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Review Article

The Outcomes of the Use of Induced Hypothermia in Patients Victims of Traumatic Brain Injury: An Integrative Review of the Literature

Layza Hellen Fernandes Menezes[1]*, Italo Kauan Ribeiro de Carvalho Martins[2], Luís Phelipe Gama de Moraes[2], Amanda Cavalcanti Pinheiro Barbas[3], Ian Gabriel Lucchese de Sá Cruz[2], Breno Dias Lima Ribeiro[2] and José Alberto Pereira Pires[2]

[1]*Universidade Federal do Maranhão (UFMA), Pinheiro, Maranhão.*

[2]*Universidade Federal do Maranhão (UFMA), São Luís, Maranhão.*

[3]*Universidade Federal de São João del-Rei (UFSJ), São João del-Rei, Minas Gerais.*

Corresponding Author Information

Layza Hellen Fernandes Menezes

Universidade Federal do Maranhão (UFMA), Pinheiro, Maranhão.

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ABSTRACT

Introduction: Traumatic brain injury (TBI) is characterized by lesions caused by external forces to the skull that result in neurological impairment. Induced hypothermia (IH) has been proposed as a strategy to minimize secondary complications. This condition predominantly affects young men; however, mortality rates are higher among older adults. Such a scenario imposes a substantial burden on public health systems due to initial treatment costs and long-term care related to sequelae. Therefore, this study aimed to gather evidence regarding outcomes associated with the use of IH as a therapeutic approach in TBI.

Methods: This study consists of a literature review developed based on a research question structured according to the PICO strategy (Patient, Intervention, Comparison, and Outcome). A search was conducted in the PubMed database using the descriptors "Brain Injuries, Traumatic" and "Hypothermia" combined with the Boolean operator AND. The selected articles were screened and analyzed, and the findings were organized accordingly. Studies available electronically, published in English, and presenting titles and abstracts addressing the association between TBI and IH were included. Of the 46 articles identified, 36 were excluded after application of the selection criteria, and 10 were included in the final review.

Results: Andrews et al. [1] conducted a systematic review that did not demonstrate a significant difference in mortality with the use of IH in patients with TBI, although lower-quality studies tended to suggest potential efficacy. Cooper et al. [2], in a randomized clinical trial, found no benefit associated with IH treatment. In contrast, Crompton et al. [3] reported beneficial effects of IH in TBI. Wu X et al. [4] did not support the use of IH for neuroprotection but suggested its effectiveness in reducing intracranial pressure (ICP). Andrews et al. [1] indicated that IH may be harmful in less severe injuries and does not provide benefits in more severe cases. Dunkley and McLeod [5] suggested that IH may improve neurological outcomes, whereas Tasker et al. [6] observed that the mortality benefits of IH were not statistically significant. Huang et al. [7] found no significant difference in mortality rates but suggested that mild IH may be beneficial for neurological recovery.

Conclusion: The efficacy of IH in TBI appears to vary according to factors such as injury severity and duration of exposure. Although IH may contribute to the reduction of ICP, most studies do not demonstrate a significant reduction in mortality and suggest a potential increase in the risk of sepsis and pneumonia.

KEYWORDS

Traumatic brain injuries, Induced hypothermia, Intracranial pressure, Neuroprotection.

Introduction

Traumatic brain injury (TBI), according to the International Classification of Diseases (ICD-10), is defined as an injury resulting from external forces to the skull that directly affect the brain parenchyma, cranial nerves, meninges, and scalp. This type of trauma may be classified according to several variables, including mechanism (closed, penetrating, or blast-related), severity, duration of loss of consciousness and post-traumatic amnesia, as well as findings on imaging studies. In this context, in conjunction with the Glasgow Coma Scale (GCS), TBI can be categorized as mild, moderate, or severe according to the degree of neurological impairment.

