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To cite this article: Irma Ahmad, Matilda Sandberg, Ole Brus, Carl Johan Ekman, Åsa Hammar, Mikael Landén, Johan Lundberg, Pia Nordanskog, Lars von Knorring & Axel Nordenskjöld (2022) Validity of diagnoses, treatment dates, and rating scales in the Swedish national quality register for electroconvulsive therapy, *Nordic Journal of Psychiatry*, 76:2, 96-103, DOI: [10.1080/08039488.2021.1939416](https://doi.org/10.1080/08039488.2021.1939416)

To link to this article: <https://doi.org/10.1080/08039488.2021.1939416>



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Published online: 04 Aug 2021.



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Validity of diagnoses, treatment dates, and rating scales in the Swedish national quality register for electroconvulsive therapy

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ABSTRACT

Background: The Swedish national quality register for electroconvulsive therapy (Q-ECT) contains data on patients receiving treatment with electroconvulsive therapy (ECT) in Sweden.

Aim: This study determined the validity of diagnoses, treatment dates, and rating scales in the Q-ECT by investigating the degree of accordance between data from the Q-ECT and patient records.

Materials and methods: From January 2016 to December 2017, 200 treatment series were randomly selected from the Q-ECT. The corresponding patient records were requested from the treating hospitals. Data on the indicative diagnosis, dates for the first and the last ECT session, and rating scales were compared between the Q-ECT and patient records using (i) a strict and (ii) a liberal method of assessment. Using the liberal method, each variable was assessed as accordant if it belonged to the same diagnosis group, or if the dates differed by less than 1 week, or ratings differed by only 1 point on the Clinical Global Impression Scale (CGI-S), or no more than 3 points on the Montgomery Åsberg Depression Rating Scale between the Q-ECT and the patient record.

Results: A total of 179 patient records were received. The strict method of assessment showed an accordance of 89% or higher for all studied variables. The liberal method showed an accordance of 95% or higher.

Conclusions: We conclude that data on the studied variables in the Q-ECT have high validity. However, limited use of some rating scales makes the results uncertain. Measures can be taken to further improve the data quality.

Abbreviations: ECT: Electroconvulsive therapy; Q-ECT: Swedish National Quality Register for ECT; ICD-10: International Classification of Diseases and Related Health Problems: tenth revision; MADRS: Montgomery-Åsberg Depression Rating Scale; MADRS-S: Montgomery-Åsberg Depression Rating Scale-Self-rating version; CGI-I: Clinical Global Impression Scale-Improvement; CGI-S: Clinical Global Impression Scale-Severity; CPRS-M: Comprehensive Psychopathological Rating Scale-Memory item; CI: Confidence interval

ARTICLE HISTORY

Received 17 February 2021

Revised 24 May 2021

Accepted 1 June 2021

KEYWORDS

Electroconvulsive therapy; registries; data accuracy


Introduction

Electroconvulsive therapy (ECT) uses electrically induced seizures to treat various disorders [1]. The primary indication for ECT is severe depression, although there are many other indicative psychiatric disorders [2]. The treatment is given in a series of sessions, where the frequency and total number depend on the severity of the patient's condition. ECT can be given as an index series or as a continuation series. The index series is the initial treatment series given to achieve

remission. In Sweden, the frequency of index series is commonly set to three treatment sessions per week. Weekly or less frequent sessions in a continuation series is sometimes given after a completed index series to prevent relapse [3].

The Swedish national quality register for ECT (Q-ECT) contains patient data from all the hospitals that offer ECT treatment in Sweden [4]. The Q-ECT was established in 2008 as a regional register after a collaborative work between the counties Örebro, Uppsala, and Dalarna. In 2011, it expanded to become a national register. The reported data include the

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 Supplemental data for this article can be accessed online at <https://doi.org/10.1080/08039488.2021.1939416>.

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personal identification number, diagnosis code in agreement with the International Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10, Swedish version), symptoms, treatment, side effects, and current medication. Medical caregivers collect the information and then register it into the Q-ECT using web-based forms. Data are registered when a treatment series has been completed, whereby index series are separated from continuation series. An index series is defined as more than one treatment per week; continuation series are defined as one treatment per week or less. Some treating units, including all units in Region Stockholm, have an automatic linking of patient records to the Q-ECT. The data provided by the register are used to evaluate the effects and quality of ECT treatment, and as the basis for further research to improve clinical practice [4].

