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Demographics of focused ultrasound thalamotomy for essential tremor and trends in deep brain stimulation surgery after its introduction in the USA

Diwas Gautam,[1] Vishal Venkatraman,[2] Joshua Horns,[3] Lexie Zidanyue Yang,[4] Hui-Jie Lee,[4] Panagiotis Kassavetis,[5] Jumana Alshaikh,[5] Paolo Moretti,[5] Ben Shofty,[6] Shervin Rahimpour [6]

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For numbered affiliations see end of article.

Correspondence to
Dr Shervin Rahimpour;
shervin.rahimpour@utah.edu

ABSTRACT

Background Essential tremor (ET) is a movement disorder that affects 4%–5% of adults >65 years. For patients with medically refractory ET, neurosurgical interventions such as deep brain stimulation (DBS) and unilateral MR-guided focused ultrasound thalamotomy (MRgFUS) are available. In this retrospective cohort study, we examined the demographics of patients with ET who have received MRgFUS and evaluated trends in DBS usage in the USA after the introduction of MRgFUS in 2016.

Methods We used multiple databases to examine the demographics of patients who received DBS and MRgFUS, and trends in DBS. To assess the demographics, we queried the TriNetX database from 2003 to 2022 to identify patients diagnosed with ET and stratify them by DBS or MRgFUS treatment by using Current Procedural Terminology codes. Patient demographics were reported as frequencies and percentages. To examine the trends in DBS for ET, the yearly frequency of DBS procedures done for ET between 2012 and 2019 was extracted from the National Inpatient Sample (NIS) database, and breakpoint analysis was performed. Additionally, the yearly frequency of MRgFUS procedures for ET was obtained from Insightec Exlabate.

Results Most of the patients (88.69%) in the cohort extracted from TriNetX database self-identified as white, followed by black or African American (2.40%) and Asian (0.52%). A higher percentage of black patients received MRgFUS treatment than DBS (4.10% vs 1.88%). According to the NIS database, from 2012 to 2020, 13 525 patients received DBS for ET.

Conclusion This study provides an overview of the characteristics of patients who undergo DBS or MRgFUS. We found notable differences in sex and race among patients who underwent each treatment type. Additionally, until at least the beginning of 2020, the number of DBS procedures for ET was not negatively affected after the introduction of MRgFUS.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Transcranial MRI-guided focused ultrasound (MRgFUS) has recently emerged as an advanced therapy option for patients with medically refractory tremor who may otherwise be poor surgical candidates for deep brain stimulation (DBS) or who are unwilling to undergo an invasive procedure. Insufficient research has been done to evaluate the demographics of the population of patients receiving MRgFUS or trends in DBS surgery after the introduction of MRgFUS.

WHAT THIS STUDY ADDS

⇒ Male patients are more likely to receive MRgFUS than female patients, and a higher percentage of patients self-identifying as black or African American received MRgFUS treatment than DBS. Additionally, we show that, until at least the beginning of 2020, the introduction of MRgFUS has not negatively affected the number of DBS procedures done for essential tremor.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study demonstrates that the emergence of MRgFUS may broaden access to advanced treatment for medically refractory tremor in those who were hesitant to undergo an invasive procedure. Future studies are needed to further examine trends in DBS surgery and to understand and determine how demographic differences affect the procedure type available to or chosen by patients.

INTRODUCTION

Essential tremor (ET) is a neurological disorder characterised by postural and/or kinetic tremor affecting the upper extremities, head and voice.[1 2] The amplitude and extend of ET can slowly increase over decades, and some individuals eventually develop disabling tremor.[1] ET affects approximately 1% of the population and 4%–5% of adults over 65 years of age.[3 4] As the population ages and the prevalence of ET increases, the number of patients in need of advanced therapies for medically refractory ET will also grow.[5] Current pharmacological treatment for ET includes medical therapies such as propranolol, primidone and topiramate.[6] These medications have been shown to significantly reduce tremor amplitude by approximately 50% in 70% of patients.[7 8] Other treatments such as benzodiazepines, gabapentin and injection of botulinum toxin type A have been suggested as second-line therapies.[8]

