HIPTCN: Prospective Observational Study of Hypocoagulated Head Trauma Patients with Normal Admission Computed Tomography Scan

HIPTCN: Estudo Prospetivo Observacional de Doentes Traumatizados Cranioencefálicos Hipocoagulados com Tomografia Computorizada Inicial Normal

ARTIGO ORIGINAL

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ABSTRACT

Introduction: Our national protocol for traumatic brain injury dictates that hypocoagulated patients with mild trauma and initial tomography scan with no intracranial traumatic changes must be hospitalized for 24 hours and do a post-surveillance tomography scan. The main goal of this study was to evaluate the clinical relevance of these measures.

Material and Methods: A prospective observational study was undertaken in four hospitals. Adult hypocoagulated traumatic brain injury patients with a normal tomography scan were included. The main outcomes evaluated were rate of delayed intracranial hemorrhage, rate of admission in a neurosurgical department, rate of complications related with surveillance and rate of prolonged hospitalization due to complications. An analysis combining data from a previously published report was also done.

Results: A total of 178 patients were included. Four patients (2.3%) had a delayed hemorrhage and three (1.7%) were hospitalized in a neurosurgery ward. No cases of symptomatic hemorrhage were identified. No surgery was needed, and all patients had their anticoagulation stopped. Complications during surveillance were reported in seven patients (3.9%), of which two required prolonged hospitalization.

Discussion: The rate of complications related with surveillance was higher than the rate of delayed hemorrhages. The initial period of in-hospital surveillance did not convey any advantage since the management of patients was never dictated by neurological changes. Post-surveillance tomography played a role in deciding about anticoagulation suspension and prolongation of hospitalization.

Conclusion: Delayed hemorrhage is a rare event and the need for surgery even rarer. The need for in-hospital surveillance should be reassessed.

Keywords: Anticoagulants; Brain Injuries, Traumatic; Intracranial Hemorrhage, Traumatic; Multicenter Study; Neurosurgical Procedures; Tomography, Spiral Computed

RESUMO

Introdução: O nosso protocolo nacional para traumatismos cranioencefálicos recomenda que doentes hipocoagulados com trauma craniano ligeiro e tomografia inicial sem alterações traumáticas intracranianas sejam hospitalizados 24 horas e façam uma tomografia computorizada pós-vigilância. O principal objetivo deste estudo foi avaliar a relevância clínica dessas medidas.

Material e Métodos: Foi realizado em quatro hospitais um estudo prospetivo e observacional. Foram incluídos adultos hipocoagulados com trauma craniano e tomografia normal. Os principais *outcomes* avaliados foram: taxa de hemorragia intracraniana tardia, taxa de internamento numa enfermaria de neurocirurgia, taxa de complicações relacionadas com a vigilância e taxa de hospitalização prolongada por complicações.

Resultados: Foram incluídos um total de 178 doentes. Quatro doentes (2,3%) apresentaram hemorragia tardia e três (1,7%) foram mantidos hospitalizados numa enfermaria de Neurocirurgia. Não foram documentados casos de hemorragia tardia sintomática. Nenhuma cirurgia foi necessária e em todos estes doentes a anticoagulação foi interrompida. Durante a vigilância, foram relatadas complicações em sete doentes (3,9%), dos quais dois exigiram hospitalização prolongada.

Discussão: A taxa de complicações relacionadas com a vigilância foi maior do que a taxa de hemorragia tardia. O período inicial de vigilância intra-hospitalar não trouxe qualquer vantagem, já que o manejo dos doentes nunca foi ditado por alterações neurológicas. A tomografia pós-vigilância desempenhou um papel importante na decisão sobre a suspensão da anticoagulação e o prolongamento da hospitalização.

Conclusão: A hemorragia tardia é um evento raro e a necessidade de cirurgia ainda mais. Deve ser reavaliada a necessidade de vigilância intra-hospitalar.

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Palavras-chave: Anticoagulantes; Estudo Multicêntrico; Hemorragia Intracraniana Traumática; Lesões Encefálicas Traumáticas; Procedimentos Neurocirúrgicos; Tomografia Computorizada de Feixe Cónico Espiral

INTRODUCTION

Traumatic brain injury (TBI) creates a large health and financial burden for healthcare services in both developed and developing countries.[1–5] Worldwide, mild TBIs occur with far greater frequency than more severe TBIs, with approximately 10-fold the burden of both moderate and severe injury.[4]

According to the literature, even though the population that is in a hypocoagulative state carries an increased risk for intracranial hemorrhage or hematoma progression following severe TBI,[6–9] there is no clear information about mild TBIs.

