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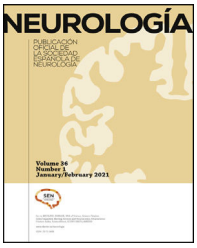

ORIGINAL ARTICLE

Unilateral thalamotomy with high-intensity focused ultrasound in refractory tremor. First results of a public hospital in Spain

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KEYWORDS
HIFU;
High-intensity focused ultrasound;
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Refractory tremor;
Essential tremor;
Thalamotomy

Abstract
Introduction: Unilateral high-intensity focused ultrasound (HIFU) thalamotomy is a novel and efficient treatment for refractory tremor. In the most recent studies, the tremor is reduced by at least 70%. The objective of this study is to analyse the results of the first series of cases treated in a public hospital in Spain.
Methods: In our centre, from March 2021 to March 2022, 46 patients have undergone a HIFU thalamotomy. The treatment area was predetermined on the inferior surface of the ventral intermediate nucleus of the thalamus using automatic anatomical segmentation on an individual basis. The data of 44 patients six months after the procedure have been analysed.
Results: The mean age of the treated patients was 70.5 ± 14.4 years, and 68% were male. The most common diagnosis was essential tremor (40 cases). Prior to HIFU treatment, the *Clinical Rating Scale for Tremor* of the treated body side (CRST A + B) was 22.4 ± 5.9, and tremor-related disability (CRST C) was 18.3 ± 4.8. The mean number of sonications was 6.8 ± 1.7. Six months after treatment, CRST scales were 4.5 ± 5.6 and 4.2 ± 5.2, respectively ($P < 0.0001$). Twenty patients had head tremor. We observed a significant improvement with HIFU (1.9 ± 0.7 to 0.7 ± 0.8, $P < 0.0001$). Only four patients presented adverse effects at six months, all of them mild.

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Conclusions: The clinical benefit after HIFU thalamotomy reaches an 80% reduction in tremor and has a low rate of adverse effects six months after the procedure. The target localisation method used allowed for fewer sonications.

PALABRAS CLAVE
HIFU;
Ultrasonidos focales de alta intensidad;
Segmentación anatómica;
Temblor refractario;
Temblor esencial;
Talamotomía

Talamotomía unilateral con ultrasonidos focales de alta intensidad en el temblor refractario. Primeros resultados de un hospital público en España

Resumen
Introducción: La talamotomía unilateral con ultrasonidos focales de alta intensidad (HIFU) es un tratamiento novedoso y eficiente para el temblor refractario. En los estudios más recientes la magnitud del temblor se reduce en al menos un 70%. El objetivo de este estudio es analizar los resultados de la primera serie de casos tratados en un hospital público en España.
Métodos: En nuestro centro, desde marzo de 2021 hasta marzo de 2022, 46 pacientes se han sometido a una talamotomía por HIFU. Se predeterminó el área de tratamiento en la superficie inferior del núcleo ventral intermedio del tálamo mediante la segmentación anatómica automática de manera individualizada. Se han analizado los datos de 44 pacientes a los seis meses del procedimiento.
Resultados: La edad media de los pacientes tratados fue de 70.5 ± 14.4 años y el 68% eran varones. El diagnóstico más común fue temblor esencial (40 casos). Previo al tratamiento con HIFU, la *Clinical Rating Scale for Tremor* del hemicuerpo tratado (CRST A + B) era de 22.4 ± 5.9 y la discapacidad funcional (CRST C) de 18.3 ± 4.8. El número medio de sonicaciones fue de 6.8 ± 1.7. A los seis meses del tratamiento fueron 4.5 ± 5.6 y 4.2 ± 5.2, respectivamente ($p < 0.0001$). En los 20 pacientes con temblor cefálico se observó una mejoría significativa (1.9 ± 0.7 a 0.7 ± 0.8, $p < 0.0001$). Solo cuatro pacientes presentaron efectos adversos a los seis meses, en todos ellos de intensidad leve.
Conclusiones: El beneficio clínico tras la talamotomía por HIFU alcanza el 80% de reducción en el temblor y tiene una tasa baja de efectos adversos a los seis meses del procedimiento. El método de localización de la diana empleado permitió realizar un menor número de sonicaciones.

