

Postmarketing Safety of Transcranial Magnetic Stimulation:

A 10-Year MAUDE Database Analysis of Adverse Events and Technological Advancements

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Abstract

Background: Transcranial magnetic stimulation (TMS) is an FDA-cleared neuromodulation technique with expanding clinical applications beyond major depressive disorder. Despite increasing utilization, there has been no published, device-agnostic analysis of TMS-related adverse events (AEs) using the FDA's Manufacturer and User Facility Device Experience (MAUDE) database.

Objective: To characterize the real-world safety profile of TMS devices based on MAUDE-reported AEs, including symptom patterns, manufacturer-level variations, device issues, and reporting delays, while contextualizing findings through a review of technological advancements in TMS.

Methods: All reports under device code OBP were extracted from MAUDE through April 2025. After deduplication, 200 unique reports were analyzed descriptively. A focused literature review was also conducted to trace safety and innovation trends in TMS device development.

Results: Of 200 reports, 94.7% involved injury, 4.1% malfunction, and 1.2% death. Common symptoms included anxiety (8.2%), neurocognitive changes (8.0%), seizures (6.9%), headache (6.9%), and tinnitus (5.6%). Neuronetics accounted for 45.5% of reports, likely reflecting market share. Median reporting delay was 1.4 months, with some exceeding 6 years. The literature review identified major innovations, including figure-of-eight and H-coils, double-containment coils,

seizure risk screening, and advanced circuitry (eg, insulated-gate bipolar transistors and metal-oxide-semiconductor field-effect transistors) enabling magnetic resonance imaging-guided and accelerated protocols. Exploratory developments include wearable systems, auricular stimulation, and artificial intelligence-based individualization.

Conclusion: MAUDE data provide novel insights into TMS safety in real-world settings. Although serious AEs are rare, standardized reporting and continued device innovation are essential to ensure safe and effective clinical use.

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Transcranial magnetic stimulation (TMS) is a US Food and Drug Administration (FDA)-cleared noninvasive neuromodulation technique widely used in the treatment of major depressive disorder, especially in patients unresponsive to pharmacotherapy.¹ Over the past decade, TMS has also gained regulatory clearance for other indications, including obsessive-compulsive disorder, migraine with aura, and smoking cessation, with expert guidelines developed to support safe and evidence-informed use.²⁻⁷ Beyond these uses, real-world practice has seen a substantial rise in off-label applications, such as for posttraumatic stress disorder (PTSD), bipolar disorder, generalized anxiety disorder, and cognitive impairment.⁸ This broadened utilization increases patient exposure and underscores the

importance of regulatory oversight. TMS is classified by the FDA as a Class II medical device, which allows manufacturers to use the 510(k) premarket notification process.⁹ While this pathway facilitates timely innovation, it places greater emphasis on postmarketing mechanisms to monitor safety and inform clinical best practices. While randomized controlled trials have established TMS as generally well tolerated, with commonly reported side effects including scalp discomfort and headache, they are not designed to detect rare or delayed device-specific adverse events.¹⁰ Controlled trials typically involve highly selected patient populations under tightly regulated conditions, limiting their generalizability to broader clinical populations.¹¹ Consequently, questions remain about how adverse

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Clinical Points

- Systematic safety data on transcranial magnetic stimulation (TMS) remain limited outside of trials. This study addresses a key postmarket gap by analyzing real-world adverse event reports from the Manufacturer and User Facility Device Experience (MAUDE) database.
- Clinicians can improve patient safety by standardizing adverse event monitoring and counseling patients about distressing symptoms such as anxiety, cognitive changes, auditory effects, and seizures.
- Safety-enhanced devices with quieter coils, smarter pulse modulation, and better targeting may reduce adverse events. Innovations such as double-containment coils, pulse-shaping circuits, and magnetic resonance imaging–guided protocols are improving safety and precision in clinical TMS.

events manifest outside controlled environments and whether manufacturer- or device-specific factors affect safety.

The FDA operates the Manufacturer and User Facility Device Experience (MAUDE) database to collect voluntary and mandatory adverse event reports related to medical devices. This database serves as a critical tool for postmarket safety monitoring, allowing clinicians, manufacturers, and regulatory agencies to identify emerging safety signals and device malfunctions.¹² Although MAUDE has been used extensively for other medical devices, no study to date has systematically analyzed TMS-related reports. This lack of focused investigation represents a missed opportunity to synthesize real-world safety signals that could inform clinical decision-making and guide future device refinement.