Portugal is regulated by a national protocol for TBIs created in 1999.[10] In accordance to a 2002 guideline from the European Federation of Neurological Societies,[11] this protocol recommends that all patients who have a mild TBI, are taking anticoagulants or have coagulopathy, and who have an initial head computed tomography (CT) scan with no traumatic changes should be hospitalized for a minimum of 24 hours and have a post-surveillance CT scan (PSCT) before discharge.

According to the literature, the advantage of the PSCT is that it detects possible delayed intracranial hemorrhage (DIH).[12] However, there is also evidence that these patients have a low risk of adverse outcomes,[13] and therefore, some argue against the clinical benefit of repeating CT when there is no neurological deterioration.[14]

The main goal of this observational study was to evaluate the clinical relevance and safety of in-hospital surveillance and PSCT for anticoagulated patients suffering mild TBI with normal initial CT scans. A broader analysis including a retrospective cohort from a single institution, already published elsewhere[15], was done. As a secondary objective, an analysis of risk factors influencing the outcomes was undertaken.

MATERIAL AND METHODS

Study design

An observational, prospective and multicenter study was undertaken across four Portuguese hospitals with a Neurosurgery department and a 24-hour emergency department (ED). The study design aimed to be as pragmatic as possible with the objective of simulating the everyday clinical practice in an emergency department. The four national hospitals that contributed with data for this study were North Lisbon University Hospital Center, Coimbra University Hospital Center, Oporto Hospital Center, and São João Hospital Center, also in Oporto. Another institution (Hospital of Braga) contributed with data from a previous study on the same topic.[15]

Participants and recruitment

Adult patients (over 18 years) attending the ED of a participating hospital between July 2018 and February 2019, with a history of head trauma in the last 24 hours and any form of concomitant hypocoagulative state, with an initial CT scan with no acute intracranial traumatic changes, were included. The inclusion and exclusion criteria are outlined in Table 1.

Since this was an observational study, each center kept its own protocol concerning the management of this type of patients. As a rule, head trauma patients in a hypocoagulative state were initially identified by the emergency team. A CT scan was performed, and then the patient was admitted for surveillance and referred to a neurosurgeon. The neurosurgeon confirmed the inclusion criteria and registered the relevant admission clinical information on the electronic health record. All patients were re-assessed, both clinically and with a CT scan, no later than 24 hours after trauma, and a decision of whether to discharge or continue surveillance in the neurosurgery ward was made by the on-call neurosurgeon. The study's form was completed during re-assessment and the consent for the study was also obtained. As a rule, anticoagulation medication (AC) was not taken during the surveillance period. If patients were then discharged, they would continue their medication as usual. If a decision was made to prolong the hospital stay, the suspension or reversion of AC was left at the discretion of the attending neurosurgeon.

Informed consent was obtained from all patients with the capacity to do so. In cases where that was not possible and relatives were available, consent was obtained from them. When that was also not possible, it was decided to waiver consent based on the non-intervention design of the study and lack of risk to patients, weighted against the possible future clinical and scientific benefits for society. This study was approved by the Ethics Committee of the North Lisbon Hospital Center.

Table 1 – Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Admitted to the ED	Declined informed consent
Age ≥ 18 years	
Hypocoagulative state (drug or coagulopathy)	
Any type of blunt head trauma < 24 hours before admission	
No traumatic intracranial changes in initial CT scan (as described by the neuroradiologist)	

Data collection

Clinical data was collected using a form filled out by the on-call neurosurgeon of the institution before discharge or admission to the ward. The forms were then processed by the lead investigator of each institution, who was responsible for correcting any errors, complete missing data and insert the information in an anonymized database. Data was gathered through clinical interview, diagnostic investigation, and clinical records.

The collected data included demographic information, risk factors according to the national TBI protocol (NTP) from 1999, admission and post-surveillance neurological examination, CT scans and outcomes (Tables 2 and 3). Clinical records of patients with DIH or complications were analyzed individually at the end of the study to gather data regarding the hospitalization period.

