

Economic Impact of Surveillance of Head Trauma Patients with Coagulopathy and Normal Initial Computed Tomography Scan (ECO-NCT)

Impacto Económico da Vigilância de Doentes com Traumatismo Cranio-Encefálico, Coagulopatias e Tomografia Computorizada Inicial Normal (ECO-NCT)

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ABSTRACT

Introduction: According to the Portuguese clinical guidelines published in 1999, patients with traumatic brain injury and coagulopathies should remain in-hospital for 24 hours for clinical and image surveillance, despite having an admission computed tomography (CT) scan showing no intracranial lesions. Growing evidence suggests this practice is not only void of clinical relevance, but that it can also be potentially harmful for the patient. Nevertheless, up until now there is no published data concerning the economic impact of this clinical practice.

Methods: A cost analysis compared retrospective data from patients admitted to our emergency department during 2022 with a hypothetical scenario in which a patient with an admission CT scan without traumatic lesions was discharged. Clinical data was also retrieved concerning the rate of a delayed intracranial bleeding on 24-hour CT scan and mortality at a six-month-period after discharge. Direct costs for the national health service were determined in terms of funding and time invested by medical teams.

Results: From a sample of 440 patients, 436 remained in-hospital for a 24-hour clinical and image surveillance, of which only two (0.5%) showed a new intracranial lesion on the second CT-scan. Neither of these two patients required therapeutic measures to control bleeding and were discharged 36 hours after admission. Out of 440 patients, one patient (0.2%) died of cardiac arrest during the 24-hour surveillance period, despite having an initial normal CT scan showing no brain lesions. Our current surveillance practice directly amounted to €163 157.00, whereas the cost of our hypothetical scenario amounted to €29 480.00: a difference of €133 677.00. The application of our surveillance guideline also meant that nine emergency shifts were devoted to this task, compared to 4.6 hypothetical shifts if patients were discharged after an initial CT scan without traumatic intracranial lesions.

Conclusion: In spite of apparently not adding any clinical value to our practice, our in-hospital surveillance may represent a significant financial and time-consuming burden, costing five times as much and demanding our medical teams twice as much work when compared to a scenario without clinical surveillance and 24-hour CT scans.

Keywords: Anticoagulants; Costs and Cost Analysis; Craniocerebral Trauma/diagnostic imaging; Tomography, X-Ray Computed

RESUMO

Introdução: De acordo com as normas de orientação clínica portuguesas de 1999, os doentes com traumatismos cranioencefálicos e coagulopatias deverão ser mantidos em vigilância intra-hospitalar por um período de 24 horas para reavaliação clínica e imagiológica, mesmo quando não existem lesões intracranianas na tomografia computadorizada crânio-encefálica (TC-CE) inicial. Existe evidência científica crescente de que não só esta prática clínica poderá ser irrelevante, como também poderá gerar mais dano do que benefício. Não obstante, até à data não existem dados publicados acerca do impacto económico desta prática clínica.

Métodos: Através de uma análise de custos foram comparados os dados retrospectivos do nosso centro hospitalar, durante o ano de 2022 com os dados de um cenário hipotético em que um doente com uma TC-CE inicial normal teria alta clínica. Simultaneamente, foram obtidos dados clínicos relativamente à taxa de hemorragia tardia na imagem de TC-CE de 24 horas e à mortalidade a seis meses. Os custos diretos para o Serviço Nacional de Saúde foram determinados em termos monetários e tempo investido pela equipa médica.