This study aims to provide a comprehensive evaluation of TMS-related adverse events reported to the MAUDE database from its inception through April 2025. Although our search included all available records, the earliest TMS-related report was filed in 2015. We examined overall reporting trends, symptom frequencies, manufacturer-level variations, device-related problems, and reporting delays. To contextualize these safety findings, we also conducted a focused review of the literature to trace key technological advancements in TMS over time. This dual approach aims to inform clinical decision-making and support quality improvement efforts among manufacturers, clinics, and regulatory stakeholders.

METHODS

Data Source and Search Strategy

Adverse event reports related were extracted from MAUDE using the device product code OBP, which corresponds to TMS systems. All publicly available

reports from the inception of the MAUDE database through April 2025 were downloaded in .csv format and imported into Microsoft Excel (Mac version, 2024) for data cleaning and analysis.¹³ All devices represented in the MAUDE database are FDA-cleared; as such, only FDA-cleared TMS systems and coils were included in this analysis.

Duplicate Identification and Dataset Refinement

A total of 230 reports were initially retrieved. Reports were arranged chronologically by event date and date received. Duplicate entries were identified using Excel's built-in filtering tools and manual verification. Reports sharing identical report numbers and dates were excluded. In cases where the report number was the same, but the event date differed, the narrative event descriptions were manually reviewed. When duplicate content was confirmed, only the most complete and representative report was retained. After this deduplication process, a final dataset of 200 unique reports was established for analysis. Three authors (A.I.A., R.Z., and A.D.) independently performed the data extraction and initial cleaning. Discrepancies were resolved through group consensus, and final dataset validation was conducted under the methodological supervision of senior author (N.W. and D.S.).

Descriptive Variables and Analytical Strategy

Event classification within the MAUDE database (eg, "Injury," "Malfunction," "Death") is determined by the reporter in accordance with FDA guidelines under Title 21 Code of Federal Regulations, Part 803.^{14,15} These classifications are not independently verified by the FDA and reflect reporter's judgment at the time of submission. Attribution of adverse events is subjective, particularly in voluntary patient-submitted reports (Form 3500), which may lack clinical corroboration compared to mandatory clinician or facility reports (Form 3500A). This analysis retained the reporter-assigned classifications and did not readjudicate causality, consistent with the descriptive nature of MAUDE-based signal detection. Symptom frequencies were extracted from the "Patient Problem" field, where multiple symptoms were tallied individually. Reports were also stratified by year received and by manufacturer. Manufacturer names were standardized for consistency (eg, "MAG & More GmbH" vs "MAG & More").

Assessment of Reporting Delays

To analyze reporting delays, the difference in months between the event date and FDA receipt date was calculated using Excel's DATEDIF function. Reports with missing or implausible dates were excluded. Descriptive statistics, including the mean, median,

standard deviation, interquartile range (IQR), minimum, and maximum values, were calculated to summarize the reporting delays.

Focused Review of Technological Advancements in TMS

To contextualize the safety findings, a focused review of the published literature was conducted to trace major technological advancements in TMS devices and protocols over time. Searches were performed using PubMed and Google Scholar, emphasizing peer-reviewed studies, device engineering reports, and clinical innovations. The review focused on literature published between 2010 and 2025, with particular attention to developments relevant to the period covered by the MAUDE dataset. Key advances in coil design, stimulation protocols, safety features, and emerging applications were synthesized to provide insight into how device evolution may influence the observed adverse event landscape.

RESULTS

Volume and Trend of TMS-Related Adverse Event Reports

Following deduplication, 200 unique TMS-related reports were analyzed. Report volume increased over time, with fewer than 15 submissions annually prior to 2021. A sharp rise was observed beginning in 2022, with 45 reports in 2022, 41 in 2023, 45 in 2024, and 9 reports in the first quarter of 2025 (Figure 1).

Event Type Distribution

Among the 200 reports, injury was the most common classification (n = 191, 94.7%), followed by malfunction (n = 7, 4.1%) and death (n = 2, 1.2%). Narrative review of both death cases revealed complex clinical contexts with no direct causality attributed to TMS. In the context of MAUDE reporting, “Injury” refers to any adverse event that may have resulted in harm to the patient, as designated by the reporter or manufacturer at the time of submission. This category encompasses a broad spectrum of clinical outcomes and does not necessarily imply permanent damage or objective confirmation. The classification is based on subjective reporting and may vary across reporters and manufacturers. These findings are summarized in Table 1.