The primary concern of the medical team in managing these cases is the prevention of secondary injuries, that is, those resulting from the initial insult. Among these, increased intracranial pressure (ICP) due to hemorrhage and extra-axial or intracerebral hematomas is particularly noteworthy. The main complications associated with these disturbances include reduced cerebral perfusion, which may progress to cerebral ischemia and subsequent necrosis. Surgical procedures commonly employed to prevent complications related to TBI include hematoma evacuation, craniectomy, and fracture repair. In cases classified as mild, surgical intervention is rarely required. Therefore, an individualized approach to patients with TBI is essential, as each clinical presentation demands specific management strategies, especially considering the lack of consensus regarding optimal pharmacological treatment [8].

Within this context, body temperature reduction through induced hypothermia (IH) has generated controversy regarding its indication and efficacy. Potentialbenefits described in the literature include reduction of intracranial pressure, increased cerebral perfusion pressure, decreased cerebral oxygen consumption, reduced concentrations of excitatory neurotransmitters and inflammatory mediators, and preservation of blood–brain barrier integrity. While some studies report beneficial effects, others do not demonstrate significant clinical advantages and even suggest potential harm in certain cases. It is important to emphasize that several factors may account for these discrepancies, particularly the distinction between prophylactic and therapeutic IH, which varies according to the timing of hypothermia initiation after injury. According to Escamilla-Ocañas [9], IH should preferably be reserved as a refractory or last-line intervention within a stepwise management approach for severe cases.

The most common sequelae of neurological impairment include hemiplegia, decreased level of consciousness associated with contralateral hemiparesis, and ipsilateral mydriasis. In some cases, neurological damage may progress irreversibly to brain death, a condition that may also raise considerations regarding organ donation [10]. Given the severity of potential outcomes, one of the proposed objectives of induced hypothermia is to prevent this cascade of adverse consequences.

Worldwide, TBI predominantly affects young men, largely due to motor vehicle accidents, interpersonal violence, and firearm-related injuries, with alcohol consumption serving as a significant contributing factor, reflecting an important sociocultural component. This epidemiological profile has substantial economic implications, as it affects individuals of productive age. In Brazil, TBI represents a major public health concern due to its significant incidence (65.54 per 100,000 inhabitants) and the considerable financial burden associated with acute treatment and long-term care for sequelae. According to DATASUS data, between 2008 and 2019, approximately 131,014 hospital admissions were attributed to TBI, resulting in total expenditures of USD 43,238,319.90. Although TBI primarily affects younger individuals, mortality rates are significantly higher among older adults, ranking below only cancer and cardiovascular diseases in terms of causes of death [11].

In summary, the present study aims to synthesize the available evidence regarding the use of induced hypothermia in traumatic brain injury. This approach seeks to clarify the current state of the art and identify gaps that may guide future research.

Methodology

The present study is a literature review addressing "Outcomes associated with the use of induced hypothermia in patients with traumatic brain injury". The guiding research question was: "What are the main impacts of induced hypothermia in patients with TBI?" The study was structured according to the PICO strategy (Patient, Intervention, Comparison, and Outcome), defined as follows: P = adults and children with TBI; I = exposure to induced hypothermia; C = individuals with TBI who did not undergo induced hypothermia; O = outcomes associated with this therapeutic approach.

The study was conducted in the following stages: formulation of the research question, database search in PubMed, critical appraisal of all selected articles, and organization of the results in September 2023.

A comprehensive literature search was performed in accordance with the PRISMA guidelines for systematic reviews. Eligible studies were those available electronically, published in English, and designed as meta-analyses, systematic reviews, clinical trials, or randomized controlled trials, with titles and abstracts addressing the association between TBI and induced hypothermia. The search was conducted in the PubMed database using the descriptors "Brain Injuries, Traumatic" and "Hypothermia," combined with the Boolean operator AND. Exclusion criteria comprised studies that did not address the relationship between TBI and induced hypothermia, abstracts that did not focus on the research topic, and study designs other than those specified in the inclusion criteria. Of the 46 articles identified, 36 were excluded after application of the eligibility criteria. Consequently, 10 studies were included in the final review (Figure 1). Data extraction

was performed independently by the authors using a structured approach, collecting the following variables: author, year, title, country, methodology, and results. The findings were presented in a descriptive format.