Outcomes

Two main types of outcomes were measured. The first was related to the neurosurgical surveillance and included the rate of DIH in the PSCT and the rate of hospitalization in a neurosurgical department for prolonged surveillance. The second consisted in complications and included the rate of complications related with surveillance and the rate of prolonged surveillance due to complications. These outcomes were also calculated after adding data from the previously published study from the Hospital of Braga.

Retrospective data

As stated before, our cohort and a previously published cohort were combined, and the main outcomes were analyzed. This previous study consisted of a retrospective collection of data that took place between June 2017 and January 2018. Detailed methods and results regarding this cohort have been published elsewhere.[15] Most of the data was similarly collected in both cohorts. The main differences comprised, firstly, the subcategorization for the type of trauma, which was only recorded for the prospective cohort; and secondly, the symptoms at the point of admission, since headache and vomiting were not included as symptoms for the retrospective cohort; lastly, the discharge Glasgow coma scale score (GCS), which was not recorded for the retrospective cohort. Demographic data from both cohorts was also compared [Supplementary Table 1 in Appendix 1 (see Appendix_01: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/13770/Appendix_01.pdf)].

Statistical analysis

Statistical analysis was done using IBM® SPSS® Statistics v21. To compare demographics from the retrospective study with our cohort the chi-square and Fisher's exact test (for expected counts less than 5) were used. For continuous variables, the two-tailed *t*-test was used. For univariate risk analysis the chi-square and Fisher's exact test were also used. A *p*-value < 0.05 was considered significant. Regression analysis could not be done due to the low number of registered outcome events.

Table 2 – Patients' demographics

	n (%) or mean (SD)
Total	178
Gender	
Female	98 (55.1)
Age*	80.95 (0.68)
Type of head trauma	
Low energy	166 (93.3)
Fall from own height	139 (78.1)
Fall from bed	14 (7.9)
Fall from stairs	9 (5.1)
Aggression	4 (2.2)
High energy	12 (6.7)
Motor-vehicle accident	5 (2.8)
Run over by vehicle	3 (1.7)
Fall from height > 3 m	4 (2.2)
Type of hypocoagulation	
Anti-vitamin K	52 (29.2)
NOAC	124 (69.7)
Heparins	2 (1.1)
Concomitant anti-aggregation	9 (5.1)
Concomitant hemorrhagic dyscrasia	1 (0.6)
NTP 1999 risk factors	
Alcohol abuse	0
Drug abuse	0
Previous neurosurgery	5 (2.8)
Epilepsy	3 (1.7)
Admission GCS score	
15	141 (79.2)
14	36 (20.2)
13	1 (0.6)
Admission symptoms	
Headache (n = 176)	30 (17.0)
Loss of consciousness (n = 177)	23 (13.0)
Amnesia (n = 176)	23 (13.1)
Vomiting (n = 177)	7 (4.0)
Focal deficit	9 (5.1)
Usual neurological status	173 (97.2)
Patients with surveillance CT scan	177 (99.4)
Timing for surveillance CT scan	
< 12 h	0
12 - 24 h	79 (44.6)
> 24 h	98 (55.4)
Worsening GCS score	4 (2.2)
New neurologic deficit	2 (1.1)

*: Age is reported as mean (standard deviation), in years.
GCS: Glasgow coma scale; h: hours; NOAC: novel oral anticoagulant; ns: non-significant; NTP: national traumatic brain injury protocol; SD: standard deviation

RESULTS

A total of 178 patients were included in the study.

Admission

Female patients represented 55.1% of the total study population. The average age was 80.95 years with a minimum age of 36 and a maximum age of 99 years (Table 2). Most patients were admitted due to low energy trauma (93.3%) and 78.1% of patients had fallen from their own height.

The most prevalent types of anticoagulation were NOAC and anti-vitamin K anticoagulants, corresponding to 69.7% and 29.2%, respectively. Only nine patients (5.1%) were concomitantly on antiplatelet drugs. One patient had a concomitant hemorrhagic dyscrasia, namely thrombocytopenia.

Only eight patients reported risk factors mentioned in the 1999 NTP. The remaining patients had either no risk factors or it was unknown if a risk factor was present or not. The most frequent risk factor listed in the protocol was history of previous neurosurgery which was reported in five patients. No patients had a known history of drug or alcohol abuse.

