

Quality care in epilepsy: Women's counseling and its association with folic acid prescription or recommendation



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ABSTRACT

Objective: This study aimed to determine if annual counseling about contraception and pregnancy in the setting of treatment for epilepsy is associated with increased recommending or prescribing of folate.

Methods: This is a retrospective cohort study with medical record abstraction. We selected records from 77 women of childbearing age who had two or more visits for epilepsy at a neurology clinic. The assessment included a review of documentation from the first three visits for epilepsy within a 24-month follow-up window. We defined perfect adherence to annual counseling about the impact of epilepsy treatment on contraception or pregnancy as defect-free care for women (DFCW). A recommendation that the patient take over-the-counter folate or a prescription for folate was independently abstracted from the chart at each visit.

Results: The group of patients who received DFCW (N = 28, 36.36%) and the group who did not receive DFCW (N = 49, 63.63%) were comparable with respect to age, disease duration, baseline history of drug-resistant epilepsy (DRE), presence of concurrent psychiatric disease, epileptologist involvement, number of antiepileptic drugs (AEDs) prescribed, seizure type, and etiology.

Twenty (71.4%) patients in the DFCW group and 42 (85.7%) in the non-DFCW group were *not* recommended or prescribed folic acid (p = 0.12).

Conclusions: Even with annual documentation of counseling about how epilepsy treatment may affect contraception and pregnancy, the “action” of prescribing or recommending folic acid during the ensuing 24 months is frequently omitted.

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1. Introduction

As new payment systems evolve, the goal has shifted from providing high volume care to high quality care. The American Academy of Neurology (AAN) made an important contribution to neurology practice by developing the Epilepsy Quality Measures (EQM) [1,2]. These measures focus on processes across the spectrum of epilepsy care including documentation of seizure type and frequency, etiology or epilepsy syndrome, review of EEG and neuroimaging, the assessment of antiepileptic drug side effects, counseling about safety, impact on reproduction, and alternatives when seizures are drug-resistant [2].

The AAN/EQM were based on existing scientific evidence linking the care processes to better outcomes when available and, in the absence of evidence, on a consensus of experts that these measures *may* reflect

better patient-centered outcomes among people with epilepsy [3]. To date, the single quality measure from this set of measures that has been endorsed by the National Quality Forum (National Agency for Healthcare Research and Quality) is that women of childbearing potential with epilepsy should be counseled about the impact of their disorder and its treatment on pregnancy, choice of AED, and the preconceptions on the use of folic acid. However, it is unknown if high quality care (as defined by medical record evidence of this care) is associated with better outcomes for women with epilepsy.

Because all women of childbearing age should consume folic acid daily to prevent serious birth defects [4], we aimed to determine if women's counseling according to the AAN/EQM is associated with the increased use of folic acid. We tested the hypothesis that the annual documentation of counseling about how epilepsy treatment (as a proxy for actual face-to-face counseling) may affect contraception and pregnancy is associated with the increased prescription or recommendation of folate in a 24-month follow-up window.

2. Material and methods

We performed a retrospective cohort study with medical record abstraction. Sampling was done as follows: eligible medical records

Abbreviations: DFCW, defect-free care for women; EQM, Epilepsy Quality Measures; AAN, American Academy of Neurology; AED, antiepileptic drug; DRE, drug-resistant epilepsy.

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were identified using the Partners Healthcare Research Patient Data Registry (RPDR), a clinical data registry that aggregates data from sources throughout the Partners Healthcare System (PHS) including the narrative, reporting, and administrative systems [5]. We performed a query for the time frame of January 2009 through June 2013 with the following inclusion criteria: 18 years old or older, with two or more visits at the Massachusetts General Hospital (MGH) outpatient neurology clinic, and with epilepsy as the principal or secondary diagnosis (ICD-10 code G40 (epilepsy and recurrent seizures) or ICD-9 codes 345.0–345.9 (epilepsy)) [6,7].