Patients with severe symptoms that may not benefit from or tolerate pharmacological intervention may be candidates for surgical alternatives. Ablation of the ventral intermedius nucleus (VIM) of the thalamus was among the first stereotactic procedures described for surgical management of medically refractory tremors.[9 10] Ablation can result in 80%–90% improvement in tremor symptoms.[11 12] Since its approval by the US Food and Drug Administration (FDA) in 1997, deep brain stimulation (DBS) has largely replaced ablative techniques.[11 13 14] The non-destructive, adjustable and reversible nature of DBS has made it an effective alternative to ablative techniques. Studies evaluating the effect of DBS on ET have shown improvement in tremors by 60%–90% on clinical rating scales.[15–17] Unilateral transcranial MRI-guided focused ultrasound thalamotomy (referred to as 'MRgFUS' throughout this manuscript) was approved by the FDA for the treatment of ET in 2016 and has emerged as an advanced therapy option for patients with medically refractory tremor.[18 19] MRgFUS of the VIM is an incisionless ablative option for patients who may otherwise be poor surgical candidates for DBS or who are unwilling to undergo an invasive procedure[19]; however, studies evaluating the demographics of the population of patients receiving MRgFUS and trends in DBS surgery after the introduction of MRgFUS are lacking.

In this study, we characterise the demographics of the population of patients receiving MRgFUS for ET and describe trends in the use of DBS from 2012 to 2019 for the treatment of ET after the introduction of MRgFUS. We hypothesise that the introduction of MRgFUS treatment for ET has not had a negative effect on the rates of DBS surgery. Additionally, we compare the ethnic/racial backgrounds and sexes of patients who underwent the two procedures.

METHODS

Data source and patient cohort

We used the TriNetX database (Cambridge, Massachusetts, USA) to extract our patient cohort. The TriNetX database is a global health collaborative clinical research platform that includes real-time electronic medical data from a network of healthcare organisations. Only patients treated in the USA were included in this study. We queried the database from 2003 to 2022 using the International Classification of Diseases, 9th or 10th Revision (ICD-9/10) diagnostic codes 333.1 and G25.0, respectively, for patients diagnosed with ET. Patients with a diagnosis of Parkinson's disease, secondary parkinsonism or dystonia were excluded (online supplemental table 1). Patients were stratified into surgical treatment groups based on the Current Procedural Terminology codes for DBS (codes 61863, 61864, 61867, 61868 and 61885) and MRgFUS (code 0398T). Patients who had received both treatment modalities (n=4) were excluded from the study.

In addition to TriNetX, we used two additional data sources to complement our study. The TriNETx database was used here to primarily understand the demographics of the patient undergoing DBS or MRgFUS. The TriNetX is a claims database and is, therefore, not comprehensive and does not include all treatments and admissions across the country. Thus, we also used the National Inpatient Sample (NIS) database to assess the yearly frequency of DBS used to treat patients with ET between 2012 and 2020. The NIS database tracks inpatient data and does not include data on MRgFUS, which is an outpatient procedure. The data from 2021 to 2023 are not reported because the NIS only releases data for a given year 3 years later. Additionally, MRgFUS is not coded via ICD codes, which is the primary coding system used in the NIS. The yearly frequency of MRgFUS procedures performed in the USA between 2016 and 2022 was obtained by the medical device company Insightec Exablate (Tirat Carmel, Israel).

Outcomes and statistical analysis

Patient demographics, including sex, race and ethnicity, were extracted where available in the dataset. Patient characteristics are reported with frequencies and percentages. Univariable tests of variation were done using Kruskal-Wallis tests for continuous variables and χ^2 tests for categorical and binary variables. A multivariable logistic regression model was used to determine the odds of undergoing MRgFUS using data from TriNetX, adjusting for age, sex, race and year.

To test whether the introduction of MRgFUS in 2016 has affected the rate of DBS use, we ran a breakpoint analysis of the number of DBS procedures by year with a starting breakpoint estimate at 2016. All statistical analyses were conducted by using R (V.4.0.3; https://www.R-project.org/) with the alpha set at 0.05.