When admitted in the emergency department, 79.2% of patients had a GCS of 15. The worse described admission GCS was 13 (in one patient), meaning that only mild and moderate TBIs were encountered. The most common admission symptom was headache (17%), followed by loss of consciousness (13%) and amnesia (13.1%). Nine patients (5.1%) had a focal neurological deficit on admission and 173 (97.2%) of all patients did not have any change in their usual neurological status.

Imaging

Only one patient did not have a PSCT scan. In total, 55.4% of patients had a repeat CT scan more than 24 hours after the traumatic event, whereas 44.6% did it between 12 and 24 hours. No patient repeated the exam in the first 12 hours.

Surveillance

During the surveillance period, six patients deteriorated. Four out of the 178 prospective patients had a worsening of their GCS score. Of these, three patients had a 1-point decrease in the scale and one patient had a 2-point decrease. Two patients developed new neurological deficits.

Outcomes

Four patients (2.3%) had a DIH and three (1.7%) remained hospitalized in a neurosurgery ward after the initial 24-hour surveillance period (Tables 3 and 4). All patients admitted to the ward had DIH. No cases of symptomatic DIH were identified. No surgery was needed in the management of these patients. In three patients, anticoagulants were stopped but not reversed after the diagnosis of DIH. In one case anticoagulation was initially reversed and the patient was kept off the medication. All patients were discharged from the neurosurgery unit and no morbidity or mortality was reported.

Complications during the initial 24-hour surveillance period were reported in seven patients (Table 3 and 5). The most common was mental changes, namely agitation and confusion (five patients). Two patients had serious complications, namely stridor due to a nasogastric intubation attempt with need of intravenous steroids, and atrial fibrillation with tachycardia caused by withdrawal of treatment with beta-blockers, of which the medical team was unaware. All four patients whose GCS score deteriorated during surveillance had a complication. No patients showed a new neurological deficit due to a complication. Two patients required prolongation of the surveillance period for more than 24 hours, but all patients were eventually discharged with no associated mortality.

Table 3 – Outcomes

	n (%)
Neurosurgical surveillance	
Delayed intracranial hemorrhage (n = 177)	4 (2.3)
Prolonged neurosurgical hospitalization	3 (1.7)
Complications	
Surveillance complications	7 (3.9)
Prolonged hospitalization	2 (1.1)

CT: computed tomography

Table 4 – Demographics and outcomes of cases with delayed intracranial hemorrhage and need for prolonged neurosurgical hospitalization in both studies

Cohort, n (%)	Prospective Retrospective	4 (57.1) 3 (42.9)
Age, mean (min - max)		80.7 (67 - 94)
Gender, n (%)	Female	6 (85.7)
Type trauma, n (%)	Low impact	7 (100)
Type AC, n (%)	AntiK NOAC	5 (71.4) 2 (28.6)
Surveillance CT, n (%)	IPH SAH ASDH IVH*	3 (42.9) 3 (42.9) 1 (14.3) 1 (14.3)
Worse GCS score/ deficit, n (%)		0 (0.0)
Neuro hospitalization, n (%)		5 (71.4)
Management, n (%)	AC suspended Ac reverted	6 (85.7) 1 (14.3)
Need for surgery, n (%)		0 (0.0)
Sequelae, n (%)		0 (0.0)
Outcome, n (%)	Discharged Death	7 (100) 0 (0.0)

*: Patient with IPH and concomitant IVH.
AC: anticoagulant; ASDH: acute subdural hematoma; AntiK: anti-vitamin K anticoagulant; CT: computed tomography; GCS: Glasgow coma scale; IPH: intraparenquimal hematoma; IVH: intraventricular hemorrhage; NOAC: new oral anticoagulant; max: maximum; min: minimum; SAH: subarachnoid hemorrhage.

Univariate risk analysis

Risk analysis was limited due to the rarity of all outcomes. For this reason, regression analysis could not be made. The complete risk analysis is presented in Supplementary Table 2 (see Appendix_01: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/13770/Appendix_01.pdf). Patients with a concomitant dyscrasia showed a statistically significant higher rate of DIH (100% *vs* 1.7%, $p = 0.023$) as well as a higher rate of prolonged neurosurgical surveillance (100% *vs* 1.1%, $p = 0.017$). Also, patients who experienced a worsening of their GCS score during surveillance had higher rates of complications (100% *vs* 1.7%, $p < 0.0001$) and prolonged surveillance due to complications (50.0% *vs* 0.0%, $p < 0.0001$). The presence of any risk factor from the NTP 1999 was not associated with worse outcomes.

