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Postpartum affective episodes in women with bipolar disorder – monitored by a structured follow-up method

Version 2

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ABSTRACT

Introduction

Bipolar disorder (BD) is a psychiatric illness characterised by episodes of depression, hypomania and mania. The first choice of medication treatment for BD is mood stabilizers. However, psychotropic medication has not been approved for use during pregnancy because some drugs have teratogenic and adverse neurodevelopmental effects. However, up to 80 % of women with BD develop some form of postpartum affective episode. Therefore, it is of great interest to investigate the medication treatment for pregnant women with BD.

Aim

Describe the medication treatment for pregnant women with bipolar disorder and outcome of postpartum affective episodes.

Methods

This was an observational study, based on retrospective review of medical records of pregnant patients with BD. The patients have visited the clinic of affective disorders, Örebro University Hospital, between the years 2013-2017. The patients were followed during pregnancy and a period of at least 6 months postpartum.

Results

The rate of postpartum affective episodes in women with bipolar disorder was 8.7%. There was no significant difference ($p = 0.36$) in outcome between the groups. A greater number of patients with BD type II were included in our cohort. A statistically significant difference ($p = 0.05$) was observed between the BD type I and type II groups, regarding lithium treatment.

Conclusion

Our study showed that the rate of postpartum affective episodes was marked lower than expected. Furthermore, except for lithium treatment, there was no statistically significant difference in medication treatment or outcome of postpartum affective episodes between BD type I and II, when monitored by this structured follow-up method.

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1. INTRODUCTION

Bipolar disorder (BD) is a chronic psychiatric illness characterised by episodes of depression, hypomania and mania [1], followed by intervals of full or partial remission [2]. Episodes of depression are more frequent, incapacitating and prolonged in comparison to manic episodes [3]. BD can further be divided into subgroups, the most commonly being type I and type II. BD type I is defined by manic episodes that last for at least 7 days. Episodes of depression also occur, usually lasting at least 2 weeks. The definition of BD type II is the occurrence of depressive and hypomanic episodes [4]. Around 2% of the world's population suffer from BD types I and II [2].

The treatment of BD focuses on acute stabilization and maintenance. The treatment can be complex because the treatment given for depression can be the cause for mania or hypomania; similarly, some treatments for mania can be the cause for rebound depression [5].

The first choice of medication treatment for BD are mood stabilizers [5]. Lithium is a mood stabilizer that stands out as a maintenance treatment for manic episodes [6] and suicidal behavior [7]. Many patients show great improvement with lithium but the response to lithium depend on individual variability [8-10]. Lamotrigine is another drug that has become more common as a mood stabilizer over the past decade when it comes to treating BD. It is a well-established anticonvulsant drug, which has proven to be effective in the treatment of BD [11].

Women treated with psychotropic medication become pregnant or plan pregnancy even though psychotropic medications are not approved for use during pregnancy [12]. The use of psychotropic drugs can have teratogenic and adverse neurodevelopmental effects [13]. Thus, the treating physicians need to balance the health of the mother against that of the fetus [14]. According to the 2014 National Institute for Health and Care Excellence (NICE) guidelines, updated in 2017, neither pregnant women nor women planning to become pregnant should be treated with lithium, with the exception if the response to antipsychotic medicine is poor [14].

15-20 % of women experience depression and anxiety during the first year postpartum, whilst postpartum psychosis happens to 1-2 women per 1000 deliveries [15]. In contrast, 50-80 % of women with BD develop some form of postpartum affective episode within six months postpartum [16]. Patients with BD type I are at particularly high risk for postpartum psychosis [15].

Advice on treatment differs between countries [17]. In an updated version (in 2014) of the document published by the Clinic of Affective Disorders, Department of Psychiatry Southwest Stockholm 2013, the treatment and follow-up routine of affective disorders during pregnancy has been described [18]. The follow-up routine is implemented at Örebro University Hospital (USÖ).

1.1 Aim

The aim of our study was to describe the medication treatment for pregnant women with bipolar disorder and outcome of postpartum affective episodes, in order to evaluate the structured method used for follow-up that could potentially become a national standardised routine.

2. MATERIAL AND METHODS

2.1 Study design

The present study is an observational study, based on retrospective review of medical records of pregnant patients with BD. Included patients had a DB diagnosis (in accordance with DSM-IV) before pregnancy and visited the Clinic of Affective Disorders, Department of Psychiatry, Örebro University Hospital, Sweden, between the years 2013-2017. The study was approved as a quality assurance project by the head of operations at the Clinic of Affective Disorders.