Clinical Symptom Frequencies in TMS Adverse Event Reports

Across the 200 reports, 645 symptom mentions were identified, with many entries describing multiple symptoms. To enhance interpretability, similar symptoms were consolidated under umbrella terms based on clinical similarity. Grouping was performed

independently by 2 investigators and reconciled by consensus. These were informed by standard neuropsychiatric symptom clustering used in clinical settings. For instance, *neurocognitive changes* included memory loss, cognitive impairment, confusion, and disorientation.¹⁶ *Generalized fatigue* encompassed fatigue, malaise, and weakness.¹⁷ *Involuntary movements* grouped twitching, tremors, shaking, and muscle cramps.^{18,19} Grouping was limited to a subset of thematically related terms and was not applied across all symptoms.

The most frequently reported symptoms were anxiety (n = 53, 8.2%), neurocognitive changes (n = 52, 8.0%), convulsions/seizures (n = 45, 6.9%), headache (n = 45, 6.9%), and depression (n = 39, 6.0%). Other commonly cited symptoms included pain (n = 36, 5.6%), tinnitus (n = 36, 5.6%), emotional dysregulation (n = 35, 5.4%), sleep dysfunction (n = 28, 4.3%), and dizziness or vertigo (n = 26, 4.0%). Less frequent but notable symptoms included suicidal ideation (n = 24, 3.7%), generalized fatigue (n = 18, 2.8%), involuntary movements (n = 16, 2.5%), nausea or vomiting (n = 14, 2.2%), and visual disturbances (n = 13, 2.0%), which encompassed blurred vision and visual impairment. Hearing-related complaints (n = 11, 1.7%) included hearing loss and hearing impairment.

Over 50 additional symptoms were reported fewer than 5 times each, including dermatologic, cardiovascular, gastrointestinal, and rare neurological events such as intracranial hemorrhage, paralysis, and hallucinations. These patterns are illustrated in Figure 2, which displays the top 18 most frequently reported symptoms in TMS-related adverse event reports submitted to the FDA MAUDE database between 2015 and 2025.

Manufacturer-Stratified Analysis of Event Types and Device Problems

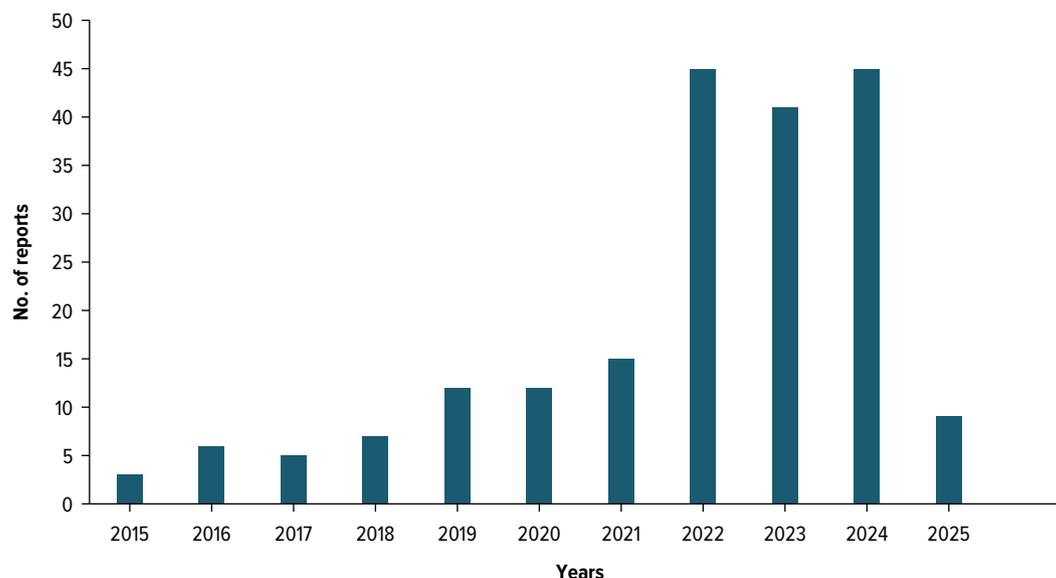
A manufacturer-level stratification revealed considerable variability in both the volume and nature of device problems. The largest proportion originated from Neuronetics, Inc (n = 91, 45.5%), followed by BrainsWay Ltd (n = 37, 18.5%), The Magstim Company Ltd (n = 28, 14.0%), MagVenture A/S (n = 25, 12.5%), and Neurosoft Ltd (n = 4, 2.0%). One report (0.5%) was attributed to MAG & More GmbH, while 14 reports (7.0%) lacked manufacturer identification and were excluded from stratified comparisons.