Resultados: De uma amostra de 440 doentes, 436 mantiveram vigilância intra-hospitalar por um período de 24 horas com reavaliação clínica e imagiológica, de entre os quais apenas dois (0,4%) demonstraram uma lesão intracraniana na segunda imagem de TC-CE. Nenhum destes dois doentes necessitou de terapêutica dirigida para controlo da hemorragia, tendo tido alta às 36 horas. Do total dos 440 doentes, um (0,2%) faleceu durante o período de vigilância de 24 horas por motivo de paragem cardiorrespiratória, após a realização de uma imagem de TC-CE sem evidência de lesão intracraniana. A nossa prática de vigilância atual envolveu custos diretos estimados em €163 157,00, enquanto o cenário hipotético fez o total de €29 480,00, representando uma diferença de €133 677,00. A aplicação do protocolo de vigilância previsto na norma também implicou um investimento adicional de nove turnos de urgência dedicados a esta prática, comparativamente com apenas 4,6 turnos se os doentes tivessem tido alta após um TC-CE inicial normal.

Conclusão: Além de aparentemente poder não acrescentar valor clínico à população de doentes analisada, este protocolo de vigilância poderá representar um custo financeiro e de tempo significativo, com um dispêndio monetário cinco vezes superior, requerendo o dobro do trabalho por parte das nossas equipas médicas.

Palavras-chave: Anticoagulantes; Custos e Análise de Custos; Tomografia Computorizada; Traumatismo Crânio-Encefálico/diagnóstico por imagem

INTRODUCTION

According to the clinical guidance outlined in the national guideline for the management of traumatic brain injuries (TBI), published by Direção-Geral da Saúde in 1999, patients with coagulopathies and a history of TBI should

remain under in-hospital surveillance, undergoing a craniocerebral computed tomography (CT) scan after initial admission, subsequently followed by another CT scan approximately 24 hours after the traumatic event, including

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cases where the initial imaging examination does not show new traumatic injuries.¹ In 2002, the European Federation of Neurological Societies published guidelines that advocated the same clinical and imaging surveillance approach.² However, in a subsequent review in 2012, they left open the possibility of forgoing the 24-hour follow-up CT imaging based on clinical criteria.³

In a prospective multicenter study, based on a national population sample and published in 2021 – “Prospective Observational Study of Hypocoagulated Head Trauma Patients with Normal Initial Computed Tomography (HIPTCN)” – Duarte-Batista *et al* concluded that, from a sample of 178 included patients, only four (2.3%) presented a new bleeding on the 24-hour follow-up image (NB24), and in three of these patients (1.7%) hospitalization was eventually required.⁴ None of these patients required surgical treatment, with hypocoagulation being reversed in one case and only interrupted in the remaining cases. Among the complications associated with the management, seven cases were also documented (five cases with agitation/confusion, one case with atrial fibrillation and one case with stridor and dyspnea).

A study has recently been published in this area, depicting various surveillance practices in this patient group, with different degrees of compliance by medical professionals to their implementation.⁵ Nevertheless, the results appear to converge with our national data, showing NB24 rates below 4%,⁶⁻¹¹ for which no targeted treatment implementation was necessary. Additionally, several risk factors with predictive power for identifying this group of patients with NB24 have been identified and include loss of consciousness associ-

ated with TBI, amnesia after TBI, non-TBI supraclavicular trauma, age over 65 years, and associated skull fracture.¹²⁻¹⁵

Although there have been several studies aimed at evaluating the clinical impact of this surveillance practice, there are still no published data regarding its economic impact. Therefore, we aimed to conduct an economic evaluation of the guideline implementation at our hospital center, through a cost analysis from the perspective of our national health service – Serviço Nacional de Saúde (SNS) – with the aim of understanding its economic impact in our reality. Additionally, clinical outcomes were analyzed in our cohort of patients with TBI and coagulopathies with initial CT imaging without traumatic intracranial injury, in order to complement our knowledge of the national epidemiology regarding this patient group.

METHODS

Study design

An observational retrospective study was conducted by reviewing electronic medical records at our hospital center [Unidade Local de Saúde de Santo António (ULSSA)], from which we developed a cost analysis model. This study followed the principles of the Helsinki Declaration of 2024 and was approved by the ethics committee of ULSSA/ICBAS under the number 2023.176 (146-DEFI/138-CE). During this analysis, the guidelines for economic evaluations of CHEERS/ISPOR were also applied.

