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Quantification of fracture rate during electroconvulsive therapy (ECT) using state-mandated reporting data

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Introduction

More than 80 years after its introduction, electroconvulsive therapy (ECT) remains the most effective treatment for both unipolar and bipolar depression, with response rates of approximately 75% and remission rates of greater than 50%.⁽¹⁾ While the general depiction of ECT in movies and television continues to be of painful and traumatic treatments,⁽²⁾ the FDA recognized the overall safety of ECT devices by reclassifying them as Class II in December 2018. Mandated among the labeling requirements was warnings about the potential for physical trauma including fractures. While historically up to 35% of patients may have fractured vertebrae during ECT done without muscle relaxants,⁽³⁾ the rate of fractures in the modern era of relevance to the FDA warning is unknown. This study quantifies the fracture rate of modern ECT using state-mandated reporting data.

Methods

Requests were sent to the Department of Health or equivalent agency of the US states which mandate reporting of ECT treatments.⁽⁴⁾ Information on the number of patients, number of treatments, and number of fractures were requested without date restriction. To account for differences in reporting among states, the annual number of patients for Texas was scaled from quarterly patient counts by 0.85, in accordance with prior methods.⁽⁵⁾ Annual treatments for Illinois was calculated by multiplying the number of patients treated by the average number of treatments per patient (6.62) from the rest of the dataset. Population data was obtained from the 2010 US Census. To most accurately represent national trends, years for which all states had data available were analyzed for pooled fracture rates, with confidence intervals calculated using the Clopper-Pearson interval. Data from all years are reported. This study was designated not human subjects research by the Partners Institutional Review Board.

Results

Data were reported by five states (CA, CO, IL, TX, VT) with a combined cohort of 80,885,086 as of 2010, or 26.2% of the US population. In total, 111,424 patients received 737,477 treatments, and 15 fractures were reported (Table 1, left). During the period for

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which all states had available data (2013-2017), 41,989 patients received 280,894 treatments with one reported fracture (Table 1, right). This corresponds to a fracture rate of 3.56 per 1,000,000 treatments (95% CI 0.09-19.8 per 1,000,000), or 2.38 per 100,000 patients (95% CI 0.06-13.3 per 100,000) treated with ECT.

Discussion

Consistent with the 2018 FDA reclassification of ECT devices as moderate risk, fractures are a very rare complication of electroconvulsive therapy, less common by an order of magnitude than the estimated fatality rate from general anesthesia in developed countries of 2.5 per 100,000,(6) and less common by more than two orders of magnitude than perforation of the colon during colonoscopy (5.8 per 10,000).(7) Only one fracture was reported during the primary analysis period, compared to 14 before 2013, perhaps reflecting continued improvements in anesthesia methods. By way of comparison, the rate of highway fatalities in the US is approximately 1 per 116 million miles traveled, so if a patient travels 200 miles each way to ECT treatments they are roughly as likely to die in transit as to break a bone during the procedure.

Strengths of this study are the use of mandated reporting data that, in contrast to data from insurance claims or from inpatient hospitalizations, should accurately reflect treatments regardless of payment source or location of treatment. The five states reported here represent all states that routinely collect ECT outcomes, and in total include more than one fourth of the US population. Although extrapolation from these states to the entire nation is not possible due to differences among regional practice,(8,9) this is nonetheless the largest dataset of its type ever reported and likely captures a significant fraction of the overall treatments performed during the study period.

Limitations of the study include reliance on outcomes reported by ECT physicians, who may not identify all fractures at the time of treatment. Additionally, significant variation in ECT practice among nations limits worldwide generalizability. Moreover, most states do not collect data on patients receiving ECT in federal facilities, so those treatments are not reflected in this data.

Conclusion

Fractures are a very rare complication of ECT in contemporary US practice, occurring at rates much lower than the morbidity and mortality risk from commonly accepted medical interventions including colonoscopies and general anesthesia.

Acknowledgments

Declaration of Interest

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Table 1:

Left: number of patients, number of treatments, and number of fractures reported by state along with the years for which data was obtained. States vary in the number of years of data retained, from a low of 8 years for Illinois to a high of 25 years for Texas. Most fractures are reported by Texas, with the last of them occurring in 2006. Right: data from the period 2013-2017, when all states reported results. This represents more than a third of all treatments and patients in the entire dataset, and during this period only a single fracture was reported

State	Year Range	Patients	Treatments	Fractures	Year Range	Patients	Treatments	Fractures
CA	2008-2017	39,114	194,853	0	2013-17	14,337	74,859	0
CO	2004-2018	7,610	78,596	2	2013-17	2,672	28,262	0
IL	2006-7;2013-18	21,494	142,261	1	2013-17	13,458	89,074	1
TX	1994-2018	41,212	293,946	12	2013-17	10,915	80,912	0
VT	2001-2018	1,994	27,821	0	2013-17	607	7,787	0
		111,424	737,477	15		41,989	280,894	1