Injury was the predominant event type across all manufacturers (94.7%), ranging from 88.9% of BrainsWay reports to 100% for MagVenture, Neurosoft, and MAG & More. Malfunctions (4.1%) were most often linked to Neuronetics and BrainsWay. The 2 deaths were associated with Neuronetics and Magstim devices.

The most common device problem was “Adverse event without identified device or use problem” (n = 82,

Figure 1.

Annual Number of TMS-Related Adverse Event Reports Submitted to the FDA MAUDE Database (2015–2025)^a



^aBar heights represent total TMS-related adverse event reports per calendar year, as recorded in the FDA MAUDE database. The sharp increase in reports after 2021 may reflect growing device use. Abbreviations: FDA = Food and Drug Administration, MAUDE = Manufacturer and User Facility Device Experience, TMS = transcranial magnetic stimulation.

41%), reported primarily from Neuronetics (n = 58) and BrainsWay (n = 11). The second most frequently reported problem was “Insufficient information or unspecified problem code” (n = 58, 29%), again largely attributed to Neuronetics (n = 39). A third recurring issue was “Output problem” (n = 11, 5.5%), most commonly in Magstim and Neuronetics reports. Less frequent but noteworthy device problems included device alarms, power loss, and unintended electrical shock, each reported sporadically across manufacturers. Device problems beyond these top 3 were highly heterogeneous and typically appeared in isolated cases. A detailed summary of manufacturer-specific reporting patterns, event types, and the most frequently cited device problems is presented in Table 2.

Temporal Discrepancies Between Adverse Event Occurrence and Report Submission

Temporal data were available for 181 of the 200 TMS-related reports (90.5%) suitable for analysis. Nineteen reports (9.5%) were excluded due to missing event dates (n = 17) or implausible sequencing in which the event date postdated the FDA receipt date (n = 2). Among the included reports, the median delay between event occurrence and FDA receipt was 1.4 months (IQR: 6.85 months), with a mean delay of 6.04 months (SD: 10.13), indicating a right-skewed distribution influenced by a small number of substantially delayed submissions.

Table 1.

Distribution of Reported TMS Adverse Events by Event Type (Injury, Malfunction, Death)

Event type	Count (n = 200)	Percentage
Injury ^a	191	94.7%
Malfunction	7	4.1%
Death ^b	2	1.2%

^a“Injury” classification reflects reporter-designated events within MAUDE and does not indicate confirmed causality.

^bBoth cases classified as “death” in the MAUDE database were reviewed in detail; narrative descriptions indicated no direct causality attributable to TMS.

Abbreviations: MAUDE = Manufacturer and User Facility Device Experience, n = number of reports, TMS = transcranial magnetic stimulation.

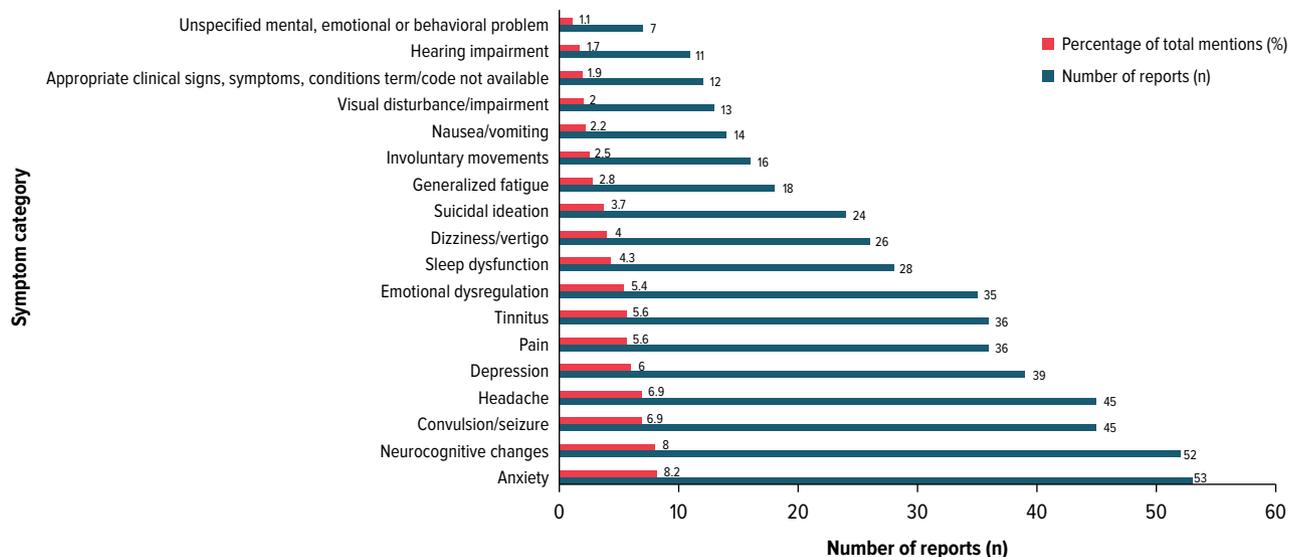
The shortest delay was 0 months, and the longest was 77.1 months.