Cost-analysis model structure

The cost analysis was based on an analytical decision

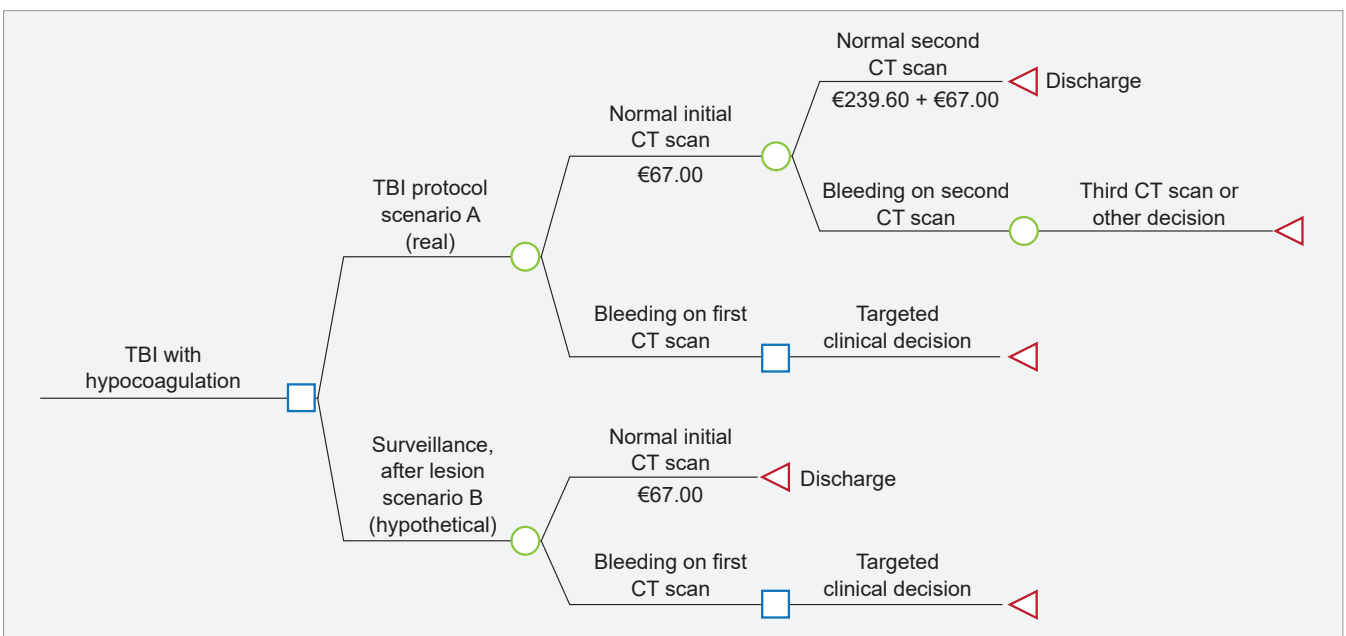


Figure 1 – Flowchart comparing scenarios A and B

model developed from a decision tree, designed with the support of TreeAge Pro Healthcare 2023 software (Fig. 1). In the first branch of the decision tree, we find a square that symbolizes the initial event of TBI in patients with coagulopathies. From there, two scenarios were analyzed:

- Scenario A: observed reality in the patient cohort of ULSSA, in which the national guideline for TBI surveillance was followed.
- Scenario B: hypothetical scenario of surveillance only in the event of a documented intracranial bleeding in the first CT scan, as advocated by clinical guidelines from other countries.

According to the results previously published in the scientific literature, the application of this cost analysis model is considered appropriate, assuming that both analyzed scenarios demonstrate clinical equivalence.^{4,6-11,16} The temporal observation horizon for both scenarios corresponds to the 24-hour surveillance recommended by the national TBI guideline. Additionally, clinical data were also collected for a six-month horizon, with the aim of obtaining information regarding associated mortality.