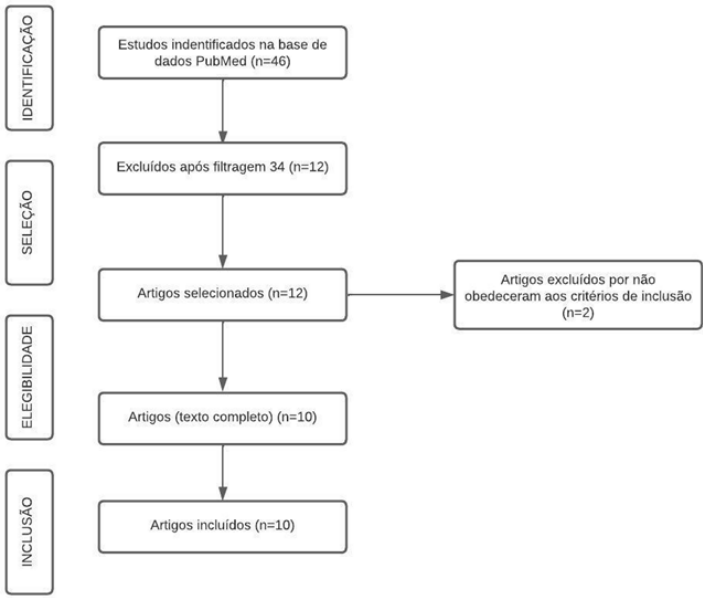

Figure 1: PRISMA 2009 flow diagram adapted for study selection.

Results

(Table 1) summarizes the 10 studies included in this review, along with information regarding author and year of publication, study title, country, methodology, and main findings. None of the selected studies were conducted in Brazil; all (100%, n = 10) were published in international journals. Regarding geographic distribution, 30% (n = 3) were conducted in China, 10% (n = 1) in the United States, 10% (n = 1) in Hungary, 10% (n = 1) in Australia, and 40% (n = 4) in the United Kingdom. All studies were indexed in the MEDLINE database and published in English (100%, n = 10). Concerning study design, 20% (n = 2) were randomized controlled trials, 20% (n = 2) were systematic reviews, and 60% (n = 6) were meta-analyses

With regard to the results identified, it is important to highlight, a priori, Andrews et al. [1], who conducted a systematic review between January 1, 2011 and March 31, 2016 to analyze the evidence regarding the therapeutic efficacy of induced hypothermia in victims of traumatic brain injury (TBI). Twenty articles were included, providing mortality data from a total of 2,270 patients, among whom a significant reduction in this outcome was observed in the group in which induced hypothermia (IH) was applied (RR = 0.84; [95% CI = 0.74 to 0.96]; p = 0.01). However, when the six high-quality studies were analyzed separately, mortality was higher among those who underwent IH (RR = 1.22; [95% CI = 0.99 to 1.57]), although this finding was not statistically significant (p = 0.06). In contrast, the remaining studies, despite being classified as low quality according to the Jadad scale, demonstrated worse outcomes in the control group, this time with greater statistical significance (RR = 0.72; [95% CI = 0.62 to 0.84]; p < 0.00001).