One thousand eight hundred ninety-five medical records were identified with the RPDR query. Two research assistants independently reviewed the medical records identified from the RPDR query. A flow-chart with sample screening and selection process (Supplementary material) details how the sample was derived. Based on the inclusion criteria, 80 medical records were selected for further data abstraction, and 1818 were excluded as follows: 178 were excluded because they were Partners Healthcare employees, 473 patients had an unconfirmed diagnosis of epilepsy, 906 patients had less than one visit per year for epilepsy care or were not taking antiepileptic medications (AED), 189 were males (in spite of limiting the original search to women), and 69 patients were older than 44 years. After the medical record review, 3 patients with evidence of folic acid prescription or recommendation prior to the first visit for epilepsy care were also excluded, leaving 77 subjects.

An electronic medical record abstraction process was developed based on the AAN/EQM performance measurement set [2]. The assessment of quality included the review of the first visit for epilepsy care and the subsequent follow-up visits within a 24-month follow-up window (establishment of care). We defined defect-free care for women's (DFCW) counseling, as a binary measure: either perfect adherence to this specific quality measure within the study time frame or not. Credit was given for evidence that the provider had a discussion with the patient about how epilepsy and its treatment may affect contraception and pregnancy at least twice in 2 years and at least once each year [7–9]. This served as the binary independent variable.

The outcome variable, folic acid recommended or prescribed, was chosen because the medical record evidence of prescription is independent of the physicians' clinical note. This was abstracted from the electronic medication list at all visits. The electronic medication list is generated independently of the narrative note, and physicians in this practice are required to reconcile the active medication list at all visits. In addition, evidence of folic acid recommendation was also gathered from the narrative note (e.g., some patients may have been taking folate over the counter). A binary score (present vs. not present) was given to active prescriptions of folic acid at any dose or any evidence that the patient is taking over-the-counter folic acid (e.g., not active in prescriptions but listed in the current medication list section or in the narrative clinic note).

Pertinent clinical information was gathered for potential stratification of covariants such as disease duration, type of seizures, epilepsy syndrome and etiology, number and type of AEDs prescribed, psychiatric comorbidities, pregnancy history, and history of drug-resistant epilepsy (DRE). Drug-resistant epilepsy was defined as a history of failure of adequate trials of two tolerated, appropriately chosen and used antiepileptic drugs (whether as monotherapies or in combination) to achieve sustained seizure freedom and was assessed at the first visit. The psychiatric comorbidities included anxiety, depression, bipolar disorder, and previous suicidal attempts.

An epilepsy specialist was present when the consulting neurologist was practicing as a part of an epilepsy center or had formal training in epilepsy care (e.g., fellowship) and cared for the patient at least once within the study evaluation period [7,8].

Two research assistants reviewed the medical records for consulting physician and demographic data and performed the quality assessment as outlined above. The research assistants were trained through an

intensive ten-week program. When conflicting or incomplete information was encountered, the medical record was discussed and reviewed by both research assistants and the principal investigator (PI). In addition, in order to assess the reliability of the data collection process, the PI abstracted a random sample of 20% of the charts previously reviewed by the research assistants. A test of interrater reliability showed a good level of agreement between the results produced by the two research assistants and the senior epilepsy fellow ($\kappa = 0.88$ and 0.77 for each pair of raters).

2.1. Sample size calculation

This sample was adequately powered to detect a 30% difference in the proportion of folic acid prescription between two samples: 80% power with an alpha of 5%.

2.2. Statistical analysis

Statistical analysis was performed using STATA® [10]. The t-test or chi-square, where appropriate, were used for the comparison between baseline demographic and clinical information.

The chi-square test was performed to assess the relationship between the proportion of patients that received defect-free care for women's counseling and the proportion of patients that had folic acid prescribed or recommended. The p-value threshold for statistical significance was 0.05.

2.3. Standard protocol approvals, registrations, and patient consents

This study was conducted under a protocol approved by the Partners Healthcare Institutional Review Board, with a waiver of informed consent.

Table 1
Demographic and clinical characteristics of the population.