Introduction

High-intensity focused ultrasound (HIFU) can be directed and concentrated on a specific area of the body using a concave transducer. When applied to brain tissue, the technique aims to achieve necrosis, raising the temperature sufficiently to cause thermocoagulation. In July 2016, the United States Food and Drug Administration approved HIFU for the unilateral treatment of refractory tremor by creating a lesion in the ventral intermediate (Vim) nucleus of the thalamus. Its effectiveness is comparable to that of thalamic deep brain stimulation (DBS) on the treated hemibody, with a lower rate of severe complications related to surgery (haemorrhage) or device implantation (infection, electrode or extension lead breakage).[1] However, as a lesional procedure, HIFU may be associated with persistent adverse events such as paraesthesia or gait instability[2]; in DBS, these may be prevented by modulating the stimulation.

The thalamus, and more specifically the Vim nucleus, is a key structure in the dentatorubrothalamic tract, which is hyperactive in patients with tremor.[3] The pathophysiology of tremor involves rhythmic activity within this circuit; although the origin of these oscillations is yet to be understood, neuronal firing in the Vim nucleus is known to be closely related to tremor.[4]

Two main unresolved issues remain regarding the use of HIFU in the treatment of tremor. On the one hand, the optimal identification of the target, which is performed through different approaches, including direct or indirect stereotactic coordinates, direct nucleus visualisation, and tractography.[5] On the other, the ability to establish the lesion volume that maximises clinical benefit while minimising the risk of adverse reactions, as well as the treatment conditions needed in each case to generate an optimal lesion.[6–9]

This study presents the first results of HIFU thalamotomy for refractory tremor at a public hospital in Spain, as well as an individualised targeting method based on automatic anatomical segmentation.

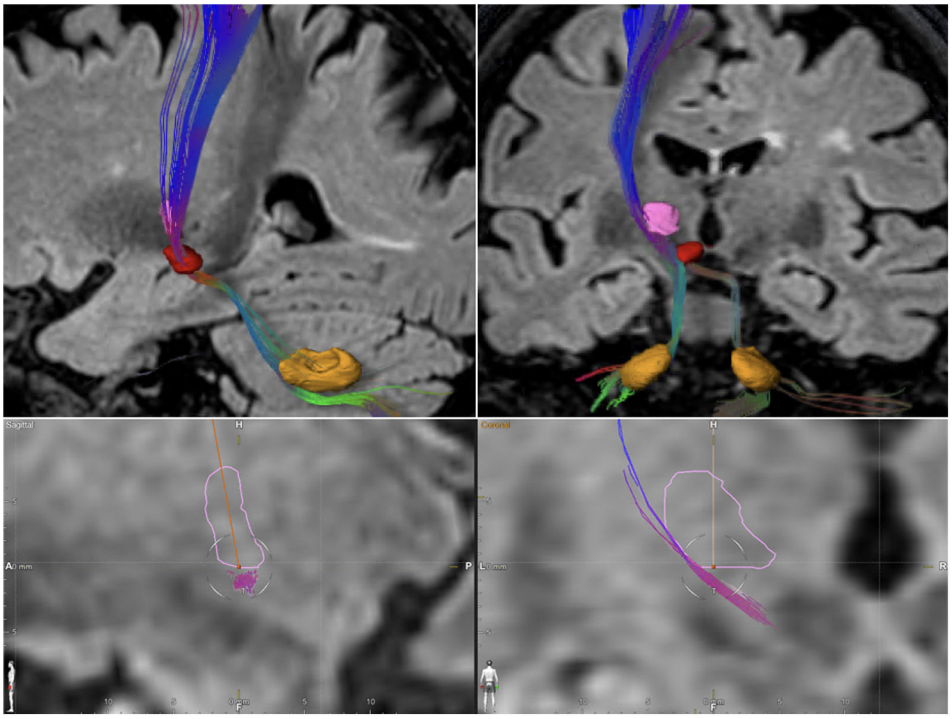

Fig. 1 Model representing the approach used in this study to determine the treatment coordinates. The dentate nucleus is shown in yellow, the red nucleus in red, and the ventral intermediate nucleus in pink.