The validity of a measurement represents the degree to which it corresponds with the real value being measured [5]. For a register to be useful, it is critical to evaluate the degree of validity to ensure data quality. During data registration, there is a risk for random errors to be made by the medical caregivers, such as unintentional selection of the wrong diagnosis code when registering the indicative diagnosis. Such errors would decrease the validity of the data. Another factor that can affect data validity is inaccurate documentation in patient records. In some cases, there is a degree of diagnostic uncertainty concerning a patient's medical condition, which can result in the presence of several different diagnoses in a patient record. Also, inaccurate documentation can mean that an ICD-10 diagnosis code is absent. The presence of several diagnoses due to diagnostic uncertainty and the absence of diagnosis codes in patient records can make the registration of the indicative diagnosis difficult, since the medical caregivers are advised to choose a single diagnosis to register into the Q-ECT. This decreases the reliability of the registration method, which in turn decreases the validity of the data being registered. Hence, to be able to utilize the register for epidemiological research and for quality assurance, it is important to investigate and ensure the quality of the data.

Aim

This study aimed to determine the validity of diagnoses, treatment dates, and rating scales in the Q-ECT by investigating the degree of data accordance between the Q-ECT and patient records.

Materials and methods

Study design and study sample

This was a cross-sectional study that compared data from the Q-ECT and corresponding patient records. A total of 7400 patients received ECT between 1 January 2016 and 31 December 2017, in Sweden, and their data were reported to the Q-ECT [6,7]. From this time period, 200 treatment series were selected from the register using random probability sampling. The corresponding patient records were requested

from 45 different treating units in Sweden by the University Hospital Örebro, Sweden. The patient records were matched with the treatment series using the patients' personal identification number, which is a unique identifier that all Swedish citizens receive at birth. One treatment series was included for each patient. Of the present sample, 150 patients of the treatment series received an index series and 50 patients received continuation series.

Assessment of diagnosis

To evaluate the validity of the Q-ECT diagnoses, the diagnosis for each treatment series was given an accordance value. The diagnosis was assessed as being either accordant or discordant. This was done using two methods of assessment. First, a strict method of assessment was used, whereby the Q-ECT diagnosis was assessed as being accordant with the patient record diagnosis if the ICD-10 code used was the same. Treatment series with discordant diagnoses according to this strict method were further assessed using a liberal method of assessment. For the liberal method of assessment, the diagnosis was assessed as being accordant if the two diagnoses belonged to the same diagnosis category (Table 1).

For six treatment series, the ICD-10 diagnosis in the patient record was only in plain text, without the accompanying code. These instances were assessed as being accordant under both the strict and the liberal method of assessment.

Assessment of dates

To evaluate the validity of the Q-ECT registered dates of the first and the last treatment in the treatment series, the dates were also given a value of accordance using two types of assessment methods. For the strict method of assessment, the dates were assessed as being accordant if they were the same between the Q-ECT and the patient records. For the liberal method of assessment, if the date registered in the Q-ECT differed from the date found in the patient record by less than 7 d, it was assessed as being accordant.

The treatment series that had both accordant first and last treatment dates were considered as being accordant in both the strict and the liberal methods of assessment.

Rating scales in the Q-ECT

Rating scales regarding the patient's symptoms and improvement after ECT treatment registered in the Q-ECT include the

Table 1. Categorization of diagnoses used in the liberal method of assessment.

Diagnosis category	ICD-10 code
Unipolar depression	F32, F33, F34, F412, F530
Bipolar disorder	F30, F31
Psychotic disorders	F20-F29
Puerperal disorders	F53

ICD-10: International Classification of Diseases and Related Health Problems, Tenth Revision.

Montgomery-Åsberg Depression Rating Scale (MADRS), the Clinical Global Impression (CGI) scale, and the Comprehensive Psychopathological Rating Scale-Memory item (CPRS-M) [8,9]. The MADRS is a 10-item clinician-rated scale that rates the severity of depression in patients that have already been diagnosed with depression [10]. The 9-item patient-rated version of this scale, the MADRS-Self-rating version (MADRS-S), is also registered in the Q-ECT [11]. The CGI-Severity (CGI-S) scale is a clinician-rated scale that estimates how mentally ill the patient is at a certain time, measured from 1 (normal, not at all ill) to 7 (among the most extremely ill patients). The clinician rates the severity of the mental illness. The factors assessed include the severity of the illness, the patient's level of distress, and what impact the illness has on the patient's functioning. The CGI-Improvement (CGI-I) scale assesses the patient's improvement after any form of treatment; it measures improvements in the patient's wellbeing compared with the baseline visit, prior to treatment. The clinician rates the improvement of the patient's condition from 1 (very much improved since the initiation of treatment) to 7 (very much worse since the initiation of treatment) [12]. The CPRS-M assesses the patient's subjective memory impairment compared with their previous ability. It is rated from 0 (indicating no memory impairment) to 6 (complete inability to remember) [9].