Variables/total of unique patients	Defect-free care for women's counseling		p-Value
	Yes N = 28	No N = 49	
Mean age in years (SD)	31 (6)	31 (7)	0.88
Disease duration in years (SD)	14 (11)	11 (9)	0.18
Drug-resistant epilepsy ^a (%)	2 (7.14)	9 (18.36)	0.17
Concurrent psychiatric disease (%)	3 (10.71)	14 (28.6)	0.06
Epilepsy specialist involvement (%)	27 (96.4)	40 (81.6)	0.06
Number of AEDs prescribed (%)			0.63
≤1	19 (67.9)	28 (57.1)	
2–3	6 (21.4)	13 (26.5)	
≥4	3 (10.7)	8 (16.3)	
Seizure type	N = 26	N = 44	0.54
Simple partial (%)	1 (3.8)	3 (6.8)	
Complex partial (%)	7 (26.9)	20 (45.5)	
Primarily generalized (%)	10 (38.8)	12 (27.3)	
Secondarily generalized (%)	3 (11.5)	3 (6.8)	
More than one (%)	5 (19.2)	6 (13.6)	
Epilepsy etiology	N = 27	N = 45	0.20
Cryptogenic (%)	3 (11.1)	10 (22.2)	
Idiopathic (%)	13 (48.1)	13 (28.9)	
Symptomatic (%)	11 (40.7)	22 (48.9)	
History of adverse pregnancy outcome	6 (25), N = 24	2 (7.7), N = 26	0.09

Demographic and clinical characteristics of the population were assessed at the first visit. This is a sample composed of female patients.

^a Drug-resistant epilepsy (DRE) was defined as history of failure of adequate trials of two tolerated, appropriately chosen and used antiepileptic drug schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom and was assessed at the first visit as well.

3. Results

The final cohort of 77 patients either received DFCW or did not receive DFCW. Table 1 details the distribution of demographic data and pertinent clinical data between these groups.

The group of patients who received DFCW ($N = 28, 36.36\%$) and the group who did not receive DFCW ($N = 49, 63.4\%$) were comparable with respect to age, disease duration, baseline history of DRE, presence of concurrent psychiatric disease, epilepsy specialist involvement, number of AEDs prescribed, seizure type, and epilepsy etiology.

The mean disease duration was 14 years (SD: 11) in patients who received DFCW and 11 years (SD: 9) in patients who did not receive it ($p = 0.18$). A previous history of DRE was present in 2 (7.14%) patients who received DFCW and 9 (18.36%) who did not ($p = 0.17$). Twenty-seven (96.4%) of the patients that received DFCW had an epilepsy specialist involved in their care, whereas 40 (81.6%) patients who did not receive DFCW had an epilepsy specialist involved in their care during the 24-month period of evaluation ($p = 0.06$).

Evidence of a folic acid prescription or the recommendation to take folate was present in 8 (28.5%) medical records in the DFCW group and 7 (14.2%) medical records in the non-DFCW group. In other words, 20 (71.4%) patients in the DFCW group and 42 (85.7%) in the non-DFCW group did not receive either a folic acid prescription or recommendation ($p = 0.12$). Fig. 1 illustrates this difference.

Twenty-one (75%) patients in the DFCW group and 23 (47.9%) patients in the non-DFCW group were never pregnant. Six (21.42%) patients in the DFCW group and 2 (4.2) patients in the non-DFCW group had documented history of adverse pregnancy outcomes. Unfortunately, information about the previous pregnancy history was not available in the medical records of 3 (10.7%) patients in the DFCW group and 22 (45.8%) patients in the non-DFCW group.

4. Discussion

The main finding of this study is that even with annual documentation of counseling about how epilepsy treatment may affect contraception and pregnancy, the “action” of prescribing or recommending folic acid during the ensuing 24 months was omitted in 71.4% of patients. In addition, there is no significant statistical association between the outlined process (counseling) and quality care (recommending or prescribing folate).

If payment reform aims to reward quality, further research is warranted to explore the discrepancies between provider's documentation and actual care and to investigate the association between administration of folic acid in the presence of anticonvulsant use and the risk of birth defects due to folic acid deficiency.