Patients and methods

All the patients included in the study underwent the same procedure. Segmentation of the Vim nucleus was performed on volumetric MRI sequences using the Brainlab® software (Boston Scientific; Natick, MA, USA). The target was defined as the intersection of 2 planes at the inferior surface of the Vim[10]: an oblique coronal orientation plane crossing the Vim nucleus at its centre and parallel to its major axis, and a sagittal plane crossing the Vim nucleus at its centre (Fig. 1), contralateral to the affected hemibody. The procedure was performed using a 3T MRI scanner (GE Healthcare Medical Systems and Solutions; Waukesha, WI, USA) and an ExAblate 4000 MRgFUS system (InSightec Inc.; Haifa, Israel). A confirmation sonication was performed to assess the clinical effect and detect any adverse effects (subtherapeutic temperature, ideally between 49 °C and 52 °C). When the clinical effect was considered satisfactory by the assessing neurologist and no adverse events were observed, at least 2 additional therapeutic sonications were delivered at the same anatomical site (55 °C to 60 °C)[8]; the procedure was monitored clinically and with continuous thermography. The eligibility threshold for HIFU treatment was a skull density ratio (SDR) $\geq$ 0.35, which was determined in the weeks before treatment. All patients received domperidone at 30 mg/day over the 3 days prior to the procedure, 8 mg ondansetron one hour before the procedure, and an additional 4 mg ondansetron before the start of the sonications.

All patients had a diagnosis of refractory essential tremor, refractory secondary tremor, or tremor-dominant Parkinson's disease. Eligibility criteria were presence of disabling, refractory tremor, whether unilateral or bilateral (not necessarily asymmetric); absence of significant cognitive impairment or sensory limitations hindering patient understanding of or cooperation during the procedure; absence of active coagulopathy (antiplatelet or anticoagulation therapy was not considered an exclusion criterion); and absence of significant midline ataxia. Patients aged under 70 years and meeting eligibility criteria for DBS were offered this possibility. In the specific case of Parkinson's disease, the medical team ruled out treatment with DBS in patients aged over 70 years and in patients with disabling and predominantly unilateral tremor but with adequate pharmacological control of other parkinsonian symptoms. Tremor was assessed before and 6 months after treatment using the Clinical Rating Scale for Tremor (CRST). The assessment included total CRST score (maximum of 148 points); CRST parts A + B score for the treated hemibody (severity of resting, postural, and kinetic tremor, and kinetic tremor during writing in the dominant hand only and in drawing; maximum of 32 points)[11]; and CRST part C score (functional disability attributable to tremor; maximum of 32 points). Data were gathered on immediate complications of treatment (within 24 hours of the procedure) and the adverse reactions identified during the first month and at 6 months after the procedure. Adverse reactions were considered to be mild when they did not lead to a significant reduction in patient independence, were transient, and were not observed in the follow-up physical examination.

Qualitative data are expressed as percentages and quantitative data as means and standard deviation (SD). Statistical differences after treatment were evaluated with the *t* test for paired samples or the Wilcoxon test, depend-

Table 1 Patient characteristics at baseline.

	N = 44
Age (years)	70.5 (14.1)
Sex (men), n (%)	30 (68%)
Side treated with thalamotomy	
Left	43
Right	1
Diagnosis	
Essential tremor	40
Parkinson's disease	3
Holmes tremor	1
Disease duration (years)	25.5 (15.1)
CRST	57.7 (15.4)

CRST: Clinical Rating Scale for Tremor. Data are expressed as means (standard deviation), unless indicated otherwise.

ing on whether the data followed a normal distribution as determined by the Shapiro-Wilk test.

Results

A total of 46 patients underwent unilateral HIFU thalamotomy at our centre during the first year that this treatment was available in the Spanish public healthcare system (March 2021 to March 2022). We excluded 2 patients from the analysis: in one, a different method was used to determine the coordinates, whereas in the other, the target temperature could not be reached (SDR = 0.36 and presence of intracerebral calcifications near the thalamotomy target), resulting in only a partial, transient improvement of tremor. Baseline clinical characteristics and the surgical coordinates and treatment parameters used are summarised in Tables 1—3.