2.2 Method used for follow-up

First trimester follow-up

The first doctor's appointment was often booked before the end of pregnancy week 12. Although, most of the patients were booked as soon as the patients discovered their pregnancy. During the appointment, the patient was informed about the teratogenic effects some psychotropic drugs may have. The dosage of all administrated drugs with a potential harmful effect on the fetus were reduced, if deemed possible. The patients were also co-administrated with folic acid.

Patients that were using lithium were planned for an extra control at the maternity ward to have the fetus' heart development under observation. Monthly lithium concentration check-ups were also performed. Furthermore, the patients received a permanent contact person at the clinic.

Second trimester follow-up

The second appointment was booked to be held between pregnancy week 13-27. During this session, the dosage of drugs were adjusted if thought necessary. After the appointment the doctor wrote a letter to the maternity ward to inform them of the patient so that they were ready and had correct information about the patients' current medication. If the patient was feeling unwell the doctor could prescribe sick leave.

Third trimester follow-up

The last appointment before the delivery was booked around pregnancy week 32-35. Psychotropic medications were adjusted, if needed. The patient was prescribed sick leave, if needed. During this visit, the doctor and the patient also made up a postpartum medication plan.

Early postpartum follow-up

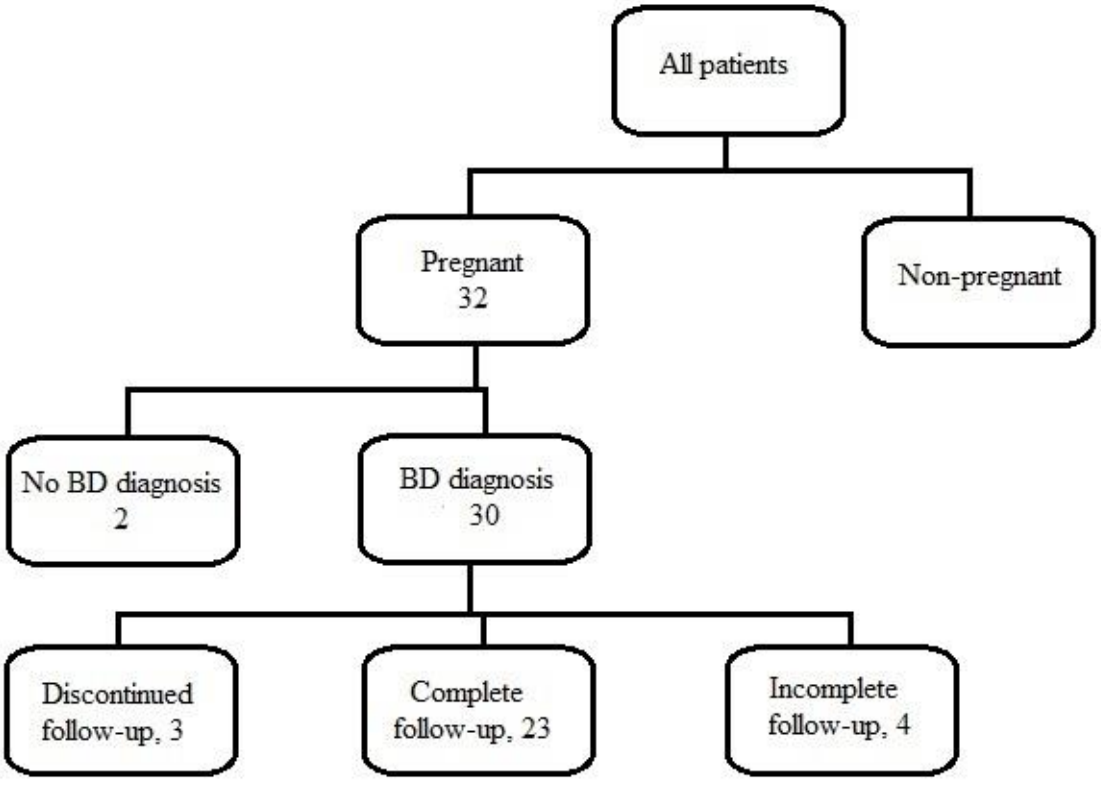
The early postpartum follow-up was performed 2-3 weeks after the delivery by the patient's contact person. This appointment gave the chance to discover if the patient was fee-ling unwell and if any medication alterations were required.