A further interesting result of this study is that the two cohorts were comparable with respect to having had an epilepsy specialist involved in care. Thus, the presence of an epilepsy specialist did not automatically ensure that counseling was optimally administered and documented or

that folic acid was prescribed or recommended. Disparities in adherence to quality indicators according to specialist involvement have been shown for the care of other chronic neurological conditions such as multiple sclerosis and Parkinson's disease [8,10–12]. Similarly, the link between practices and delivery models and desired outcomes is yet to be defined.

Our results are subject to several limitations. First, this is a single-center retrospective review. A larger multi-institutional prospective trial is needed to establish the validity and generalizability of our findings.

Second, acquisition of accurate outcome data can be challenging in retrospective studies using chart review. Of note, this medical record data abstraction was detailed, labor-intensive, and time-consuming in order to most accurately provide information with respect to adherence to quality indicators and folic acid prescription or recommendation. We chose to evaluate the first 3 visits within a 24-month care period. We may have missed the quality data in subsequent visits (e.g., the physician may have met a criterion at the 4th visit at the third year of follow-up). While we may have provided a more precise estimation of quality by grading the EQM across all visits within a longer-term follow-up period, we preferred to conservatively capture the establishment of care and consider the same total number of “chances” in which each provider had to comply with the quality metrics.

The third important limitation is that this study did not capture all the possible care processes that the patients could have received that might impact folic acid prescriptions and use, including consultations and prescriptions outside the Partners Healthcare System. We did not gather information about the adequacy of the prescribed folic acid dose, when present: higher doses of folic acid are recommended for patients with epilepsy compared to the general female population [13,14].

In addition, we could not directly gather information about a patient's probability of becoming pregnant, for instance, sexual preference and anatomical or physiological causes of infertility. This and some other exceptions may be raised in the implementation and evaluation of any quality metric. Regardless, our rating method considered that if a woman of childbearing age was not applicable to receive the outlined counseling, there should be documentation of the reason.

Increasing time constraints on an outpatient visit, the variable expertise of primary care physicians and neurologists, and the lack of patient-oriented tools are barriers to high quality care for patients with chronic neurological conditions [15,16]. In this scenario, the data gathered are the platform for further prospective studies with focus on patient-reported outcomes, such as patient's perspective of care over time and the association between outcomes and costs [17].

In conclusion, the measurements of epilepsy quality of care should always incorporate counseling and education [2,3,18–22]. Further studies are needed to evaluate the effectiveness of office-based health counseling for women with epilepsy, to explore the discrepancies between provider's documentation and actual care, and to investigate the association between administration of folic acid in the presence of anticonvulsant use and the risk of birth defects due to folic acid deficiency.

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.yebeh.2014.12.039>.

Authorship details

LMVRM and DBH conceptualized and designed the study. LMVRM, JJ, and RA performed data collection and management. LMVRM and DBH performed the analysis. LMVRM drafted the original manuscript. LMVRM, DYM, and DBH significantly reviewed and revised the manuscript.

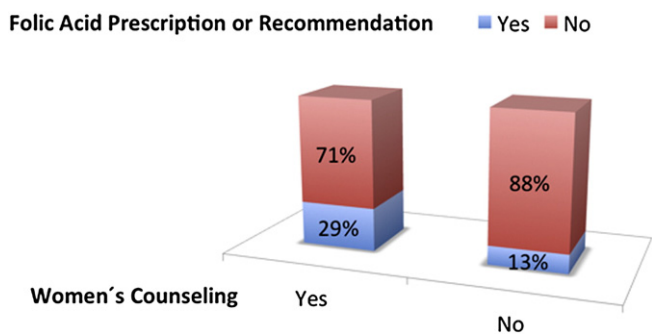


Fig. 1. Documentation of women's counseling vs. folic acid prescription. Evidence of folic acid prescription or recommendation was present in 8 (28.5%) medical records in the DFCW group, and in 7 (14.2%) medical records in the non-DFCW group.

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Disclosures

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