Tremor severity in the treated hemibody, as measured with CRST parts A + B, decreased by 80% (from 22.4 [5.9] to 4.5 [5.6]; $P < .0001$) at 6 months after treatment. Functional disability improved in parallel with clinical status, showing a 77% decrease in CRST part C scores (from 18.3 [4.8] to 4.2 [5.2]; $P < .0001$). In the 20 patients presenting head tremor at the initial assessment, significant improvements were observed in the head tremor variable of the CRST (from 1.9 [0.7] to 0.7 [0.8]; $P < .0001$). Overall, head tremor improved in 15 patients, 10 of whom are currently asymptomatic. Similarly, in the subgroup of 13 patients presenting vocal tremor at the initial assessment, significant improvements were observed in CRST vocal tremor score (from 1.9 [0.4] to 1.1 [0.9]; $P < .0012$). Four patients remained asymptomatic. Lastly, total CRST score decreased by 57% (from 57.7 [15.4] to 24.6 [15.8]; $P < .0001$) at 6 months after the procedure. Further detail is provided in Table 4 and Fig. 2.

A total of 19 patients (43%) presented adverse reactions during the procedure, mainly headache or vertigo, which were generally mild. Thirty-three patients (75%) presented some type of adverse reaction during the first month after HIFU. Instability and dysarthria were the most prevalent adverse reactions, reported by 26 and 8 patients, respectively; however, only a small proportion of these patients (5 and 2, respectively) reported these reactions as moderate or presented objective findings during the neurological examination. Other adverse reactions were weakness or poor coordination in the treated hemibody (n = 3; one patient presented central facial palsy during the 72 hours following the procedure), dysmetria (n = 1), diplopia (n = 1), and hypoaesthesia in the parietal region (n = 3, related to the mounting of the stereotactic frame). At 6 months after the procedure, only 4 patients (9%) reported any persistent adverse reactions: 2 cases of very mild dysarthria, one case of mild instability, and one case of hypoaesthesia in the parietal region of the scalp and a subjective feeling of loss of strength in the treated hemibody. These data are further described in Table 5.

Table 3 Treatment parameters.

	N = 44
SDR	0.50 (0.07)
Skull area (cm^2)	340.1 (30.6)
No. of active elements	934.9 (47.0)
No. of sonications	6.8 (1.7)
Maximum power delivered (J)	16 855.8 (8138.7)
Maximum temperature reached (°C)	57.3 (1.9)

SDR: skull density ratio. Data are expressed as means (standard deviation).

Three patients underwent a second procedure due to tremor recurrence; although the intensity was milder in all cases, improvement was less than 50% compared to baseline. Worsening occurred within the first few weeks after treatment. Interestingly, these patients were among the first to be treated with HIFU (the second, fifth, and eighth patients), reflecting the existence of a learning curve with any technique.

Discussion

In our study, tremor in the treated hemibody improved by 80%, a rate comparable to those reported by other recent studies (80%,[8,9] 71%,[12] and 84%[13]). The earliest studies report improvements ranging from 40% to 55%,[2,14,15] whereas a meta-analysis conducted in 2018 estimated a mean improvement of 62%.[16] Although a slight worsening of tremor may be expected over time, a considerable number of patients present significant stability at 6 months of follow-up.[12,13] In our study, head and vocal tremor improved and even fully resolved in a significant percentage of patients.

Table 2 Coordinates initially established by direct visualisation of the ventral intermediate nucleus, in millimetres.

Lateral to AC-PC line (X-axis)	Anterior to PC point (Y-axis)	Superior to AC-PC line (Z-axis)	AC-PC length
14.4 (1.4)	7.5 (1.0)	1.0 (1.1)	24.8 (1.4)

AC: anterior commissure; PC: posterior commissure. Data are expressed as mean (standard deviation).

Table 4 Progression of tremor at 6 months after HIFU thalamotomy.

	Initial assessment	6 months	*P*
Tremor in treated side (0-12)	7.3 (2.4)	1.0 (1.5)	< .0001
Head tremor[a] (0-4)	1.9 (0.7)	0.7 (0.8)	< .0001
Vocal tremor[b] (0-4)	1.8 (0.4)	1.1 (0.9)	.0012
CRST A + B (0-32)	22.4 (5.9)	4.5 (5.6)	< .0001
CRST C (0-32)	18.3 (4.8)	4.2 (5.2)	< .0001
CRST (0-148)	57.7 (15.4)	24.6 (15.8)	.0001

CRST: Clinical Rating Scale for Tremor. Tremor in treated side: resting, postural, and kinetic tremor.
[a] 20 patients.
[b] 13 patients.