Assessment of rating scales

To evaluate the validity of the Q-ECT registered rating scales, two assessment methods were used. First, a strict method of assessment was applied that judged accordance if the rating scale score was the same in the Q-ECT as the patient records. When the CGI-S score before treatment, CGI-S score after treatment, and CGI-I score were not noted in the patient records, the plain text was read to assess if the registered variable in the Q-ECT was commensurable or incorrect. In cases of doubt, the patient records were reviewed by MS and AN, and a consensus was reached as to whether the rating scale noted in the Q-ECT was commensurable compared to the plain text in patient records. Patient records without extensive notes were not included in the plain text assessment.

Second, a liberal method of assessment was used to evaluate rating scales registered in the Q-ECT that were discordant according to the strict method of assessment. For the liberal method of assessment, the CGI-S score before treatment, CGI-S score after treatment, CGI-I score, and CPRS-M score registered in the Q-ECT were accordant if the value differed from the value found in the patient records by no more than one point. The MADRS score before treatment, MADRS score after treatment, MADRS-S score before treatment, and MADRS-S score after treatment registered in the Q-ECT were considered accordant using the liberal method of assessment if they differed from the scores found in patient records by 3 points or less.

The Q-ECT guidelines are different for continuation series and index series regarding the assessment of rating scales. For all patients that receive an index series, all rating scales

are assessed before and after the treatment. However, when a patient receives a continuation series, the CGI-S scale, MADRS, MADRS-S, and CPRS-M are only completed during the follow-up appointment, which is usually after the treatment series. Thus, all 50 requested continuation series in this study were analyzed as rating scales assessed after ECT treatment, and no CGI-I scale was completed for these treatment series (Figure 1).

Statistical methods

A statistical power analysis was performed to determine the required size of the study sample. The 95% confidence intervals (CIs) for the degree of accordance between the Q-ECT and patient records were calculated using binomial distribution with the Clopper-Pearson method that estimates the CIs by approximating a normal distribution [13]. Based on the results from validation studies of other quality registers [14,15], we expected that 5% of the data in the Q-ECT would be discordant with those of the patient records. Based on this assumption, the power analysis indicated that 203 patients were needed to show a statistically significant degree of accordance of at least 93%. Descriptive statistics and statistical analysis were performed using SPSS Statistics (IBM SPSS Statistics version 25 (IBM corporation, Armonk, NY).

Ethics

In conjunction with registration of data into the Q-ECT, all patients are informed that their data can be used for research purposes. Patients have the right to refrain from registration and to demand a deletion of their data from the register. The requests for patient records were sent to the treating physicians, who decided if the record could be sent to the register or not. This study is part of a bigger research project called 'Data quality in the Swedish National Quality Register for ECT', which was approved by the Regional Ethics Committee in Uppsala (approval number 2018/408).

Results

Included treatment series

Of the 200 requested patient records, a total of 179 records were received by the time data were analyzed.

For some patients, information on the indicative diagnosis, treatment dates, or rating scales were missing, in either the Q-ECT or patient records. Therefore, the result for the indicative diagnosis was based on data from 164 treatment series and 174 treatment series for treatment dates (Figure 1). The final analytic sample was different for every studied rating scale, mostly because of missing data in patient records. The causes for missing data in patient records regarding the rating scales were that (i) not all rating scales were applied for every patient receiving ECT treatment, (ii) several rating scales were not noted in the patient records, or (iii) insufficient excerpts of patient records were received from the treating unit. As