RESULTS

Patient

After applying all inclusion and exclusion criteria, we identified 1539 patients in the TriNetX database diagnosed with ET who underwent DBS or MRgFUS between 2003 and 2022. The cohort diagram is shown in figure 1.

To better understand the patient population receiving treatment for ET, the demographics of the patient cohort were tabulated by treatment group. Of the 1539 patients with ET in our cohort, 1173 (76.22%) underwent DBS and 366 (23.78%) underwent MRgFUS (table 1). The median age of the cohort was 70 years, with the median age of patients undergoing DBS being lower than that of patients who underwent MRgFUS (69 vs 73 years, $p<0.001$). Although the cohort consisted mostly of male patients (60.62%), a significantly lower proportion of MRgFUS

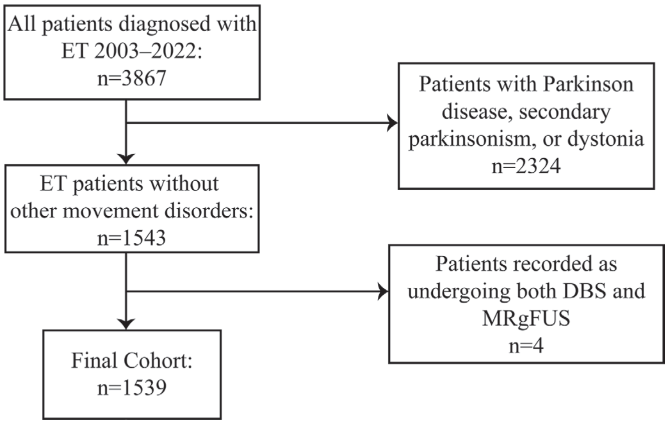

Figure 1 Patient inclusion flow chart. DBS, deep brain stimulation; ET, essential tremor; MRgFUS, MRI-guided focused ultrasound.

patients were male compared with patients who underwent DBS (56.18 vs 74.86%, p<0.001). Most (88.69%) patients in the cohort extracted from the TriNetX database self-identified as white, followed by black or African American (2.40%), Asian (0.52%), American Indian or Alaska Native (0.19%), Native Hawaiian or Other Pacific Islander (0.13%), and unknown (8.06%). Similarly, 84.43% of patients who received MRgFUS treatment were White, although a slightly higher percentage of black patients received MRgFUS treatment than received DBS (4.10% vs 1.88%, p=0.029).

Odds of receiving MRgFUS

A multivariable logistic regression of data retrieved from TriNetX was used to estimate the odds of receiving MRgFUS treatment. Male patients had significantly higher odds of receiving treatment (OR 2.788, 95% CI 1.974 to 3.973, p<0.001) than female patients (table 2). Non-white patients had higher, but non-significantly different, odds of treatment (OR 1.974, 95% CI 0.94 to 4.19, p=0.073). The odds of treatment increased with each year after 2016 (OR 1.801, 95% CI 1.618 to 2.019, p<0.001).

Trends in MRgFUS and DBS use

The frequency of DBS utilisation for patients with ET before and after the introduction of MRgFUS in 2016 was analysed using the NIS database. The yearly frequency of DBS utilisation among ET patients has increased since 2012 up until 2020 as shown in table 3. Between 2012 and 2020, 13 525 patients received DBS for ET. From 2012 to 2015, 5255 (38.9%) patients received DBS treatment for ET, whereas from 2016 to 2020, 8270 (61.1%) patients received DBS for ET (table 4). Recognising that the number of elective procedures performed was reduced in 2020 due to the COVID-19 pandemic, we examined the yearly frequency of DBS utilisation among ET patients through March 2020 in table 3. A total of 1640 DBS procedures were performed for ET in 2020, 520 of these occurred between January and March 2020. 1.96% of ET patients received DBS in all of 2020, whereas when considering only the data from January to March, 2.35% of ET patients received DBS. This is consistent with the increasing frequency of DBS utilisation for ET.

