

Use of sertraline and agomelatine in hemodialysis patients: A case series report

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Objective: Major depressive disorder (MDD) is one of the most common psychiatric issues in hemodialysis population. However, the research on proper diagnostic tools and its treatment is still insufficient. The study was performed to investigate the safety and effectiveness of sertraline and agomelatine in a group of hemodialysis patients. **Patients and Methods:** 78 adult patients from one dialysis centre in Poland were included into the study. The Beck Depression Inventory II (BDI-II) was used to screen for depressive symptoms and was followed by the clinical interview with the psychiatrist. Nine patients diagnosed with major depressive disorder received antidepressant treatment with sertraline or agomelatine, according to the best clinical practice. The additional treatment with vortioxetine was used if the initial one was not effective. The time of observation was 24 weeks. The psychiatric follow up as well as the laboratory data were obtained during the course of observation. **Results:** All patients receiving sertraline achieved remission of depressive symptoms. In patients receiving agomelatine no remission was observed despite dose augmentation. The side effects of antidepressants were mild and did not result in treatment discontinuation. No abnormalities in liver enzymes levels were observed. In five cases the significant decrease of haemoglobin level was noticed, with no cases of bleeding reported. **Conclusion:** In patients receiving sertraline the antidepressant effect was satisfactory. No remission of depressive symptoms was observed in patients taking agomelatine. The side effects of antidepressants were mild and transient. Further research on depression treatment in hemodialysis patients is needed, including newer medications.

Keywords: hemodialysis, depression, sertraline, agomelatine

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Abbreviations: BDI-II, Beck Depression Inventory-II; CGI-S, Clinical Global Impression-Severity scale; CKD, chronic kidney disease; DSM-5, Diagnostic and Statistical Manual of Mental Disorders 5; ERBP, European Renal Best Practice; ESRD, end-stage renal disease; MADRS, Montgomery-Asberg Depression Rating Scale; MCI, mild cognitive impairment; MDD, major depressive disorder; MMSE, Mini Mental State Examination; PSP, Personal and Social Performance Scale; QoL, quality of life; SSRIs, serotonin reuptake inhibitors

INTRODUCTION

Chronic kidney disease (CKD) and depression plays a significant role in global health (GBD Chronic Kidney Disease Collaboration, 2020; GBD 2019 Diseases and Injuries Collaborators, 2020). Patients suffering from end-stage renal disease (ESRD), requiring renal replacement therapy, are at a high risk of major depressive disorder (MDD) (Kimmel *et al.*, 2019). According to the studies, around twenty to forty percent of maintenance hemodialysis patients suffer from major depressive disorder, depending on the methodological approach used (Palmer *et al.*, 2019). Individuals with chronic kidney disease have significantly lower quality of life (QoL) (Fletcher *et al.*, 2022) and higher mortality rate (Ozieh *et al.*, 2021). Furthermore, depression is the known independent risk factor of decreased QoL (Belayev *et al.*, 2015) and mortality (Farrokhi *et al.*, 2014), as well as higher nonadherence in hemodialysis population (Gebrie *et al.*, 2019). Patients undergoing hemodialysis are often excluded from clinical trials, due to the safety reasons, as pharmacokinetics of antidepressants in hemodialysis are not fully explored (Constantino *et al.*, 2019). The European Renal Best Practice (ERBP) suggests treatment with serotonin reuptake inhibitors (SSRIs), as the first line in patients who meet depression criteria (Nagler *et al.*, 2012). However, the recognition and treatment of depression in ESRD patients remain insufficient (Lopes *et al.*, 2004; Pena-Polanco, 2017).

Sertraline is known to be safe and does not require additional doses after the dialysis session (Schwenk *et al.*, 1995; Constantino *et al.*, 2019). However, its effects in hemodialysis patients may be heterogeneous (Kubanek *et al.*, 2021). Studies evaluating safety and efficacy of this SSRI in ESRD patients usually had small samples and lacked placebo control (Palmer *et al.*, 2016). In the randomized, controlled trial by Friedli *et al.* there were no significant differences between sertraline and placebo group in improving depression symptoms. (Friedli *et al.*, 2017).

Agomelatine is the atypical antidepressant with melatoninergic agonism and 5-HT_{2c} antagonism. It was shown to be effective and well tolerated in treating major depressive disorder in general population (Cipriani *et al.*, 2018). It is not contraindicated in patients with severe renal impairment, however the data considering CKD population is scarce (Chen *et al.*, 2018). One of the side effects of agomelatine is liver enzymes elevation and it

requires aminotransferase monitoring in the course of treatment. Vortioxetine is an antidepressant with multimodal activity used in major depression disorders treatment, recognized as having the best efficacy and safety in head-to-head studies (Koesters *et al.*, 2017; Cipriani *et al.*, 2018).