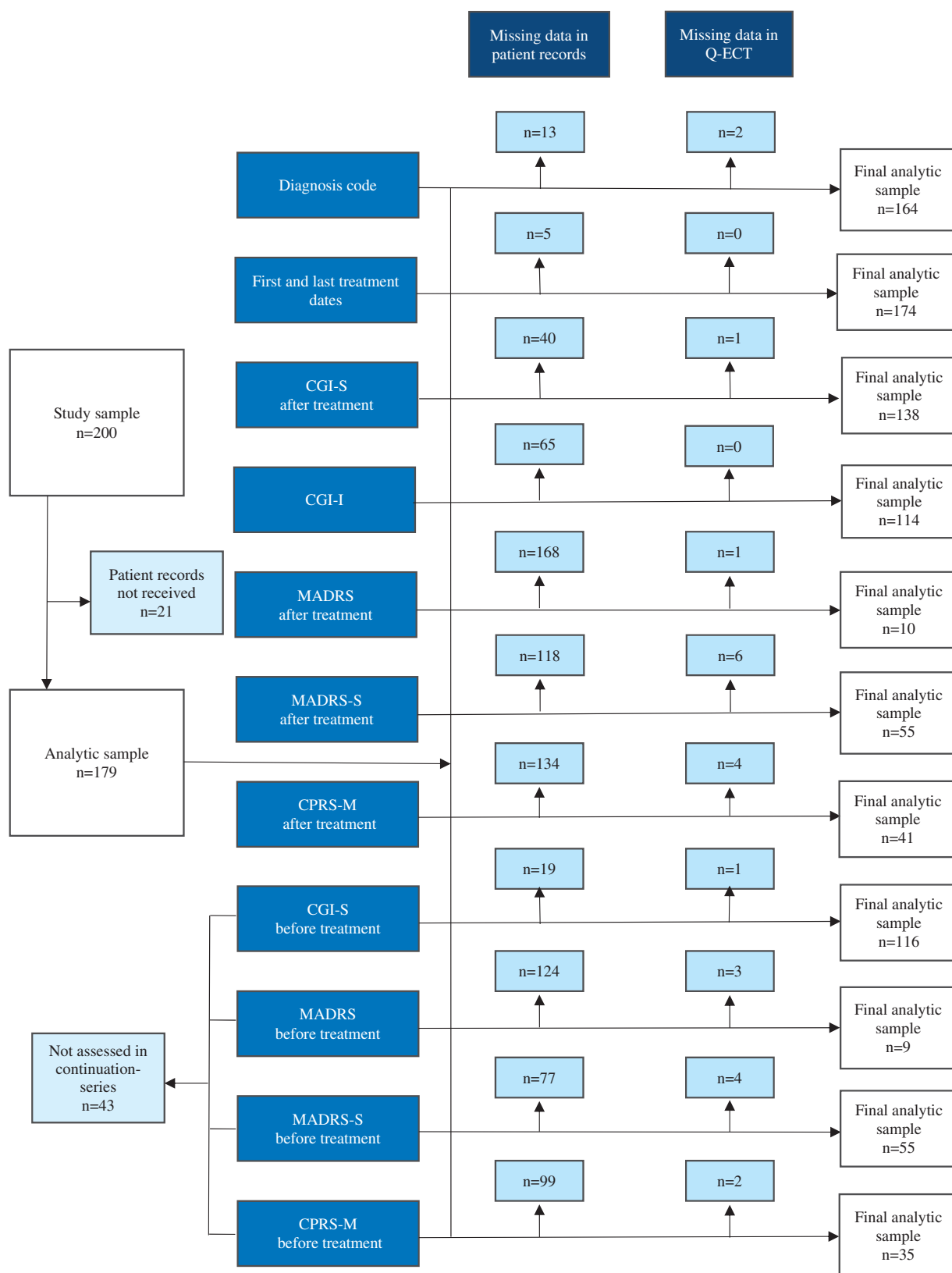


Figure 1. Number of treatment series (*n*) included in the final analytic samples and causes of missing data. CGI-I: Clinical Global Impression Scale-Improvement; CGI-S: Clinical Global Impression Scale-Severity; CPRS-M: Comprehensive Psychopathological Rating Scale-Memory item; MADRS: Montgomery-Åsberg Depression Rating Scale; MADRS-S Montgomery-Åsberg Depression Rating Scale-Self-rating version; Q-ECT: Swedish National Quality Register for ECT.

mentioned, when the CGI-S score before treatment, CGI-S score after treatment, and CGI-I score were not noted in the patient records, the plain text of the patient record was read to assess

whether the noted variable in the Q-ECT was commensurable or incorrect. Therefore, the final analytic sample of these variables was larger. Another cause for missing data in patient

records for these variables was a lack of information about the patient's clinical features that meant assessment was not possible.