The yearly frequency of MRgFUS procedures for ET was obtained from Insightec. Between 2016 and 2022, 4819 MRgFUS procedures for ET or tremor-dominant Parkinson's disease were performed in the USA. The frequency of procedures completed has increased every year after 2016, with the highest number of procedures (1890) being performed in 2022 (figure 2).

A breakpoint analysis was conducted to determine whether there were any changes in DBS usage after the introduction of MRgFUS (figure 3). The frequency of DBS procedures for ET treatment has increased from

Table 1 Patient demographics

Patient characteristic	Total (n=1539)	DBS (n=1173)	MRgFUS (n=366)	P value
Age, median (Q1–Q3)	70 (63–76)	69 (62–75)	73 (67–78)	<0.001
Male sex, n (%)	933 (60.62)	659 (56.18)	274 (74.86)	<0.001
Race, n (%)				0.029
American Indian or Alaska Native	3 (0.19)	3 (0.26)	0 (0)	
Asian	8 (0.52)	5 (0.43)	3 (0.82)	
Black or African American	37 (2.40)	22 (1.88)	15 (4.10)	
Native Hawaiian or other Pacific Islander	2 (0.13)	1 (0.09)	1 (0.27)	
Unknown	124 (8.06)	86 (7.33)	38 (10.38)	
White	1365 (88.69)	1056 (90.03)	309 (84.43)	
Ethnicity, n (%)				0.066
Hispanic or Latino	19 (1.23)	16 (1.36)	3 (0.82)	
Not Hispanic or Latino	1387 (90.12)	1066 (90.88)	321 (87.7)	
Unknown	133 (8.64)	91 (7.76)	42 (11.48)	

DBS, deep brain stimulation; MRgFUS, MR-guided focused ultrasound.

Table 2 Adjusted odds of MRgFUS use among patients with essential tremor*

Variable	OR (95% CI)	P value
Age (increase in odds of undergoing procedure by each year of life)	1.001 (1 to 1.002)	0.019
Female sex	Reference	Reference
Male sex	2.788 (1.974 to 3.973)	<0.001
White race	Reference	Reference
Non-white	1.974 (0.94 to 4.19)	0.073
Treatment year (increase in odds of undergoing procedure by year from 2016)	1.801 (1.618 to 2.019)	<0.001

*137patients were excluded from multivariate model because of missing variables.
MRgFUS, MR-guided focused ultrasound.

2012 to March 2020. This analysis estimated the breakpoint at the year 2015.

DISCUSSION

Using nationwide databases, we conducted an analysis of the trends in the use of DBS and MRgFUS for the treatment of ET. The results demonstrate that the rate of DBS was not negatively affected after the introduction of MRgFUS in 2016, and in fact the number of DBS procedures for ET increased. We also demonstrated significant demographic differences in the usage of MRgFUS, with older and male patients more likely to get this treatment. A slightly higher percentage of African American patients were treated with MRgFUS than DBS.

Demographic differences in treatment for ET

About 60% of the study cohort was male, which is consistent with national epidemiological data on ET that demonstrates a higher prevalence among males.[20 21] However, male patients still demonstrated a higher likelihood of undergoing MRgFUS, suggesting an unequal distribution of treatment between males and females. This is consistent with earlier studies that suggest that women are also less likely than men to undergo DBS surgery for movement disorders.[22] These results highlight the need for further studies evaluating the factors that influence a patient's decision to receive or not receive advanced therapies.

The study cohort consisted mostly of patients who self-identified as white, but we found that the odds of receiving MRgFUS were higher, although statistically insignificant, among patients who identified as non-white. Earlier studies on disparities in neurosurgical care have demonstrated that white patients are much more likely to receive surgical treatment for movement disorders.[23 24] Potential reasons for this general disparity include lack of access to tertiary care centres and specialised hospitals and healthcare hesitancy among minority patients such as those who identify as black or Hispanic.[25–27] While we observed a greater percentage of patients who received MRgFUS self-identified as black or African American, the proportion of black patients undergoing this procedure for ET is lower than the overall proportion in the general US population. Our TriNETx analysis revealed that only 4.10% of patients undergoing MRgFUS self-identified as black or African American, whereas this demographic constitutes 13.6% of the total US population.[28] Potential reasons for this observed disparity could be due to referral bias. It has been previously reported that providers may be less likely to refer to black patients for subspecialist opinions, standard of care treatments and procedures.[29] This underscores the importance of understanding barriers to care for minority patients.