In Cooper et al. [2], a multicenter randomized clinical trial with blinded outcome assessment was conducted, including data from 511 patients across six countries on three different continents, between December 2010 and May 2018. A total of 266 patients were randomly assigned to receive prophylactic hypothermia. The target temperature was 33°C or 35°C (in cases of bleeding) for at least 72 hours or up to 7 days in the presence of elevated intracranial pressure. The remaining 245 patients were maintained under normothermia (37°C). Six months after the trauma, 117 patients in the hypothermia group (48.8%) and 111 in the normothermia group (49.9%) achieved favorable outcomes (risk difference = -0.4% [95% CI = -9.4 to 8.7];

RR with hypothermia = 0.99 [95% CI = 0.82 to 1.19]; p = 0.94). Among those who experienced adverse events within the first 10 days after randomization, new or worsening intracranial bleeding occurred in 18.1% of the hypothermia group and 15.4% of the normothermia group. Regarding pneumonia, 55% of patients in the hypothermia group developed this complication, compared with 51.3% in the normothermia group.

Crompton et al. [3], in their meta-analysis aimed at quantifying the positive outcomes of induced hypothermia (IH) in TBI patients by analyzing mortality rates, neurological outcomes, and adverse effects, included 3,848 patients (men = 73.4%), of whom 1,922 were treated with hypothermia and 1,926 comprised the normothermic control group. Treatment with hypothermia resulted in a 35% increase in favorable outcomes (RR = 1.35; [95% CI = 1.18 to 1.54]; p < 0.00001), and this positive effect was maintained in the long term. However, the studies suggested that pneumonia as an adverse event was 28% more likely when TBI patients were subjected to hypothermia (RR = 1.28; [95% CI = 1.01 to 1.62]; p = 0.04). In pediatric patients, outcomes were less favorable. Among children treated with hypothermia, there was a 66% increase in mortality compared with those maintained under normothermia (RR = 1.66; [95% CI = 1.06 to 2.59]; p = 0.03), in addition to a 10% increase in unfavorable neurological outcomes (RR = 0.9; [95% CI = 0.8 to 1.01]; p = 0.06).

Wu X et al. [4] conducted a systematic review evaluating the use of early induced hypothermia in patients with traumatic brain injury, including a total of 1,207 patients. Regarding mortality, the analysis demonstrated no significant difference between the hypothermia group and the control group (RR = 1.11; [95% CI = 0.90 to 1.37]). In terms of favorable neurological outcomes at six months, the analysis indicated a slight advantage for the hypothermia group compared with the control group (RR = 1.03; [95% CI = 0.91 to 1.16]), although this difference was not statistically significant. In summary, this study found no robust evidence supporting the use of early prophylactic hypothermia as a primary neuroprotective strategy in adults with TBI, regardless of the duration of hypothermia. However, hypothermia may be effective in reducing refractory elevated intracranial pressure (ICP).

The study conducted by Andrews et al. [1] aimed to investigate the effects of therapeutic hypothermia (TH) on reducing intracranial hypertension in patients with traumatic brain injury. It was designed as a randomized, controlled, standardized clinical trial with blinded outcome assessment. Eligible participants

with intracranial pressure (ICP) greater than 20 mmHg were randomized to receive standard care with osmotherapy (control group) or standard care plus TH, titrated as the primary intervention to maintain ICP below 20 mmHg. TH was maintained for at least 48 hours and continued as necessary to keep ICP at or below 20 mmHg, with core temperature maintained between 32°C and 35°C. The analysis included 386 patients in the intention-to-treat (ITT) group and 257 in the per-protocol (PP) group. The results indicated that hypothermia as an initial strategy to reduce ICP below 20 mmHg is potentially harmful in patients with less severe injury. Accordingly, the authors recommend caution in the use of hypothermia after TBI, particularly in the context of ICP reduction. The study also raises important questions regarding the appropriate timing for initiating hypothermia in TBI patients and emphasizes the importance of effective ICP control through other measures, such as sedation, positioning, and optimization of arterial blood gas levels. In summary, the findings suggest that this approach may be detrimental in patients with lower injury severity while failing to demonstrate clear benefits in those with more severe injuries, thereby discouraging its use in this clinical context.