DISCUSSION

This study presents the first comprehensive analysis of adverse event reports related to TMS submitted to the FDA’s MAUDE database, offering real-world insights into device safety, symptom profiles, and manufacturer patterns. Reporting volume increased sharply after 2021, coinciding with expanded clinical use and greater awareness of regulatory reporting. The COVID-19 pandemic significantly disrupted mental healthcare

Figure 2.

Top 18 Most Frequently Reported Symptoms Associated With TMS Adverse Event Reports Submitted to the FDA MAUDE Database (2015–2025)^a



^aA total of 645 symptom mentions were extracted and grouped into clinically relevant categories. Bars display both absolute counts and percentage of total mentions. Abbreviations: FDA = Food and Drug Administration, MAUDE = Manufacturer and User Facility Device Experience, TMS = transcranial magnetic stimulation.

delivery globally, and its downstream effects on safety reporting warrant consideration.²⁰ Although the increase in MAUDE reports occurred after the peak pandemic period, residual factors such as care delays, social isolation, economic stressors, and worsening psychiatric burden likely contributed to increased demand for TMS during the recovery phase.²¹ In one study, patients whose treatment was interrupted by COVID-related restrictions showed clinical response, with postpandemic response at 30.0% compared to 48.8% prepandemic ($\chi^2 = 5.79, P = .016$).²² Pandemic-related shifts in health communication, including greater digital engagement and patient self-advocacy, may have further amplified voluntary reporting behaviors.²³ Discrepancies between media portrayals and academic literature, particularly in clinical specificity, may also influence how patients interpret and report TMS-related experiences.²⁴ As a passive surveillance system, MAUDE is subject to underreporting, inconsistent data quality, and reporting delays. Its findings should be interpreted as qualitative signals rather than population-level incidence rates.

A significant observation from this dataset is the predominance of injury-related reports, accounting for 94.7% of cases, with malfunctions and deaths comprising 4.1% and 1.2%, respectively. The most reported malfunctions involved output problems, device power loss, and device alarm issues. Both reported deaths were due to substance-related overdose, with no evidence of direct TMS causality. This distribution supports the existing safety profile of TMS in clinical use.

Symptom profiles were diverse. Anxiety (8.2%) was the most frequently reported symptom. While TMS often reduces anxiety in patients with depression or PTSD, some patients may experience acute distress during treatment due to coil noise, muscular activation, or preexisting psychiatric vulnerability.^{25–27} Headache was reported in only 6.9% of MAUDE entries, whereas a pooled analysis of 884 patients found a 30%–40% incidence.¹⁰ This likely reflects underreporting of mild, self-limiting symptoms. Neurocognitive changes, reported in 8% of MAUDE entries, are notable given that TMS has not been linked to lasting cognitive deficits in clinical trials. A meta-analysis of 30 randomized trials found no consistent cognitive changes.²⁸ A subsequent review of 31 trials also concluded that rTMS did not impair cognition across disorders such as depression, schizophrenia, or Alzheimer’s disease.²⁹ This discrepancy may reflect heightened sensitivity to cognitive changes during TMS treatment, a pattern consistent with nocebo effects observed in other neuromodulation studies.³⁰ Cognitive complaints are also prevalent in psychiatric disorders and may be mistakenly attributed to TMS.³¹ Clinicians should monitor these concerns closely, provide anticipatory guidance, and distinguish transient, illness-related symptoms from those that arise during treatment.