Table 3 Yearly frequency of deep brain stimulation (DBS) utilisation among essential tremor (ET) patients through the end of 2020 and March 2020

Year	Frequency of ET	Frequency of ET among all NIS discharges	Frequency of DBS for ET
2012	80760	0.22	1125 (1.39%)
2013	82225	0.23	1225 (1.49%)
2014	83665	0.24	1395 (1.67%)
2015	80780	0.23	1510 (1.87%)
2016	73515	0.21	1465 (1.99%)
2017	79125	0.22	1485 (1.88%)
2018	83760	0.24	1685 (2.01%)
2019	89105	0.26	1995 (2.24%)
2020	83685	0.26	1640 (1.96%)
January–March 2020	22065	0.26	520 (2.35%)

NIS, National Inpatient Sample.

Table 4 DBS use before and after 2016

Years	Frequency of DBS for ET
2012–2015	5255 (38.9%)
2016–2020	8270 (61.1%)
Total	13525

DBS, deep brain stimulation; ET, essential tremor; MRgFUS, MRI-guided focused ultrasound.

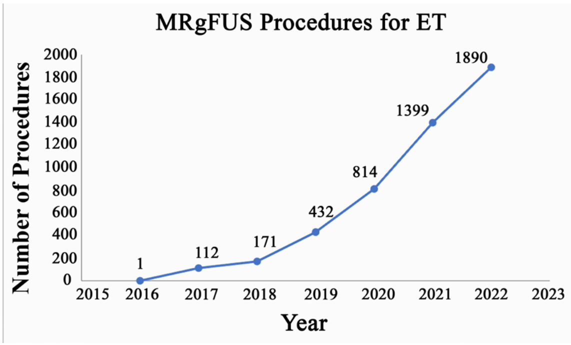

Figure 2 Plot showing the number of MRI-guided focused ultrasound (MRgFUS) procedures performed each year between 2016 and 2022. ET, essential tremor.

Use of DBS before and after the introduction of MRgFUS

Using national data from the NIS, we determined that there has been an increase in DBS use for ET since the introduction of MRgFUS in 2016, with 5255 (38.9%) procedures completed by the end of 2015 and 8270 (61.1%) completed after the beginning of 2016. Additionally, our breakpoint analysis on DBS usage for ET identified an inflection point in 2017.

Because our data overall indicate that the introduction of MRgFUS has been associated with an increase rather than a reduction or a stasis in the number of DBS procedures to treat ET, we suggest that the availability of this less invasive procedure may be having a positive effect on the number of patients seeking neurosurgical consultation for their condition. Thus, neurosurgeons should introduce patients seeking MRgFUS to DBS as well and discuss the risks and benefits of both procedure types, allowing patients to make an informed choice between the two, depending on which procedure is a better fit.

Since medical device companies such as Abbott and Boston Scientific gained FDA approval for their DBS devices in 2016, the increase in DBS use could be attributed to increased marketing and competition between device companies.[30] Emergent evidence demonstrating the efficacy and safety of DBS, and greater patient and provider confidence in the procedure may also be a significant reason for the increase in DBS procedures since 2016.[31–33] It is also important to note that our analysis does not control for the difference in the frequency of ET diagnoses before and after 2016.

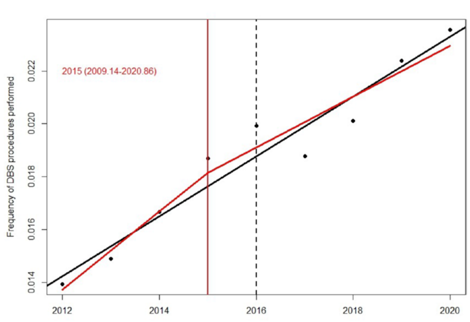

Figure 3 Breakpoint analysis of deep brain stimulation (DBS) usage. Scatterplot showing the frequency of DBS procedures by year. Solid black line represents unbroken linear regression. Solid red line represents breakpoint analysis, with the value and 95% CI reported. Dotted black line marks the year 2016 when MRI-guided focused ultrasound was approved by the Food and Drug Administration for treatment of essential tremor.