Clinical data

The study included patients with a history of TBI and coagulopathy, with initial CT scan showing no evidence of new intracranial bleeding observed in the emergency department of ULSSA in 2022. Inclusion and exclusion criteria are described in Table 1.

Among the analyzed patient group, we identified those who had a normal 24-hour follow-up CT scan and those who had new intracranial bleeding. In the latter group, clinical decision-making was analyzed to determine whether any additional medical or surgical therapy would be implemented. Data regarding patient demographics (age and sex), neurological condition at admission (Glasgow Coma Scale Score), trauma mechanisms, etiology of coagulopathy, and six-month mortality were also collected (Table 2). In the event of death within the first six months after the traumatic event, it was recorded whether the death occurred within the first 24 hours after discharge or later. The

information corresponding to the occurrence of mortality was obtained from the hospital records of ULSSA. Death certificates were not consulted in cases of mortality occurring after this 24-hour period, as the primary objective of this study concerned the evaluation and comparison of clinical and economic outcomes within this specific timeframe.

All cases of non-compliance with the TBI guideline due to refusal or discharge against medical advice were also recorded (Table 2). The etiology of coagulopathy was characterized as pharmacological and non-pharmacological, with the former further subdivided into anticoagulation due to direct oral anticoagulants (DOAC), vitamin K antagonists (VKA), and heparins.

All included patients had their anticoagulation therapy suspended during the observation period and resumed this

Table 2 – Sample characteristics

Age	
Average:	80.5 years
Sex	
Male:	196 (44.5%)
Female:	244 (55.5%)
Coagulopathy	
DOAC	348 (79.1%)
AVK	86 (19.5%)
Enoxaparin	3 (0.7%)
Liver failure	2 (0.4%)
Haemophilia	1 (0.2%)
Glasgow Coma Scale Presentation	
15	360 (81.8%)
14	78 (17.7%)
13	2 (0.4%)
Trauma mechanism	
Fall from standing height	408 (92.7%)
Fall from over standing height	21 (4.8%)
Direct impact	11 (2.5%)
Mortality	
< 24 hours before discharge	1 (0.2%)
> 24 hours after discharge	27 (6.1%)
Indeterminate cause	4 (0.9%)
Cardiopulmonary arrest	9 (2.0%)
Respiratory tract infection	5 (1.1%)
Urinary tract infection	3 (0.7%)
Gastrointestinal bleeding	2 (0.4%)
Ischemic or hemorrhagic stroke	2 (0.4%)
Progression of oncological disease	2 (0.4%)
Bacteriemia	1 (0.2%)

Table 1 – Inclusion and exclusion criteria

Inclusion criteria	
Admission for TBI in the last 24 hours, in the emergency department of ULSSA	
Age above 18 years	
Coagulopathy: Pharmacological or non-pharmacological	
Initial CT scan without intracranial bleeding <i>de novo</i>	
Exclusion criteria	
Patients on vitamin K antagonists, with INR values < 1.4	
TBI more than 24 hours prior	

medication only after follow-up imaging showed no new intracranial bleedings.

Costs for the National Health Service

The costs for the SNS were calculated based on the cost-tables provided in the annual analytical accounting report of 2022, drafted by the Management Department of ULSSA. According to this report, the 24-hour stay in the emergency department is priced at €239.60 per case, which corresponds to the cost of a patient's stay in the surgical area of ULSSA, including the costs associated with their monitoring and provision of healthcare (including medication and associated consumables) (Table 3). It should be recognized that the method of calculating this value is confidential, so it may include both fixed and variable costs for each of the patients analyzed. The cost associated with each CT scan is priced at €67.00, as stipulated in decree n.º 254/2018, published by the Portuguese government in the Regional Legislative Decree (Table 3).¹⁷