Seizures, observed in 6.9% of reports, remain a rare but serious adverse event. A 2021 analysis of 586,656 sessions reported a seizure rate of 0.31 per 10,000 sessions (0.71 per 1,000 patients), with higher risk observed with H-coils compared to figure-of-eight coils.³² These findings support earlier meta-analyses

Table 2.

Manufacturer-Stratified Summary of Report Counts, Event Types, and Most Commonly Cited Device Problems Associated With Transcranial Magnetic Stimulation (TMS) Devices Submitted to the FDA MAUDE Database (2015–2025)^a

Variable	Neuronetics	BrainsWay	Magstim	MagVenture	Neurosoft	MAG & More
Total reports (n)	91	28	28	25	4	1
Event type						
Injury (n, %) ^b	85 (93.4%)	33 (89.2%)	25 (89.3%)	25 (100%)	4 (100%)	1 (100%)
Malfunction (n, %)	5 (5.5%)	4 (10.8%)	2 (7.1%)	0 (0%)	0 (0%)	0 (0%)
Death (n, %) ^c	1 (1.1%)	0 (0%)	1 (3.6%)	0 (0%)	0 (0%)	0 (0%)
Device problems^d						
Most common device problem (n, %)	Adverse event w/o identified problem (58, 63.7%)	Adverse event w/o identified problem (11, 29.7%)	Output problem (5, 17.9%)	Adverse event w/o identified problem (4, 16%)	Device alarm (1, 25%)	...
Second most common device problem (n, %)	Insufficient information (39, 42.9%)	Insufficient information (9, 24.3%)	Adverse event w/o identified problem (6, 21.4%)	Output problem (2, 8%)
Third most common device problem (n, %)	Output problem (3, 3.3%)	Device alarm (2, 5.4%)	Insufficient information (4, 14.3%)	Device power loss (1, 4%)

^aPercentages are based on total reports per manufacturer. Reports with unknown manufacturers (n = 14) were excluded from stratified comparisons but included in overall analyses. Ellipses indicate missing or unavailable data.
^b"Injury" classification reflects reporter-designated events within MAUDE and does not indicate confirmed causality.
^cBoth deaths were substance-related overdoses without evidence of direct TMS causality.
^dDevice problem terms reflect MAUDE problem codes provided by the FDA.
Abbreviations: FDA = Food and Drug Administration, MAUDE = Manufacturer and User Facility Device Experience, n = number of reports, TMS = transcranial magnetic stimulation, w/o = without.

showing negligible rates similar to sham.³³ Key risk factors include protocol deviations, proconvulsant medications, and neurologic comorbidities. Technological advancements, including insulated-gate bipolar transistors (IGBTs) and metal-oxide-semiconductor field-effect transistors (MOSFETs), now allow more precise pulse shaping, potentially reducing cortical overstimulation and seizure risk.³⁴

Suicidal ideation (SI), present in 3.7% of reports, must be interpreted cautiously. Given TMS's indication for treatment-resistant depression, such reports likely reflect baseline illness severity rather than iatrogenic harm. A retrospective study of 711 patients found a suicide rate of 0.1% during treatment, with most showing reduction in SI.³⁵ Emotional dysregulation (5.4%) was also noted, but large-scale reviews show no elevated mania risk, supporting the importance of structured monitoring in mood disorder populations, particularly those with bipolar risk.^{36–38}

Tinnitus (5.6%) and other auditory issues (1.7%) were reported at low frequencies. Although clinical trials support the auditory safety of TMS, coil output can reach up to 120 decibels, exceeding the National Institute for Occupational Safety and Health threshold of 85dB.^{39,40} Therefore, the use of well-fitted hearing protection is essential during TMS sessions to mitigate the risk of acoustic trauma.³ Recent hardware advances such as double-containment coils have significantly reduced acoustic output, helping devices better meet occupational safety standards and improve user

experience.⁴¹ Visual effects (2%) were mostly minor, although rare reports of retinal detachment in older patients raise concern over transient intraocular pressure shifts or muscle strain.⁴²