Late postpartum follow-up

The last postpartum follow-up was booked around 6 months after the delivery. This was the final appointment to control if the patient had developed a postpartum affective episode. This meeting also gave the doctor a chance to examine whether the patient and the new-born baby had developed a normal attachment.

2.3 Study participants

The cohort originally consisted of 32 patient cases. Inclusion criteria were pregnant patient with a DSM-IV diagnosis of a bipolar spectrum disorder that had been followed for at least 6 months postpartum. The final cohort, after exclusion, included 23 patients.



BD, bipolar disorder

Figure 1. Overview of the study participants. Of all the patients that visited the clinic of affective disorders at USÖ between the years 2013-2017, 32 patients were pregnant. 30 of them were diagnosed with bipolar disorder, while two of the patients were not diagnosed. Three patients moved during their pregnancy, while four patients had not yet reached 6 months postpartum. The remaining 23 formed the cohort.

2.4 Data collection

Review of the clinic's calendars from the years 2013-2017 were made to obtain the cohort. Medical record review was conducted on the individuals who were part of the cohort. Patients' list of diagnosis and medicine lists during pregnancy were retrieved. Doctor's notes from the postpartum follow-up sessions were studied to document the incidence of postpartum affective episodes. In our study, the definition of postpartum affective episode is occurrence of an episode of depression, hypomania or mania within 6 months after delivery.

2.5 Statistical methods

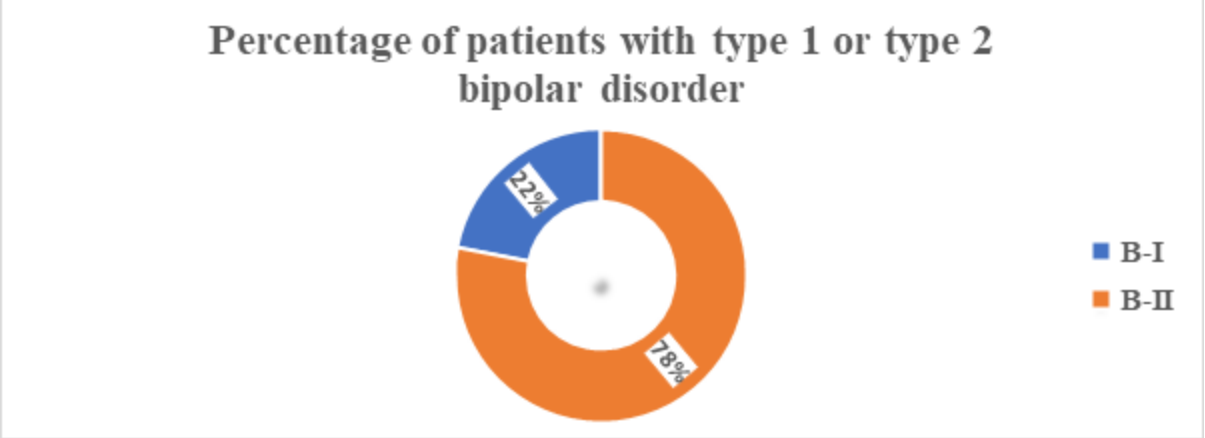
Microsoft Excel, version 2013, was used for statistical analyses. Mean and standard deviation was calculated. Continuous variables were analysed with unpaired two sample Student t-test. Categorical variables were analysed with Fisher's exact test. All p-values ≤ 0.05 were considered to be statistically significant.

2.6 Ethical considerations

By accessing the patient's medical records, one gets access to sensitive patient information. Therefore, during the study, great importance was put on protecting the patient's integrity and personal data was handled with great caution. Personal data was encrypted and stored on a USB. The decryption key was stored separately. The author was the only one to have access to the content on the USB-memory. All data was deleted after completion of our study, in accordance with The General Data Protection Regulation.

The study in question was approved as a quality assurance project by the head of the Clinic of Affective Aisorders. No ethical approval was required.