In addition to these direct costs, the costs associated with the time spent by each medical professional when implementing the TBI surveillance guideline were also estimated. This guideline involves medical history taking, patient observation, clinical information recording, diagnostic imaging examination, patient handover between medical specialties, essential medication prescribing during in-hospital stay, communication of the plan with family members and/or caregivers, clinical and imaging reevaluation, and discharge decision. During clinical practice (scenario A), our research team measured the average time required to observe and to make clinical decisions regarding these patients, reaching a minimum value of 15 minutes. Therefore, it is considered necessary to allocate a minimum of 15 minutes of work for the completion of all these medical activities, according to the authors' experience. In the case of the hypothetical scenario (scenario B), since a normal initial CT scan would necessarily determine clinical discharge, only the following activities would be considered necessary: medical history taking, patient observation, clinical informa-

tion recording, diagnostic imaging examination viewing, and discharge determination. Since there is no data available to accurately calculate the additional time required to comply with scenario A, we assumed that these procedures would take half the working time needed to comply with scenario B (Table 4).

RESULTS

In total, 440 patients were included, with an average age of 80.5 years, among whom only two (0.4%) presented a new intracranial lesion on the 24-hour follow-up CECT scan. Among this sample population, four patients were admitted for in-hospital surveillance in the emergency department but were discharged against medical advice or abandoned treatment, resulting in a total of 436 patients who completed the assessment. None of these 440 patients were admitted to the hospital ward; therefore, the entire surveillance process took place in the emergency department, with no additional costs generated from hospital admissions.

Regarding the neurological assessment of our population, 360 patients (81.8%) scored 15 points on the Glasgow Coma Scale, 78 patients (17.7%) scored 14, and only two patients (0.2%) scored 13 (Table 2). The majority of these traumatic incidents resulted from falls from standing height (408 patients - 92.7%), while the remainder occurred due to falls from a height greater than standing height (21 patients - 4.8%) or direct impact head trauma (11 patients - 2.5%) (Table 2).

The identified coagulopathies were distributed as follows:

- Four hundred and thirty-seven (99.3%) patients with pharmacological coagulopathy, among whom 348 (79.1%) had taken DOAC, 86 (19.5%) had taken VKA, and three (0.7%) had received enoxaparin;
- Two (0.4%) patients with coagulopathy due to chronic liver disease, and one (0.2%) patient with coagulopathy secondary to hemophilia.

The costs associated with scenario A include in-hospital surveillance (i.e., patients' stay in the emergency department) – €104 465.00 (€239.60 x 436) – and the CT scans – €58 424.00 [€67.00 x (436 x 2)], for patients who complied with the assessment. Additionally, the cost associated with imaging was added for the four patients who were discharged against medical advice or abandoned treatment –

Table 3 – Hospital costs

	CT scan (unitary cost)	24-hour surveillance (vigilance and overall care)
Cost	€67.00	€239.60

Table 4 – Scenario costs

	Initial CT scan Number (cost)	24-hour CT scan Number (cost)	24-hour in-hospital surveillance	Total cost
Scenario A (real scenario)	440 (€29 480.00)	436 (€29 212.00)	436 (€104 465.00)	€163 157.00€
Scenario B (hypothetical scenario)	440 (€29 480.00)	0	0	€29 480.00

$$\text{Cost} = 436 \times [\text{€}239.60 + (\text{€}67.00 \times 2)] + 4 \times \text{€}67.00 = \text{€}163\,157.00$$

Figure 2— Applied formula for costs to scenario A

€268.00 (€67.00 x 4). This amounts to €163 157.00 (Fig. 2). Regarding scenario B, we considered only the cost of an initial CT scan, totaling €29 480 (€67.00 x 440) (Fig. 3).

The difference in costs directly associated with health-care between the two scenarios amounts to €133 677.60.