Manufacturer-stratified analysis showed Neuronetics with the highest number of reports (45.5%), followed by BrainsWay and Magstim. This likely reflects broader market exposure rather than safety differentials. Nonspecific categories like "adverse event without identified use problem" were disproportionately linked to Neuronetics and BrainsWay, pointing to reporting inconsistency. The International Medical Device Regulators Forum has called for standardized terminology to enhance signal detection across devices.¹⁴ Technical issues such as coil overheating and mechanical failures were also reported, but recent design upgrades have addressed many concerns, illustrating how postmarket surveillance can drive quality improvements.^{41,43,44}

A key operational finding was the variability in reporting delays, with a median of 1.4 months and a mean of over 6 months. A review of over 4 million MAUDE entries found that 30% were filed beyond the FDA-mandated 30-day window, with nearly 10% submitted over 180 days late.⁴⁵ Such delays hinder timely identification of safety signals and delay public health responses. Potential improvements include automated surveillance tools, electronic health records integration, and greater awareness of reporting timelines.

While several technological advancements were discussed in relation to specific adverse events, a broader

review of the literature highlights additional innovations that continue to shape the safety and clinical utility of TMS. Device evolution has progressed from circular to figure-of-eight coils for improved focality, and H-coils have enabled deeper cortical and subcortical stimulation.^{46,47} Advanced pulse-shaping technologies, incorporating IGBTs and MOSFETs, support protocols such as theta burst stimulation, accelerated paradigms, and magnetic resonance imaging–guided personalization.^{34,48,49} Investigational approaches such as Stanford Neuromodulation Therapy have shown promising results for rapid symptom improvement in treatment-resistant depression.⁵⁰ Exploratory modalities, including auricular, transcutaneous, and paired peripheral nerve stimulation, may further reduce stimulation burden while enhancing neuroplasticity.^{51–53} Research into wearable systems and artificial intelligence (AI)-driven individualization reflects a broader shift toward adaptive, patient-centered TMS treatment models.

Clinical Implications and Future Directions

The findings of this study support the need for structured safety monitoring in TMS practice and underscore the clinical relevance of recent device innovations. Clinicians should remain vigilant for symptoms such as seizures, neurocognitive changes, and auditory or visual disturbances, particularly in vulnerable populations. Standardized patient education, anticipatory guidance, and structured follow-up may help mitigate distress and clarify attribution of symptoms. Device selection should prioritize safety-enhancing features, including advanced coil architecture, pulse modulation circuitry, and acoustic insulation, which may reduce stimulation burden and improve tolerability. From a systems perspective, improving the consistency and completeness of MAUDE reporting could strengthen safety signal detection. Expanding automated reporting, harmonizing terminology across manufacturers, and integrating real-world data from electronic health records may enhance postmarket surveillance. Future research should explore device-specific risks, longitudinal safety outcomes, and collaborative strategies to support safer and more personalized TMS delivery.

Limitations

This study has several limitations inherent to the structure of the MAUDE database. As a passive surveillance system, it likely underrepresents the true frequency of adverse events, and the quality and completeness of reports can vary widely. The analysis was descriptive and not intended to establish causal relationships or compare devices inferentially. Additionally, device usage volume across manufacturers could not be normalized, which limits interpretation of report frequency. Finally, although a focused literature

review was conducted to contextualize safety findings, a systematic review was not performed due to time and resource constraints. The aim was to highlight clinically and technologically relevant innovations across the study period rather than exhaustively catalog all published evidence. Despite these limitations, the study provides valuable real-world insights into TMS safety and highlights how postmarket data can inform both clinical practice and device innovation.

CONCLUSION

This study provides the first structured analysis of TMS adverse events reported to the FDA's MAUDE database, highlighting key safety signals and manufacturer trends. Most events were nonfatal and clinical, with seizures, anxiety, neurocognitive changes, and tinnitus underscoring the need for careful screening, patient education, and adherence to protocols. Advancements in coil design, pulse modulation, and imaging-based personalization may reduce these risks and enhance tolerability. Continued integration of postmarket surveillance with device innovation and clinical practice will support safer and more effective use of TMS.

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Author Contributions: Conceptualized and designed the study: (Awan, Waheed, Singh); conducted data extraction from the MAUDE database and performed data cleaning and coding: (Awan, Zahra, Dad); conducted the descriptive analysis and interpretation: (Awan, Zahra, Waheed); provided overall supervision of the project, including methodological guidance and final manuscript review: (Singh). All authors contributed to the drafting, critical revision, and final approval of the manuscript.

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