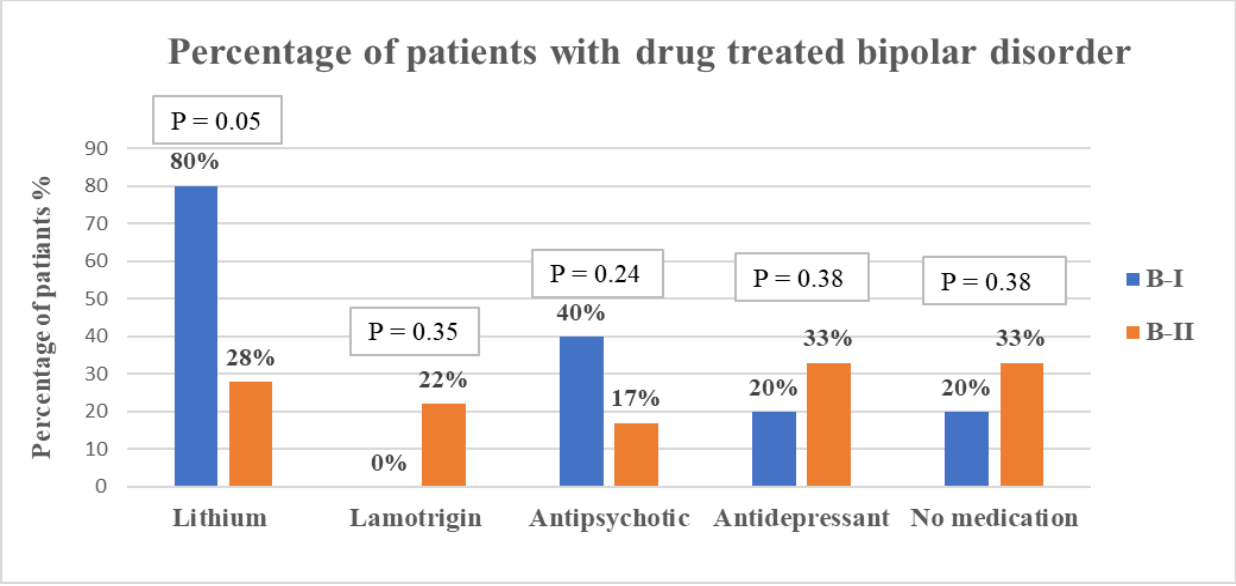
3. RESULTS



BD, bipolar disorder; B-I, bipolar disorder type I; B-II, bipolar disorder type II

Figure 2. Percentage of pregnant women with bipolar disorder (N=23) at USÖ during 2013-2017 with BD types I and II.

There is an imbalance between the BD type I and type II groups. Three quarters of patients included in our cohort had BD type II (Fig 2). Of all 23 patients, 5 have been diagnosed with BD type I, while 18 of the patients have BD type II diagnosis.



BD, bipolar disorder; B-I, bipolar disorder type I; B-II, bipolar disorder type II

Figure 3. Percentage of pregnant women with bipolar disorder (N=23) at USÖ during 2013-2017 with different medication treatment for BD. The summed percentages for each group (B-I and B-II) exceeds 100% because patients were prescribed simultaneous treatment with more than one type of drug.

The drugs that were included in figure 3, in the antipsychotic treatment group were quetiapine (3), olanzapine (1) and flupentixol (1). The antidepressant agents used were escitalopram (2), citalopram (1), sertraline (1), bupropion (1), venlafaxine (1) and mirtazapine (1).

Both BD type I and type II were of same age (29.7 years (±5.2)). The most commonly used drug was lithium (39%), followed by antidepressants (30%), antipsychotics (22%) and lamotrigine (17%).

Almost all patients with BD type I were treated with lithium, while few patients with BD type II were prescribed the drug ($p = 0.05$). No patient with BD type I was prescribed lamotrigine, whereas 22% of patients with BD type II were treated with the drug. However, no statistical difference was obtained between the two groups concerning treatment with lamotrigine ($p = 0.35$), antipsychotics ($p = 0.24$) and antidepressants ($p = 0.38$) (Fig 3).

Among the various medication treatments mentioned in our study for the treatment of BD type I and type II, 30% of the patients did not receive any medication treatment for BD. The summed percentages for each group, BD type I (160%) and BD type II (133%), exceeded 100% due to the fact that patients were prescribed simultaneous treatment with more than one type of drug (Fig 3).

Two patients developed a postpartum affective episode (8.7%). Both patients, one with BD type I and the other with BD type II, were undergoing lithium treatment. The patient with BD type I suffered a moderate postpartum depression, whereas the patient with BD type II developed a severe postpartum depression.