All requested patient records were received from 34 out of the total 45 treating units. The 21 missing patient records belonged to 11 treating units (Supplementary Table 1).

Degree of accordance between the studied variables in the Q-ECT and patient records

Using the strict method of assessment, 154 out of 164 treatment series were assessed as being accordant in the diagnosis that indicated ECT (Table 2). The remaining 10 treatment series had discordant diagnoses. The strict method of assessment resulted in a degree of accordance of 94% (95% CI = 89–97%) regarding the indicative diagnosis. The 10 diagnoses defined as discordant using the strict method were further assessed using the liberal method of assessment. Using the liberal method, eight out of the 10 discordant diagnoses showed accordance. Including the eight discordant treatment series that showed accordance under the liberal method of assessment, there were a total of 162 patient records out of 164 with accordant diagnoses. Thus, the liberal method of assessment resulted in a degree of accordance of 99% (CI = 96–100%) in the indicative diagnosis.

Using the strict method of assessment, 156 out of 174 treatment series had accordant treatment dates regarding both the first and the last treatment in the treatment series

(Table 2). Thus, a degree of accordance in the treatment dates of 90% (CI = 84–94%) was obtained. Out of the 18 remaining treatment series, five had discordant first treatment dates and 13 had discordant last treatment dates. The 18 treatment series that were discordant for either the first or the last treatment date were further assessed using the liberal method of assessment. Out of these, 15 treatment series had Q-ECT registered treatment dates that differed from the patient record dates by less than 7 d. Thus, these 15 treatment series were classified as being accordant regarding both the first and the last treatment date in the liberal method of assessment. The total number of treatment series with accordant treatment dates changed from 156 to 171 under the liberal method of assessment. This resulted in a degree of accordance of 98% (CI = 95–100%).

Using the strict method of assessment, the proportion of agreement between the Q-ECT and the corresponding patient records was high for most rating scales. For eight rating scales, the proportion of accordance was 95% or higher, and for one rating scale, the MADRS-S before treatment, the proportion of accordance was 89% (Table 2). Using the liberal method of assessment, the accordance was 95% or higher for all rating scales (Tables 2 and 3).

Discussion

The degree of accordance for diagnoses, treatment dates, and rating scales was in line with our expectation of at least

Table 2. Number and proportion of treatment series that were accordant between the Swedish National Quality Register for ECT and the final analytic sample of medical records for the studied variables.

	Final analytic sample	Accordance in the strict method of assessment	Proportion of agreement, % (95% confidence interval)	Accordance in the liberal method of assessment	Proportion of agreement, % (95% confidence interval)
Diagnosis code	164	154	94 (89–97)	162	99 (96–100)
First and last treatment dates	174	156	90 (84–94)	171	98 (95–100)
MADRS before treatment	9	9	100 (66–100)	9	100 (66–100)
MADRS after treatment	10	10	100 (69–100)	10	100 (69–100)
MADRS-S before treatment	55	49	89 (78–96)	52	95 (85–99)
MADRS-S after treatment	55	52	95 (85–99)	54	98 (90–100)
CPRS-M before treatment	35	34	97 (85–100)	34	97 (85–100)
CPRS-M after treatment	41	39	95 (83–99)	41	100 (91–100)

CPRS-M: Comprehensive Psychopathological Rating Scale-Memory item; MADRS: Montgomery-Åsberg Depression Rating Scale; MADRS-S Montgomery-Åsberg Depression Rating Scale-Self-rating version.

Table 3. Number and proportion of treatment series that were accordant between the Swedish National Quality Register for ECT (Q-ECT) and the final analytic sample of medical records for Clinical Global Impression Scale.

	Final analytic sample	Accordance in the strict method of assessment	Proportion of agreement, % (95% confidence interval)	Accordance in the liberal method of assessment	Proportion of agreement, % (95% confidence interval)
CGI-S before treatment					
Variable noted in patient records	35	34	97 (85–100)	35	100 (90–100)
Assessed by reading plain text ^a	81	79	98 (91–100)	80	99 (93–100)
Total	116	113	97 (93–99)	115	99 (95–100)
CGI-S after treatment					
Variable noted in patient records	23	22	96 (78–100)	23	100 (85–100)
Assessed by reading plain text ^a	115	110	96 (90–99)	112	97 (93–99)
Total	138	132	96 (91–98)	135	98 (94–100)
CGI-I					
Variable noted in patient records	17	17	100 (80–100)	17	100 (80–100)
Assessed by reading plain text ^a	97	93	96 (90–99)	95	98 (90–100)
Total	114	110	96 (91–99)	112	98 (94–100)

^aWhen these variables were not noted in the patient records, the plain text of the patient record was read to assess if the noted variable in the Q-ECT was commensurable or incorrect.