Dunkley e McLeoud [5] conducted a systematic review aimed at evaluating the effects of therapeutic hypothermia (TH) in patients with traumatic brain injury. All studies included in this review used the Glasgow Outcome Scale (GOS) to measure neurological outcomes, although at different time points after the initial injury, ranging from 6 months to 2 years. In all studies, a score ≥ 4 was defined as a favorable outcome, whereas a score ≤ 3 was considered unfavorable. This review suggests that TH may have the potential to improve neurological outcomes in TBI patients; however, study findings were heterogeneous, with some contradictions regarding its efficacy. It is important to note that the included studies varied in quality, with limited information regarding randomization methods and allocation concealment, which affects the reliability and validity of the results. Furthermore, the small sample sizes preclude confident generalization of the findings to the broader population.

The study conducted by Tasker et al. [6] consisted of a systematic review of English-language literature using the descriptors "hypothermia", "traumatic brain injury", "head injury" and "intracranial pressure" in the PubMed database between 2000 and 2016. Inclusion criteria required systemic induced hypothermia for 12 hours or more, as well as survival to discharge from the pediatric intensive care unit. The benefits of hypothermia compared with normothermia in relation to mortality were not statistically significant, despite variability in cooling times, target temperatures, and duration of temperature control among the studies included in the meta-analysis. The meta-analysis itself demonstrated low statistical heterogeneity; however, hypothermia-related parameters differed across studies. Additional analyses based on hypothermia duration revealed no significant association with mortality in the 24-, 48-, and 72-hour groups. Results were not influenced by the duration of low-temperature exposure. In cumulative Bayesian analysis, hypothermia demonstrated a 40% probability of reducing morbidity compared with normothermia and a 28% probability of achieving a relative risk reduction in mortality greater than 20%. Treatment of pediatric TBI with hypothermia did not yield sufficiently positive results compared with normothermia, as reported in the article. Overall, the quality of available randomized controlled trials was low, limiting definitive conclusions.

Huang et al. [7] conducted a meta-analysis including 15 studies and found that mild hypothermia, compared with conventional management of traumatic brain injury, did not result in a statistically significant difference in mortality rates (RR 0.94; [95% CI = 0.77–1.14]; p = 0.53). However, mild hypothermia demonstrated a positive effect on neurological progression and recovery in TBI patients (RR 1.20; p = 0.04; [95% CI = 1.01–1.42]), with the greatest effect observed at follow-up of 12 months or longer. Nevertheless, further research is required to validate these findings.

Table 1: Studies evaluating the association between induced hypothermia and traumatic brain injury.

Author	Title	Country	Methods	Results
Olah et al. [12]	POLAR Study Revisited: Therapeutic Hypothermia in Severe Brain Trauma Should Not Be Abandoned	Hungary	This multicenter randomized trial conducted across six countries included 511 patients. Cooling parameters were adjusted and calculated using COIN methodology, mortality rates were estimated by odds ratios, and publication bias was assessed using the trim-and-fill method and Egger's test.	The study suggested that prophylactic hypothermia is not neuroprotective after severe TBI and that prolonged hypothermia may exert immunosuppressi ve effects.
Chen et al. [13]	A meta-analysis of the effects of therapeutic hypothermia in adult patients with traumatic brain injury	China	Twenty-three studies were included, comprising a total of 2,796 patients. Publication bias was assessed using funnel plots and sensitivity analysis performed with STATA version 15.1. Statistical analyses were conducted using Review Manager (RevMan) version 5.3, and quantitative synthesis was performed using the Mantel–Haenszel chi-square test.	The meta-analysis demonstrated that hypothermia may increase mortality rates in patients with traumatic brain injury in high-quality studies. However, it may be beneficial in cases of elevated intracranial hypertension when therapy is initiated within 24 hours.
Wu X et al. [4]	The effectiveness of early prophylactic hypothermia in adult patients with traumatic brain injury: A systematic review and meta-analysis	China	Six randomized controlled trials were included, totaling 1,207 patients. Risk of bias was assessed using the Cochrane tool, and statistical analysis was conducted with Review Manager 5.3.	The study found no solid evidence supporting early prophylactic hypothermia (within 6 hours of injury) as a primary neuroprotective strategy in adult patients with TBI.