Results for the combined cohort

After combining the two studies, a total of 384 patients were included in the analysis. Some statistically significant differences were identified when comparing the two populations [Supplementary Table 1 in Appendix 1 (see Appendix_01: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/13770/Appendix_01.pdf)]: significantly more patients had low energy trauma in the retrospective cohort (93.3% *vs* 98.5%, $p = 0.015$); the retrospective study included significantly more patients on anti-vitamin K anticoagulants than on NOACs (62% and 38%, respectively, *vs* 29.2% and 69.7%, $p < 0.0001$); there were also statistically significant differences regarding the type of NTP 1999 risk factors identified. The most common risk factor on the HIPTCN cohort was history of previous neurosurgery (2.8% *vs* 0%, $p = 0.021$) and on the other study alcohol abuse was more frequent (3.9% *vs* 0%, $p = 0.008$). Differences in admission symptoms were also identified namely on the frequency of headaches, loss of consciousness and focal deficits, all significantly more common in the HIPTCN group; finally, significantly less patients did a PSCT in the retrospective study (90.3% *vs* 99.4%, $p < 0.0001$) and more PSCT were done more than 24 hours after the first CT ($p = 0.002$).

Table 5 – Demographics and outcomes of cases with complications during the surveillance period in both studies

Cohort, n (%)	Prospective Retrospective	7 (100) 0 (0.0)
Age, mean (min - max)		83.7 (74 - 97)
Gender, n (%)	Female	3 (42.9)
Type trauma, n (%)	Low impact	6 (85.7)
Worse GCS score, n (%)		4 (57.1)
New deficit, n (%)		0 (0.0)
Complication, n (%)	Agitation/confusion Atrial fibrillation Stridor and dyspnea	5 (71.4) 1 (14.3) 1 (14.3)
Prolonged surveillance, n (%)		2 (28.6)
Outcome, n (%)	Discharged Death	7 (100) 0 (0.0)

GCS: Glasgow coma scale; max: maximum; min: minimum

Table 6 – Outcomes for the combined cohort

	n (%)
Neurosurgical surveillance	
Delayed intracranial hemorrhage (n = 363)	7 (1.9)
Prolonged neurosurgical hospitalization	5 (1.3)
Complications	
Surveillance complications	7 (1.8)
Prolonged hospitalization	2 (0.5)

CT: computed tomography

The outcomes of the combined analysis are described in Table 6. Of a total of 363 patients who did a PSCT, seven (1.9%) had DIH. Five patients (1.3%) had to be admitted to the neurosurgery ward for further surveillance. These estimates are even lower than the ones from the HIPTCN study cohort alone. There were no cases of symptomatic DIH. No complications were reported in the retrospective study, giving a total of seven complication in 384 patients (1.8%), with two patients (0.5%) needing hospitalization for more than 24 hours due to those complications.

When the individual cases of DIH were analyzed (Table 4 and 5), no patients needed surgical intervention, developed sequelae, or died, and were all discharged home. All patients had their anticoagulation treatment suspended or reversed.

DISCUSSION

To the authors' knowledge, HIPTCN is the first and only multicentric prospective study analyzing hypocoagulated patients suffering from TBI with a normal initial CT scan. It included four national neurosurgical centers from different locations which adds to its value by depicting the national population. Its observational design also contributed to this.

Demographics were as expected. Most patients suffered low energy trauma, specifically falls from their own height.[4] All patients were under anticoagulation (AC) with a distribution in accordance with current practice.[16] On admission, most patients were asymptomatic. This is in accordance with the literature.[12,13]

The only significant risk factor associated with worse outcomes was concomitant dyscrasia. However, as mentioned below, this must be interpreted with caution and further studies should be carried out.

The results from this study showed a rate of DIH on PSCT of 2.3% (1.9% for the combined analysis), which is in accordance with the literature.[14] Of these patients not all had to be kept under prolonged surveillance, but all patients had their AC drugs stopped or even reversed.