CGI-I: Clinical Global Impression Scale-Improvement; CGI-S: Clinical Global Impression Scale-Severity.

93% when the liberal method of assessment was used to compare the variables. These results were derived from 179 of the 200 selected treatment series. Our results indicate that the Q-ECT has a high validity, concerning the measurement of these variables.

The use of the liberal method of assessment resulted in a higher degree of accordance in the indicative diagnosis than when the strict method of assessment was used. This outcome demonstrates that the diagnoses assessed as discordant under the strict method of assessment between the Q-ECT and patient records were quite similar. The diagnoses had different ICD-10 codes, but belonged to the same diagnosis category. Indicative diagnoses for ECT being similar become a problem when the same patient has several different, but similar, diagnoses submitted in the patient record. The registration of the diagnosis that truly indicated ECT treatment into the Q-ECT then becomes difficult, since the medical caregiver must choose one of the similar submitted diagnoses. Consequently, the choice of indicative diagnosis becomes somewhat subjective. The presence of similar diagnoses in the patient records was common when different medical doctors recorded the diagnoses for the same patient. This could be a result of a degree of diagnostic uncertainty concerning the patient's condition.

The degree of accordance in the dates of the first and last treatment only reached the hypothesized degree of accordance when the liberal method of assessment was used. Notably, the degree of accordance was substantially higher using the liberal method of assessment. This means that many of the discordant dates identified in the patient records by the strict method of assessment were relatively close to the Q-ECT registered date. An important factor that may contribute to the difficulty of registering the correct date for a treatment is the determination of when an index series is completed and transitioned into a continuation series. This can sometimes be poorly defined in patient records. In some cases, the medical caregivers might register the date of an index series for a treatment that is actually part of a continuation series. This was seen in some of the treatment series investigated, and these were considered discordant.

The accordance was higher when using the liberal method of assessment for most of the registered rating scales. This shows that the difference between the assessed rating scales registered in the Q-ECT and those registered in the patient records was quite small. The rating scale with the lowest accordance between the Q-ECT and patient records was the MADRS-S before treatment, which was 89% using the strict method of assessment. For a few treatment series, the date when the MADRS-S was assessed and registered was different in the Q-ECT compared to the date found in the patient records. This could be because the dates were incorrectly registered in one of the two sources. The reason could also be that another assessment was registered in the Q-ECT than the one noted in the patient record, and that the Q-ECT assessment was not noted in the patient records at all.

Several studies have been carried out to investigate the data quality of different quality registers in Sweden. For

example, Petersson et al. validated data in The Swedish Maternal Health Care Register [16]. The study found a degree of accordance between 90 and 100% for the included variables [16]. Another validation study was carried out by The National Board of Health and Welfare in Sweden to investigate the degree of accordance between The Swedish National Inpatient Register and the original patient records to further determine the validity of the register [17]. In this study, a strict and a liberal method were used to assess the degree of accordance of the main diagnosis between the two sources. When the strict method of assessment was used, the degree of accordance was between 83 and 86%. When the liberal method of assessment was used, the degree of accordance was 86% [17]. Löfgren et al. also conducted a study to determine the data quality of The Swedish National Register for Breast Cancer [18]. The study showed that the degree of accordance between the register and original patient records was above 90% for almost all the included variables. Data from these registers were deemed as reliable and valid [18]. Our study showed a varying degree of accordance regarding different variables, between 89 and 100%, which is similar to these previous validation results from other registers. Therefore, the Q-ECT can be considered to have a high validity.

Strengths, limitations, and future research

A key strength of this study was the access to patient records from a large sample of patients. Another strength was the use of a strict and a liberal assessment method to determine the degree of accordance between the registered Q-ECT variables and patient record variables. This allowed further investigation of the extent to which the variables were discordant after determining the value of accordance using the strict method, which did not demonstrate how much the variables differed from one another. Understanding how much Q-ECT variables differ from patient record variables is important to determine the clinical significance of the discordance. If a variable for a given treatment series was assessed as discordant by the liberal assessment method, then the variable differed substantially between the Q-ECT and patient records and could not be deemed as valid.