Considering the time investment of medical professionals in the management of this patient group, scenario A requires 109 hours and 30 minutes of work [15 minutes x 436 (number of patients who complied with the assessment)] + [7.5 minutes x 4 (number of patients who did not comply with the assessment)], which is equivalent to approximately nine shifts of 12-hour emergency work. Scenario B would require 55 hours of work, equivalent to approximately 4.6 shifts of 12-hour emergency work, or 4.4 shifts less than scenario A.

Both patients with NB24 had risk factors described in the scientific literature for the occurrence of new bleeding, namely the presence of non-TBI supraclavicular trauma and age equal to or greater than 75 years. Neither of the patients had a skull fracture on the initial CT scan. In one of these patients, coagulopathy reversal therapy with prothrombin complex was implemented, resulting in complete resolution of the lesion documented in a new 24-hour follow-up scan. In the other patient, anticoagulation was suspended, and they were discharged, being reevaluated after seven days with a repeat CT scan showing signs of resorption of the previously documented lesion. None of these risk factors were identified in all other patients in our sample without a NB24.

During the analysis period, 28 patients died, with only one (0.2%) of these cases occurring during the 24-hour surveillance period, with the cause of death not directly associated with the trauma. The patient was a 95-year-old female with severe dementia, anticoagulated for atrial fibrillation, who experienced a sudden cardiac arrest while undergoing a 14-hour in-hospital observation. A brain CT scan was performed approximately eight hours after the traumatic brain injury, showing no evidence of brain trauma. The patient remained neurologically stable until the cardiac arrest. The remaining patients were discharged from the hospital and died over 72 hours later, also from causes not associated with the traumatic event under analysis. Of note, one

patient died one month after the traumatic brain injury with a new intracranial bleeding without trauma history. The patient had been discharged after a second normal brain CT scan and reinitiated anticoagulation. One month later, the patient had a massive intracranial bleeding which caused her death. In four of these 28 patients, it was not possible to determine the cause of death: one died seven days after the traumatic brain injury, while the other three died more than one month later. In these cases, the cause of death was labeled as “indeterminate” in Table 2.

DISCUSSION

This economic evaluation corresponds to a single-center and retrospective study, and as such, it suffers from some intrinsic limitations, notably the inability to extrapolate our data to the national reality. In fact, this study represents the reality of only one neurosurgical center, although this national TBI guideline (corresponding to scenario A) describes practices that are present in other hospitals across our country. However, since the guideline represents a normative value of clinical practice in the national territory, accounting for all seven hospitals with neurosurgical care in the emergency department,¹⁸ the expected cost for the SNS during the year 2022 amounts to €1 142 099.00 (scenario A x seven neurosurgical centers), with the difference between scenarios A and B being equivalent to €935 739.00. However, it should be noted that this is not a precise and rigorous economic assessment. On the one hand, it may underestimate the true costs of guideline adherence on a national scale, since not all hospitals managing these patients in Portugal have neurosurgical departments (and thus are not included in this calculation). On the other hand, it may also introduce bias due to the heterogeneity in case mix among the different neurosurgical departments across the country. It is worth noting that this is an underestimated value since it does not cover all national hospitals complying with this guideline, making its estimation difficult. If we consider the application of this guideline over the past 10 years, the national differences between scenarios A and B would correspond to €9 357 390.00. This is an extrapolation that does not account for external economic effects, such as the inflation rate, but still allows us to envision the

$$\text{Cost} = \text{Number of patients complying with the TBI protocol} \times [\text{€}239.60 + (\text{€}67.00 \times 2)] + \text{Number of patients not complying with the TBI protocol} \times \text{€}67.00$$

Figure 3 – Formula for costs

overall impact of this clinical practice on the SNS, especially considering that it started in 1999.

It is also important to note that one of the caveats of our analysis is the potential overestimation of the final value of €239.60 due to the inclusion of both fixed and variable costs, given the confidentiality of the calculation method. While this represents a limitation in our economic analysis, it is, in our perspective, the only method available to estimate the cost for these patients. Additionally, we recognize the difficulty in precisely determining the cost savings related to chronic medication, as even when patients are at home, some of this medication is subsidized by the government. This further underscores the potential overestimation of the total cost savings attributed to the non-compliance with this guideline.