All patients who required prolonged hospital stay in the neurosurgery ward had DIH on PSCT, but none were admitted because of clinical deterioration. In fact, of all patients with a DIH, none had a neurological deterioration during surveillance which points to the mildness of these traumatic changes. Another important point is that no patient in the

entire study required further neurosurgical intervention, namely surgery. The patients who were kept in the hospital only required further clinical and imaging surveillance, changes in medication and were all discharged with a favorable outcome with no neurological sequelae.

The rate of complications related with surveillance was higher than the rate of DIH (3.9% *vs* 2.3%). Most complications were mild mental changes but there were also serious ones. In fact, all patients with GCS worsening during surveillance and, hence, a clinical deterioration, had one complication which explained the deterioration. This argues against the harmlessness of hospital surveillance, especially in this age group. It is well known that a longer length of stay in the hospital is associated with greater functional decline.[20–22]

The results for the combined cohort were in line with the individual analyses of the studies, despite some demographic differences. The rate of DIH was even lower, 1.9%. The rate of complications was lower since there were no reported complications in the retrospective cohort. This might be due to the retrospective design of the included study associated with underreporting of this type of complications.

For the study population, the initial period of in-hospital surveillance did not convey any advantage since the management of patients was never dictated by neurological changes. One might even say surveillance was indeed a disadvantage since it was associated with an almost 4% rate of complications. The complications in our patients resulted either from acts or omission from the medical team (nasogastric intubation attempt and inadvertent withdrawal of chronic beta-blockers) or from maladaptation of the patient to the hospital environment. The latter kind of complications is surely underreported in the literature but truly a common clinical situation in the routine practice of our hospitals.

Considering these results, it would seem beneficial to think about new protocols which reduce or even remove the initial in-hospital surveillance period. This could be replaced, in selected patients, with home-surveillance and proper information for patients and caregivers regarding red-flags. With this approach, surveillance complications would be averted, not to mention the cost reductions for health-care providers and convenience for the patient in avoiding a hospital admission. Some authors have suggested abandoning the 24-hour surveillance period. In their multicentric retrospective cohort, Verschoof *et al*[23] found nine patients with DIH but in six patients, intracranial hemorrhage was found retrospectively upon reassessment of the first CT scan, leaving only three patients with true DIH. All patients who deteriorated in the first 24 hours were found to have hemorrhage in the first CT scan. Three out of nine patients needed surgery (evacuation of chronic/subacute subdural hematoma in all cases). The authors also performed a meta-analysis with nine more studied, with a total of 2885 patients and found only seven patients with symptomatic DIH (0.2%), therefore questioning the need of a 24-hour surveillance period and PSCT in these patients. Previously, another meta-analysis with 1584 patients had already taken similar conclusions.[24]

On the other hand, in our cohort, PSCT played a non-negligible role in the management of TBI, since it was the basis for decision making regarding AC and prolongation of hospitalization. As stated before, one might argue against the need of PSCT since all these changes were rare, mostly mild and with no clinical consequences to patients. Besides, during all prolonged hospitalizations there was no need to change the initial patient management of patients regarding TBI. In fact, studies supporting the exclusion of PSCT from protocols already exist in the literature.[17–19] Nevertheless, due to the observational nature of this study, it is impossible to draw any conclusions not supporting the use of PSCT because it dictated the management of AC therapy and so, we cannot know if the outcomes would have been as good with a different approach. Therefore, our results cannot support exclusion of PSCT from current protocols. With the aim of avoiding hospital admission, a good compromise could be maintaining PSCT as an outpatient test.

This study has its limitations. Firstly, it is an observational study and, as such, it is impossible to draw definitive conclusions regarding the impact of PSCT or in-hospital surveillance on morbidity and mortality. Even so, the authors believe that this evidence can contribute to guide future national protocols on the subject. Moreover, the observational nature of the study makes it a better surrogate of current clinical practice. Secondly, risk analysis must be interpreted with caution due to the rarity of event occurrence for the outcomes which limit statistical power and precluded the use of regression models. Again, risk analysis was not the main objective of this study, which was not designed with that purpose.

CONCLUSION

DIH and symptomatic DIH are rare events. The rate of complications associated with a 24-hour surveillance period was higher than the rate of DIH. For this cohort, PSCT, and not surveillance, guided the management of these patients which all had a positive outcome. Surgery was not needed in any patient. In accordance with these findings and the known literature, changes in current protocols could be hypothesised such as home-surveillance and ambulatory PSCT.

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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 2013.

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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