An additional benefit to the introduction of MRgFUS is the potential reduction of treatment disparities through decreased costs. Although the exact out-of-pocket costs are not known, a recent study by Ravikumar *et al* suggests that MRgFUS is overall cheaper per procedure than DBS.[34] Their cost-effectiveness study determined that on average, MRgFUS for ET costs about US$18 000, while DBS can cost anywhere from US$26 000 to US$52 000 depending on the staging of battery placement and operative complications.[34] Thus, while the up-front costs of purchasing an MRgFUS device might be high, the costs might be recouped by opening up access to more patients through a cheaper overall procedure compared with DBS.

Limitations and future directions

Our study is limited by the comprehensiveness of our data sources. The TriNetX database does not capture all admissions and treatments nationwide, yielding a smaller study cohort. The TriNetX database is useful in examining the demographic data of patients who received MRgFUS treatment for ET, but it is not comprehensive enough to study how the frequency of DBS procedures being done for ET has changed over time. Instead, we used the NIS database to observe trends in DBS procedures for ET. The NIS database cannot be used to study the demographics of patients who received MRgFUS because the NIS does not report on outpatient procedures. Furthermore, the yearly frequency of DBS usage for ET was only extracted between the years 2012 and 2020 because data were unavailable from 2003 to 2011 and 2021 to 2023. Rates of DBS surgery may have also been affected by the COVID pandemic in ways not captured by this analysis.[35] Additionally, it is important to note that MRgFUS received approval for staged second-side treatment in January 2023.[36] This advancement could make MRgFUS more attractive to patients, and rates may continue to change in the future. Lastly, TriNetX does not include institutional identifiers, so we are not able to evaluate how the frequency of DBS or MRgFUS procedures for ET has changed on an institutional level.

CONCLUSIONS

Our study provides a general overview of the characteristics of patients who have undergone either DBS or MRgFUS for the management of medically refractory tremor from 2003 to 2022. We show notable differences in sex and race among patients who underwent each treatment type. We used the NIS database to examine the trends in DBS usage between 2012 and 2020. We show that the number of DBS procedures being performed to treat ET has not been negatively affected since the introduction of MRgFUS in 2016 until 2019. Future studies are needed at the institutional level across multiple sites after the approval of second-side MRgFUS treatment to further examine trends in DBS surgery and to allow for a better understanding of demographic differences among patients who have undergone either procedure.

Author affiliations
[1]University of Utah Health, Salt Lake City, Utah, USA
[2]Duke University School of Medicine, Durham, North Carolina, USA
[3]Department of Surgery, Surgical Population Analysis Core, University of Utah Health, Salt Lake City, Utah, USA
[4]Department of Biostatistics, Duke University School of Medicine, Durham, North Carolina, USA
[5]Department of Neurology, University of Utah Health, Salt Lake City, Utah, USA
[6]Department of Neurosurgery, University of Utah Health, Salt Lake City, Utah, USA

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Contributors DG: methodology, guarantor, writing–original draft; VV: methodology, writing–original draft; JH: formal analysis, writing–review and editing; PK: writing–review and editing; JA: writing–review and editing; PM: writing–review and editing; BS: writing–review and editing; SR: conceptualisation, methodology, guarantor, project administration, writing–review and editing and reporting guideline. DG and SR are guarantors for this work.

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Patient consent for publication Not applicable.

Ethics approval This study was exempt from review by the institutional review board and the need for patient consent because it included deidentified data from a national database without patient identifiers.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data may be obtained from a third party and are not publicly available. The data that support the findings of this study are available from TriNETx Healthcare Network, National Inpatient Sample and Insightec Exablate. Restrictions apply to the availability of these data, which were used under license for this study.

ORCID iD
Shervin Rahimpour http://orcid.org/0000-0003-2718-181X

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