We acknowledge that there are other direct costs associated with complying with this guideline which were not presented due to the impossibility of their objective quantification, such as the cost associated with hospital transportation provided by the SNS. In addition to these, there are indirect costs unrelated to healthcare, namely, the loss of productivity and working hours, especially for family members, considering that in most cases the patients are elderly and, therefore, retired.

In an economic evaluation, we cannot overlook the opportunity cost associated with the investment of medical and other healthcare professionals' work in complying with this surveillance guideline, which may limit their availability to dedicate time to other patients, thereby hindering adequate healthcare practice for each patient in our SNS.

Our analysis combines economic and clinical data, which converge in the same direction as data already published in other countries, thus highlighting the need to adapt our clinical activity to the epidemiology of the population we treat. With an NB24 rate of 0.4%, without apparent clinical repercussions on our sample, and an associated cost difference of at least €133 677.00 in ULSSA, our data demonstrate that this surveillance constitutes an additional cost for the SNS, without a clear clinical benefit.

It should also be noted that during the surveillance period recommended by the traumatic brain injury guidelines (scenario A), only one major complication was recorded, contrasting with the complications observed by other authors.⁴ This complication did not occur in any of the NB24 cases but rather in a patient whose initial CT scan showed no evidence of traumatic lesions, likely having suffered a sudden death event of cardiogenic origin given the previously described comorbidities, which may have occurred independently of the guideline implementation. Therefore, we believe it should not be classified as a complication resulting from the guideline implementation, and, as such, it was not included in the economic impact assessment. If, at

the time of this fatality, the brain trauma surveillance guideline in effect at our hospital had been like that of scenario B, it is possible that this death would have occurred outside the hospital. However, since the initial CT scan was normal, there would still have been no additional neurological surveillance measures to offer this patient, and in the event of a new cardiogenic event, the patient should have received the same care as any other individual in an out-of-hospital setting, including the activation of emergency services and hospital referral if warranted. Given the patient's previously mentioned comorbidities, the occurrence of a sudden cardiac arrest would not likely trigger a medico-legal autopsy if it had happened outside the hospital, as there is a highly plausible cause of death: most likely an arrhythmic event in a globally frail patient.

Considering that our data, along with the findings of Duarte-Baptista *et al*,⁴ do not demonstrate a clinical benefit from maintaining 24-hour surveillance for this patient group, we believe it is reasonable to consider that the omission of such surveillance seems unlikely to contribute to complications within the first 24 hours post-discharge. This raises an important point for further discussion: if no other European countries with published brain trauma injury guidelines require such surveillance, where is the evidence of increased complications and mortality due to the absence of 24-hour monitoring in these same countries?

CONCLUSION

The application of the national TBI guideline at ULSSA represents significant costs. Historically, it is justified by the prevention of complications that, in our sample, did not occur in a clinically relevant manner, similar to what has been published by other European hospitals.

Assuming that all other conditions remain unchanged regarding compliance with this guideline in the other hospitals across our country, we can thus understand the impact of its implementation on the SNS.

The inherent limitations of our study lead to an underestimated evaluation of the real economic impact of this guideline on the SNS but still allow for a more informed discussion regarding the relevance of its revision. Subsequent studies encompassing other hospital centers (with and without neurosurgery departments) may provide a more accurate estimate of the clinical impact and the costs of this guideline on the SNS and help identify each hospital's heterogeneities, thereby presenting a clinical and economic scenario closer to our national reality.

AUTHOR CONTRIBUTIONS

TRC, RB: Study conception and design; data acquisition, analysis and interpretation; writing and critical review of the manuscript.

SO, AF, SS, FVS, VSP, MT, EC, AC: Study design; data analysis and interpretation; writing and critical review of the manuscript.

All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

The authors have declared that no competing interests exist.

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