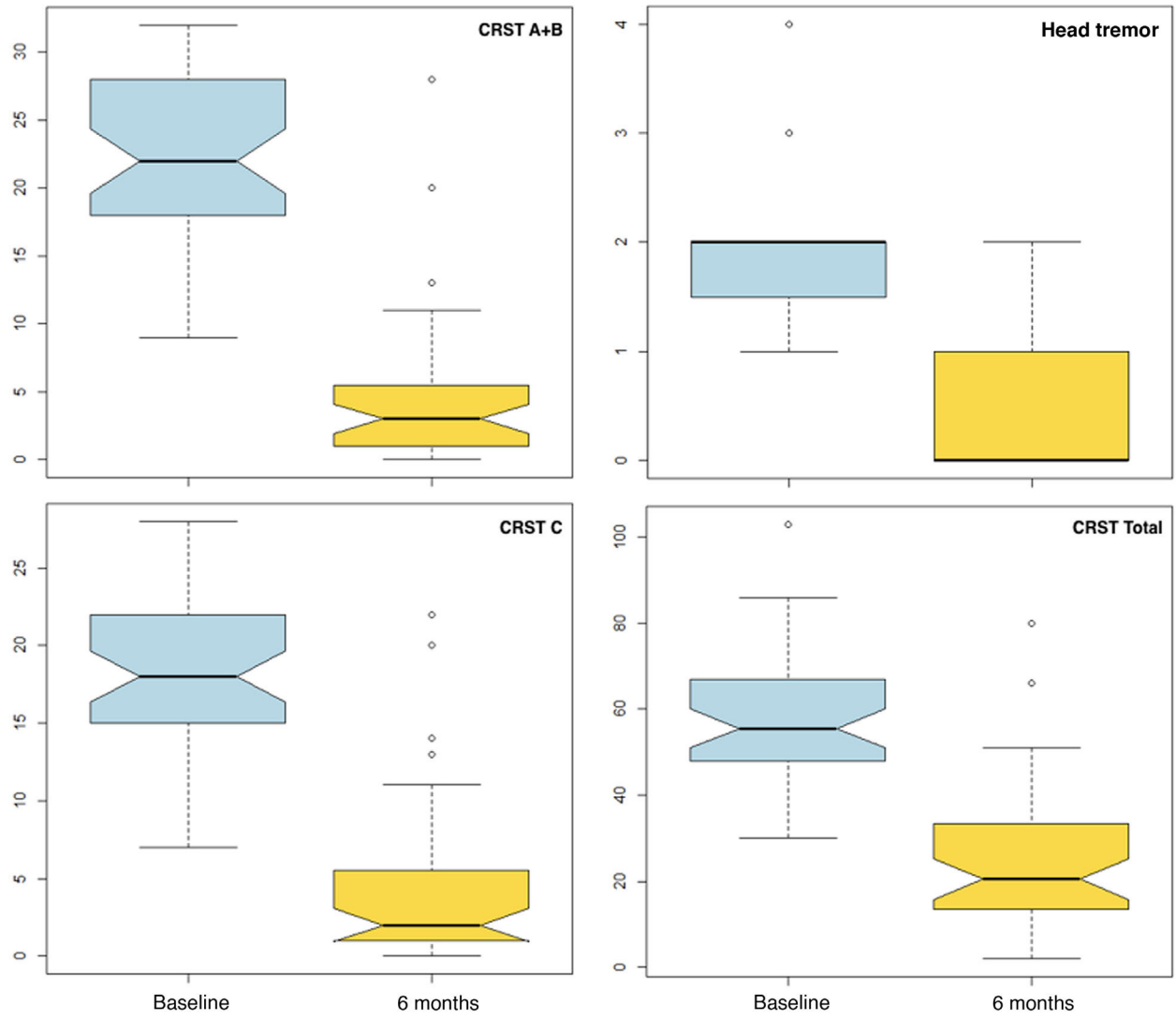

Fig. 2 Progression of tremor at 6 months of treatment with HIFU as assessed with the Clinical Rating Scale for Tremor. CRST: Clinical Rating Scale for Tremor.