Andrews et al. [1]	Mortality Risk Stratification After Traumatic Brain Injury and Hazard of Death Treated Hypothermia in the Eurotherm 3235 Trial	Reino Unido	This randomized, controlled, standardized clinical trial included blinded outcome assessment. Patients were stratified into risk tertiles according to the extended IMPACT model score.	Hypothermia used as a first-line strategy to reduce ICP below 20 mmHg was potentially harmful in patients with less severe injury and showed no clear benefit in more severe cases. The study did not recommend hypothermia after TBI, particularly for ICP reduction.
Dunkley. S; McLeoud. A [5]	Therapeutic Hypothermia in patients following traumatic brain injury: a systematic review	Reino Unido	Eight studies were included and evaluated using the CASP checklists for randomized controlled trials or cohort studies, depending on design. Despite the lack of high-quality research, the review suggested that induced hypothermia may improve neurological outcomes with a low risk of severe complications.	However, patients with cerebral contusions appeared to derive little or no benefit compared with normothermia.
Tasker R. et al [6]	Updating evidence for using hypothermia in pediatric severe traumatic brain injury: conventional and bayesian meta-analytic perspectives.	Estados Unidos	Seven randomized controlled trials were included. Data were analyzed using RStudio; heterogeneity was estimated with the DerSimonian–Lai rd method; and Bayesian analysis was performed using JAGS 4.2.0.	Conventional meta-analysis could not exclude the possibility of no difference between hypothermia and normothermia in mortality or poor outcomes. However, Bayesian analysis suggested a one-in-three probability of achieving a relative risk reduction in mortality greater than 20% with hypothermia.
Andrews et al. [1]	Updated systematic review of therapeutic hypothermia for dult patients following traumatic brain injury	Reino Unido	Twenty-one studies were included, encompassing 2,299 patients with acute closed TBI. The Cochrane tool was used to assess risk of bias, and a modified Jadad scale was applied for quality stratification.	High-quality studies demonstrated no significant differences in mortality, unfavorable outcomes, or pneumonia incidence. Nevertheless, strict fever control was suggested to reduce mortality.
Cooper et al. [2]	Effect of Early Sustained Prophylatic Hypothermia on Neurologic Outcomes Among Patients With Severe Traumatic Brain Injury	Austrália	This multicenter randomized clinical trial with blinded outcome assessment included 511 patients across six countries, of whom 266 were randomized to the hypothermia group. Analyses were conducted using SAS 9.4, with a two-sided p value < .05 considered statistically significant.	After six months, no neurological benefit was observed with early prophylactic hypothermia compared with normothermia.
Huang et al. [7]	Effect of mild hypothermia on prognosis of patients with severe traumatic brain injury: A meta-analysis with trial sequential analysis	China	Fifteen studies were included, totaling 2,523 patients. Data were analyzed using Review Manager 5.3, and publication bias was assessed with Comprehensive Meta-Analysis (CMA) version 3.0.	No statistically significant difference in mortality was observed between mild hypothermia and normothermia. However, patients receiving mild hypothermia demonstrated improved neurological outcomes.
Crompton et al. [3]	Meta-Analysis of Therapeutic Hypothermia for Traumatic Brain Injury in Adult and Pediatric Patients	Reino Unido	Twenty-eight randomized controlled trials and 21 observational studies were included, comprising 3,848 adult and pediatric patients. Statistical analysis was performed using RevMan 5.3.	The study suggested that hypothermia is beneficial in adult TBI patients, particularly when targeting 33°C for 72 hours followed by gradual rewarming. Conversely, unfavorable outcomes predominated in pediatric patients.

Source: Prepared by the authors.