One limitation of this study was the presence of missing data. For 10.5% of treatment series, the patient records were not received, which is a significant proportion. Notably, five treating units did not send any of the requested patient records from their unit. This means that data from these units were completely missing. It is possible that any or some of these five units have a more discrepant method of registration into the Q-ECT than the other included treating units. For example, a given treating unit may have an excellent method of registration that results in a high degree of accordance between the Q-ECT and patient records for that specific unit. The exclusion of this treating unit may have resulted in this study attaining a lower degree of accordance than expected. The reverse situation may also exist, leading to a distorted result of a higher degree of accordance.

Considering the possibility of these occurrences, there is a risk that the present results may be somewhat biased.

Moreover, the CIs regarding the accordance of the MADRS, MADRS-S, and CPRS-M rating scales were large, because the study was powered to study variables that are present in all records, such as dates and diagnoses. This means that the accordance between patient records and the Q-ECT was not determined to be significantly above the pre-determined proportion of 93% in these rating scales. Thus, although the point estimate of accordance using the liberal assessment method was high for all the examined information, there is still some uncertainty regarding the accordance of these rating scales.

The patient records were requested for the first time almost two years prior to the analysis. Approximately one year in advance, the patient records were reviewed to evaluate which corresponding patient records had not been received and how many of the received excerpts were not extensive enough to be used, because of missing data on the different variables. The corresponding treating units were once again asked to send the patient record excerpts or to send complementary notes of the patient records already sent. Given the amount of time given to the treating units, we considered it unlikely that the units would return the request later. In some cases, the treating physician decided that the patient record should not be sent because the patient had restricted access to their record, or the physician thought there was a risk that the patient would not like his or her record being used for this study.

Another limitation is the assessment that was made to evaluate whether the CGI-S and CGI-I scores registered in the Q-ECT were commensurable or incorrect, by only reading the plain text of patient records. Determining the value of these rating scales in hindsight on the basis of plain text that describes the patients' clinical features could lead to uncertainty regarding the data. Generally, the patients' clinical features were described in detail in the patient records, but there is nonetheless a risk of misclassification of the CGI-S/CGI-I. The CGI-S/CGI-I assessed by the plain text method and the actual recording of a rating essentially showed the same proportion of agreement. This suggests that these methods to establish the accordance between the Q-ECT and patient records are comparable.

In future studies, missing data should be considered in the power calculations. Further studies could also investigate different treating units' methods of registration to determine whether automatic data linking improves data quality. Furthermore, providing feedback to the treating units regarding the results of these studies could potentially increase data quality.

Data from the Q-ECT have been used in several studies [9,19,20]. For these studies to produce reliable and useable results, it is important that the data source is valid. The findings of this study indicate that Q-ECT data have a high validity and are reliable enough to be used for quality assurance and research.

Conclusion

This study found that Q-ECT data has a high validity for the studied variables, including the diagnosis that indicated ECT, the date of the first and the last treatment in the treatment series, and the CGI-S scale, CGI-I scale, MADRS, MADRS-S, and CPRS-M scores. However, limited use of the CPRS-M, MADRS, and MADRS-S makes the validity of these rating scales uncertain. There is room for further improvement of the use of these rating scales and of the data quality.

Acknowledgments

The authors thank the patients, nurses, and doctors who provided data to the Swedish National Quality Register for ECT.

Funding

The study was supported by Region Örebro County ALF and Nyckelfonden at Örebro University Hospital. The funding source had no influence on study design; the collection, analysis, and interpretation of data; the writing of the report; or the decision to submit the manuscript for publication.

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Disclosure statement

The authors report no conflict of interest regarding this research. AN has received lecturer honoraria from Lundbeck. CJE, ÅH, ML, JL, PN, LvK and AN participate in the steering committee of the register and made substantial contributions to the design of the study and interpretation of the data. AN was the project leader. IA acquired and analysed data on diagnoses and dates and wrote the first draft of the paper, MS collected data on rating scales, and analysed and drafted the text, tables, and figures on these data. OB planned the statistical analyses. All authors revised the manuscript critically, approved the final version and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Funding

The study was supported by Region Örebro County ALF and Nyckelfonden at Örebro University Hospital. The funding source had no influence on study design; the collection, analysis, and interpretation of data; the writing of the report; or the decision to submit the manuscript for publication.

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