4. DISCUSSION

The results show that only two patients (8.7%) developed a postpartum affective episode. 70% of the study population was using some form of psychotropic medication during pregnancy. The most commonly used drug was lithium (39%), followed by antidepressants (30%), antipsychotics (22%) and lamotrigine (17%). There was no significant difference between the BD type I and type II groups when it come to treatment with lamotrigine, antipsychotics and antidepressants. However, comparing treatment with lithium between the groups it showed that a greater number of patient with BD type I used the drug.

Our result shows the rate of postpartum affective episodes in women with bipolar disorder (8.7%) is similar to that of other women. Previous studies have shown that around 50-80% of women with BD relapse with mental illness during the postpartum period [16, 18]. Furthermore, the study by Viguera et al. also concluded that depressive episodes were more likely [18]. The finding of a low outcome rate is of great importance and a receipt of quality assurance of a well-implemented care program.

In our cohort, 39% were prescribed lithium treatment. According to the current treatment routine in Örebro University Hospital, lithium treatment is recommended to women with BD during pregnancy if they are at high risk of relapse of mental illness [19]. This routine is in agreement with the recommendation from the results of a recent meta-analysis of five randomised clinical trials. The meta-analysis revealed that lithium decreased the risk of relapses in BD, with best effect on preventing manic episodes [20]. Though, the use of lithium during pregnancy varies between countries. In a UK study based on primary health care records, they discovered that lithium was rarely prescribed during and around pregnancy. The same study showed that women using lithium were most likely to discontinue treatment during pregnancy [21]. However, our result show that the current treatment routine in Örebro University Hospital with lithium has a marked low outcome rate of postpartum affective episodes.

The statistically significant difference ($p = 0.05$) between the BD type I and type II groups, regarding lithium treatment, may be due to the fact that patients with BD type I are at greater

risk for postpartum psychosis compared to patients with BD type II [15]. Thus, needing a more potent mood stabilizing treatment.

In our study, lamotrigine was the only anticonvulsant drug prescribed for treatment of BD. Previous studies have discovered a rise in the use of lamotrigine, while use of other anticonvulsants, such as valproate, has decreased. This chance of treatment is due to the drugs severe teratogenic effects of the drug [22]. The increased use of lamotrigine can be explained by recent evidence suggesting that there is no greater risk of major congenital malformations with lamotrigine use, when compared to untreated women with epilepsy that are pregnant [23-24]. However, in a study by Holmes L.B. et al., an increased risk of isolated cleft palate or cleft lip deformity was reported when treated with lamotrigine dosage over 200 mg [25]. Additional studies are required on the risks and benefits of using lamotrigine during pregnancy.

One of two patients that suffered relapse of mental illness developed a severe postpartum depression that took several months to recover from. Today, treatment with electroconvulsive therapy (ECT) can be indicated during pregnancy if the condition is considered severe or the depression is treatment resistant [19]. A small case report described the effectiveness of ECT for treatment of severe, treatment resistant postpartum depression. They concluded that ECT was a useful treatment choice with speedy symptom resolution [27]. Recently, a study by Rundgren et al. further supported the use of ECT in postpartum affective states [28]. This treatment option could have speeded up the recovery of our study participant so that she could connect with her child earlier.

The need to investigate use of psychotropic medication during pregnancy out of the children's perspective is required. It is of great clinical interest to have better understanding of how drugs affect the child, because the treating physicians are facing the dilemma of balancing the health of the mother against that of the fetus. Petersen et al. performed a study where child outcome with the association of psychotropic medication use dureing pregnancy was investigated, such as major congenital malformations [21]. By studying this field further, we can provide the treating physicians with more evidence, with the help of which more effective future treatment plans can be established.

One must keep in mind that it can be ethically difficult to carry out studies on pregnant women. Particularly, concerning treatment that potentially can be harmful for the fetus. Hence, a possible reason for the lack of evidence on the risk and benefits of prescribing psychotropic medications during pregnancy.

4.1 Limitations

A limitation of our study was the small size of the cohort, giving the study very low statistical power. Although we knew that our findings would not have great significance, we proceeded with our study in hopes of making it a hypothesis generating study. In further studies, multicentre trials should be considered in order to increase the study population.

Furthermore, there was no control group used in our study. This was due to the fact that it was hard to find a sufficiently compatible group that had similar risk of developing postpartum affective episodes. A control to evaluate the method used for follow-up was not possible to find because all patients in Örebro had been treated in accordance with the followed-up method. The thought of including BD patients from other psychiatric clinics to form a control group was investigated. However, there was no registry of this patient group, which meant that there was no efficient way of obtaining the patient information within the given timeframe.

