesorado*), for clinical and research purposes, and were made available in both hospitals free of charge.

The evaluation of each patient by a neurosurgeon was requested and, according to his clinical judgment, it was decided whether to install an intraparenchymal probe (Spiegelberg SND 13.1.53, 3PN probe, Hamburg, Germany) for ICP monitoring, thus giving rise to the study groups (monitoring group = with ICP monitoring; control group = without ICP monitoring). The intraparenchymal Spiegelberg probe has a balloon at its tip, which is filled with a small, controlled amount of air and is connected to an ICP monitor of the same brand (model HDM26.1). The system meets the specifications of the American national standard for ICP monitoring [23].

All patients with ICP monitoring were treated according to the management guidelines of the Brain Trauma Foundation [24], the main aims of which are to preserve the CPP above 60 mm Hg and the ICP below 15 mm Hg, as well as to maintain vital functions and to prevent complications of other systems and organs. Nevertheless, because this study was aimed at assessing the cost-effectiveness of ICP monitoring under normal clinical conditions, compliance of these guidelines was not strict. The control group received standard treatment on the basis of the expected pathophysiology after head trauma.

The economic evaluation of ICP monitoring was carried out from the point of view of the patient service provider/payer.

The strategies that were compared were the inclusion of ICP monitoring to guide the treatment of pediatric patients with STBI versus the standard approach, in which ICP monitoring is not used.

Costs

The cost of hospitalization included only direct medical costs and those related to clinical complications, supplies such as medicines, laboratory analyses, imaging studies (ultrasound, computed tomography scans, x-rays), surgeries, and length of stay in the pediatric intensive care unit and in the general pediatric ward. The amounts of these supplies were obtained from the clinical records, and this information was corroborated every day.

The source for the prices of medicines was the 2015 Catalog of the Mexican Social Security Institute Purchasing Department, Yucatán office (unpublished data, 2015). The costs of hospital stays, laboratory analyses, and other studies were taken from the *Official Journal of the Federation* (*Diario Oficial de la Federación*, Mexico) dated April 29, 2014 [25]. The cost of the intraparenchymal probe was the list price provided by the supplier. The ICP monitors did not generate any cost because they were loaned to the hospitals when the probes were purchased. No discount rates were applied to any of the items. All costs are reported in Mexican pesos (Mex$) (exchange rate: ~Mex $18.1 for US $1 on August 19, 2016).

Effectiveness

The measure of effectiveness was the QALY. The Health Utilities Index 2 (HUI-2) [26] was used to estimate the utilities for QALY. The HUI-2 produces a quantity on the basis of health preferences, and when it is used for children, it contains six dimensions: sensation, mobility, emotion, personal care, knowledge, and pain. Each of these dimensions has values ranging from 1 to 4 or 5 points.