The meta-analysis conducted by Chen et al. [13] evaluated the effects of therapeutic hypothermia in adult patients with traumatic brain injury based on 23 studies, encompassing a total of 2,796 patients, all diagnosed with TBI, with one group receiving therapeutic hypothermia (TH) and another serving as the control group. Mortality rates were reported in 22 studies, showing lower prevalence in the group treated with hypothermia when applied therapeutically (RR 0.66; [95% CI = 0.49–0.88]; p = 0.006), that is, after the onset of complications. Treatment success was more evident when hypothermia was initiated within the first 24 hours (RR 0.83; [95% CI = 0.71–0.96]; p = 0.01) and in post-craniectomy cases (RR 0.69; [95% CI = 0.48–1.00]; p = 0.05). A reduction in inflammatory response and biochemical cascade was observed due to decreased metabolic rates influencing cerebral blood flow. Consequently, intracranial pressure was reduced and the blood–brain barrier preserved, constituting a benefit of TH in this specific subgroup. However, an increased risk of pneumonia (RR 1.48; [95% CI = 1.11–1.97]; p = 0.007) and sepsis was observed among individuals whose body temperature was reduced, in addition to reduced hepatic metabolism, a scenario that may precede propofol infusion syndrome. Thus, TH proved to be detrimental in patients with less severe traumatic injury, with timing of induction being a decisive factor, as severe complications were reported when initiated late.

In the revisited POLAR randomized clinical trial by Olah et al. [12], which enrolled 511 patients across six countries, severe TBI cases were evaluated under prophylactic hypothermia and normothermic management. No significant difference in neurological outcomes was observed between the two groups, suggesting that early therapeutic hypothermia may be unnecessary. Hypothermia was induced with up to 2,000 mL of intravenous saline solution at 4°C. Among 233 patients, the median time from injury to the initial target temperature of 35°C was 2.5 hours; for 186 patients, the median time to reach 33°C was 10.1 hours, and 85% of these received less than 48 hours of hypothermia. Statistical analysis demonstrated similar percentages of favorable outcomes in both treatment groups, as well as comparable rates of new intracranial bleeding, coagulopathy, pneumonia, and infusion syndrome (associated with propofol). Therefore, the potential neuroprotective effect of this intervention was not demonstrated when used as a preventive measure against secondary brain injury and may be detrimental due to its immunosuppressive effect. Although it was concluded that hypothermia may be more beneficial when targeting temperatures between 35°C and 33°C, with prolonged cooling (>48 hours) and slower rewarming (<0.25°C/h), most patients subjected to low temperatures did not reach the 33°C target due to complications and clinical decision-making. The primary outcome in this cohort of 511 adults was the proportion of patients with favorable neurological status at six months (48.8% after hypothermia versus 49.1% after normothermia), with no statistically significant difference; the relative risk with hypothermia was 0.99 ([95% CI = 0.82–1.19]; p = 0.94).

Conclusion

Among the factors influencing the performance of treatment with induced hypothermia (IH) are temperature fluctuations during the hypothermic period, the minimum target temperature to which the patient is subjected, the duration of exposure to low temperatures, the time elapsed between trauma and initial care, the severity of traumatic brain injury (TBI), characteristics of the lesions, intracranial pressure (ICP) values and progression of potential secondary insults, Glasgow Coma Scale (GCS) score, the patient's epidemiological profile, whether emergency procedures were performed prior to induction, the experience and multidisciplinary composition of the healthcare team, intensive care unit support, and the protocol adopted for rewarming to normothermia.

Furthermore, methodological rigor and appropriate population randomizationin studies addressing this topic must be considered, as investigations of lower scientific quality have demonstrated outcomes that diverge from those regarded as more consolidated evidence. Therefore, more robust and methodologically sound studies are required to achieve a higher level of reliability regarding the outcomes of induced hypothermia in the treatment and prevention of secondary brain injury following TBI.

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