As the patient group was not in a registry, all included patients were retrieved manually by going through old diaries to see which of the patients were pregnant during their visited at the clinic. Thus, human error can not be ruled out.

5. CONCLUSION

Our study showed that the rate of postpartum affective episodes was marked lower than expected. Furthermore, except for lithium treatment, there was no statistically significant difference in medication treatment or outcome of postpartum affective episodes between BD type I and II, when monitored by this structured follow-up method.

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COVER LETTER

May 23, 2018

Dear Editor,

It would be a great honor for us if you would consider the enclosed manuscript entitled "Postpartum affective episodes in women with bipolar disorder – monitored by a structured follow-up method" for publication in Journal of Affective Disorder.

This manuscript would really be appreciated by your readers for the following reasons:

- Our result shows the rate of postpartum affective episodes in women with bipolar disorder is similar to that of other women, when monitored by our structured follow-up method. The finding is of great importance and a receipt of quality assurance of a well-implemented care program. The structured method used for follow-up of the patients is a well- designed routine that is easy to implement in clinics around the world without much problem. It can be used as a guide to how women with bipolar disorder can be followed-up during, and for some time after, pregnancy.

- Many women use psychotropic medication during pregnancy, even though none has been licensed for use in pregnancy. There is a lack of evidence on the risk and benefits of prescribing psychotropic medication during pregnancy. Therefore, it is of great clinical interest that further studies are conducted. This pilot study could impel larger prospective studies in the future and in such way increase the knowledge of medication during pregnancy.

The study has not been published and is not intended to be submitted elsewhere.

Yours sincerely,

Madiha Cheema
Master of medicine
Örebro University
Sweden

PRESSRELEASE

Bipolär sjukdom (BD) är en psykisk sjukdom som kännetecknas av depressiva och maniska skov som kommer i perioder. Det finns flera typer av BD, men delas generellt in i typ I och typ II. Förstahandsvalet vid läkemedelsbehandling av BD är stämningsstabiliserande mediciner. Idag finns det inga psykofarmaka som är godkänd för användning under graviditet eftersom vissa läkemedel har visat sig ha fosterskadande effekt. Dock insjuknar upp till 80 % av kvinnor med BD i någon form av postpartum affektiv episod. Därför har vi valt att undersöka hur läkemedelsbehandlingen ser ut för gravida med BD samt även studera hur många som insjuknar i en postpartum affektiv episod.

Datasamlingen bygger på journalgenomgång av gravida patienter med BD som besökte Affektiva kliniken vid Universitetssjukhuset Örebro mellan år 2013-2017. Våra resultat bygger på en grupp av 23 patienter. Fler med BD typ I behandlades med litium. Andra läkemedel som användes för behandling av BD var lamotrigin, antidepressiva och antipsykotika. Våra resultat visar att förekomsten av postpartum affektiva episoder hos kvinnor med bipolär sjukdom är lik den hos andra kvinnor, när de följs upp med vår strukturerade uppföljningsmetod.

Eftersom vår studie bygger på en liten grupp är det svårt att dra betydelsefulla slutsatser utifrån våra resultat. Det återstår en lång väg innan man vet allt om läkemedelsbehandlingen av gravida med BD och dess effekt på fostret.

ETHICAL CONSIDERATIONS

Studien baseras på journalgenomgång. Att utföra journalgenomgång utan att ha någon koppling till patientens vård kan uppfattas som intrång på patientens integritet. Ett övervägande måste göras mellan principen att göra gott och principen att inte skada. I detta fall blir det alltså ett övervägande mellan att göra gott genom att försöka förbättra behandling för denna urvalsgrupp via denna utredning. Samt principen att inte skada vilket i den aktuella situationen handlar om att göra intrång på patientens integritet genom att gå igenom hens journal utan någon vårdrelaterad anledning. Eftersom studien i fråga görs i kvalitetssäkrings syfte krävs inget etiskt godkännande. Istället har ett uppdragsbevis utfärdats av verksamhetschefen på Affektiva mottagningen.

Data hanterades med stor försiktighet. All data lagrades på ett USB med kodade personuppgifter. Avkodningsnyckeln förvarades separat i ett låst skåp. Skrivbenten var den enda om hade tillgång till innehållet på USB-minnet. All data raderades efter genomförandet av studien i enlighet med dataskyddsförordningen.