To our knowledge, this is the first study to report such outcomes for unilateral HIFU thalamotomy. Several previous studies have demonstrated that axial tremor can improve with unilateral thalamic DBS,[17] which is undoubtedly consistent with our findings. Nonetheless, presence of predominant head or vocal tremor should not currently be considered an eligibility criterion for unilateral thalamotomy.

The direct localisation method used in our study was individualised, based on automatic anatomical segmentation and previous experience with the technique. Among the 44 patients included in our study, coordinate repositioning was

Table 5 Adverse reactions.

During the procedure		N = 44
Headache		7 (16%)
Nausea		3 (7%)
Vertigo		4 (9%)
Dysarthria		4 (9%)
Paraesthesia		3 (7%)
After the procedure	**1 month**	**6 months**
Gait instability	26 (59%) | **5 (11%)**	**1 (2%)**
Dysarthria	8 (18%) | **2 (5%)**	**2 (5%)**
Clumsiness, weakness	3 (7%) | **1 (2%)**	**1 (2%)**
Diplopia	1 (2%)	-
Hypoaesthesia in parietal region	3 (7%)	**1 (2%)**

Adverse reactions of moderate intensity or observed during follow-up are indicated in bold.

needed in only 13 cases, due to suboptimal clinical response after the confirmation sonication. In most of these cases, coordinates were adjusted by 1 mm posteriorly or inferiorly, in accordance with the anatomy of the Vim nucleus and the dentatorubrothalamic tract. The mean number of sonications performed in our patients was very low (6.8, including the 2 mandatory alignment sonications and one clinical confirmation sonication) compared to the numbers reported in other studies using fixed stereotactic coordinates.[8,12,13] To achieve optimal results, current consensus supports the use of so-called high-temperature effective sonications,[18] that is causing an effective lesion at the point achieving maximum tremor suppression without the need for further adjustments, which may mask the clinical benefit due to oedema,[6] in addition to reducing the predictability of the energy needed for subsequent sonications.[19] In this regard, larger lesion volumes are not necessarily correlated with greater tremor reduction, but they do present a correlation with a higher rate of adverse reactions.[7,8] In fact, imprecise targeting may require a larger lesion; therefore, accurate coordinate planning seems to be the most decisive factor for successful outcomes. In our method, adjustment of coordinates is not based solely on the appearance of adverse reactions (as is the case with involvement of the medial lemniscus). In fact, only 3 patients presented transient paraesthesia during the procedure, and none reported this symptom in the days following HIFU. On the anteroposterior axis, our target midpoint is located 7.5 mm anterior to the posterior commissure, which is equivalent to 30% of the length of the anterior commissure—posterior commissure (AC-PC) line. This stands in contrast with the standard 25% used in fixed stereotactic coordinate methods, meaning that our target is more anterior and, therefore, further from the medial lemniscus.

Though adverse reactions to HIFU thalamotomy are frequent, they are generally mild and transient,[7,8,13] as observed in our series. The most frequent adverse reactions in our study were gait instability (which is often even subjective) and dysarthria, which coexisted in numerous patients. Both symptoms have been associated with inferior displacement of the lesion toward the cerebellothalamic tract,[7,8] which explains its occurrence in our series and its transient nature: when the inferior surface of the Vim nucleus is targeted, oedema may partially extend toward the cerebellothalamic tract. As previously mentioned, none of our patients presented sensory alterations from the day after the procedure. At 6 months, only 4 patients reported some type of adverse reaction, with reactions being mild in all cases.

Our study presents several limitations, including a short follow-up period of only 6 months. Furthermore, we did not systematically analyse lesion volume, mainly due to the difficulty of scheduling follow-up MRI studies within the public healthcare system. Lastly, we included 3 cases of tremor-dominant Parkinson's disease and one case of symptomatic tremor; these cases would ideally have been analysed separately, as more limited improvement may be expected in these cases.[20]

Ethics

The study complies with the ethical principles of the World Medical Association's Declaration of Helsinki and was approved by the research ethics committee of Santiago de Compostela (research project code 2022/181).

Declaration of competing interest

The authors have no conflicts of interest to declare.

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