METHODOLOGY

Patients over eighteen years old from one dialysis centre in Gdańsk (Poland), who had been receiving hemodialysis treatment for at least three months, were recruited. The study received approval of the Independent Bioethics Committee for Scientific Research of the Medical University of Gdańsk. All patients gave their written informed consent. Dialysis Center provides public health services for approximately 200 patients. There is no psychiatric or psychological assistance provided in patients' routine. Individuals suffering from major psychiatric disorders other than depression were excluded. The study group received the high-flux hemodialysis or hemodiafiltration three times per week. Cognitive functions were evaluated using Mini Mental State Examination (MMSE) and assessed clinically by the psychiatrist (Folstein *et al.*, 1975). MMSE was completed subsequently at the end of observation. Patients diagnosed with moderate and severe cognitive impairment were excluded from the further depression diagnosis. The clinical and laboratory data of the study group was also obtained.

The depression screening was performed using Beck Depression Inventory II (BDI-II), followed by the psychiatric assessment (Beck *et al.*, 1996). The diagnosis of major depressive disorder was based on the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5). Psychiatrists were using Montgomery-Asberg Depression Rating Scale (MADRS), Clinical Global Impression-Severity scale (CGI-S) and Personal and Social Performance Scale (PSP) to evaluate the severity of depression symptoms and psychosocial functioning of patients (Montgomery *et al.*, 1979; Morosini *et al.*, 2000; Busner *et al.*, 2007). MADRS is a standard in monitoring depressive disorders and improvement during treatment. Tests were performed in the middle of the dialysis session, at

least one hour after the initiation and one hour before the termination of the procedure.

Individuals who were diagnosed with major depressive disorder by the psychiatrist and agreed to receive the antidepressant treatment were subjected to further observation. The medications were chosen according to the best clinical practice guidelines. Six patients received treatment with sertraline in the daily dose of 25-100 mg. One patient had been already receiving sertraline (50 mg/day) before the study. Two patients received agomelatine treatment (25–50 mg/day). The time of observation was twenty-four weeks. Psychiatric evaluation, laboratory and dialysis parameters control were performed every six weeks. The additional treatment and dose changes were adjusted during the time of observation. ERBP guidelines suggest that trials with SSRIs in patients, who meet criteria for moderate MDD, should last for eight to twelve weeks, followed by medical evaluation (Nagler *et al.*, 2012). However, the psychiatric clinical practice's assessment for depressive and anxiety patients is usually done after four weeks.

RESULTS

The cognitive functions were rated in 82 patients. According to the MMSE screening and clinical assessment mild cognitive impairment (MCI) and mild dementia were observed in thirty two percent of patients, while moderate dementia in four percent. Patients that agreed to remain in the study and were not diagnosed with moderate or severe dementia were subjected to further evaluation. 78 patients underwent the depression screening and clinical assessment of the psychiatrist. The percentage of individuals with depressive symptoms using BDI-II alone was forty-three. In the clinical interview, performed by the psychiatrist, the criteria of MDD requiring antidepressant treatment were fulfilled in thirteen cases. Two patients did not agree to receive antidepressants. Three patients had been already treated for depression before the study. One person, who had been receiving sertraline, was monitored for possible adverse events. In the group treated with antidepressants there were five women and four men. The age range was between 36

Table 1. Clinical data and test results of patients with depression diagnosis

No.	Sex	Age	CCI	DM	Dialysis time (years)	MMSE	BDI-II	MADRS	CGI-S	PSP	Medication
1.	M	51	3	no	5	28	7	29	5	55	sertraline
2.	F	63	6	yes	7	29	23	14	3	90	agomelatine
3.	M	37	5	yes	2	30	31	31	5	62	sertraline
4.	M	36	7	yes	5	23	24	22	4	41	sertraline
5.	F	64	7	yes	2	28	14	15	3	71	agomelatine
6.	F	66	4	no	2	29	8	30	5	49	sertraline
7.	F	76	8	yes	3	–	14	10	2	25	sertraline
8.	M	60	5	no	2	21	8	30	6	30	sertraline
9.	F	70	8	yes	1	27	25	13	2	35	sertraline -during treatment

M, male; F, female; CCI, Charlson Comorbidity Index; DM, diabetes mellitus; MMSE, Mini-Mental State Examination; BDI-II, Beck Depression Inventory II; MADRS, Montgomery-Asberg Depression Rating Scale; CGI-S, Clinical Global Impression – Severity scale; PSP, Personal and Social Performance Scale

Table 2. Test results during antidepressant treatment.

No.	I MADRS	II MADRS	III MADRS	remission after 24 weeks	I MMSE	II MMSE	I CGI-S	II CGI-S	I PSP	II PSP
1.	29	–	–	–	28	28	5	–	55	–
2.	14	10	11	no	29	30	3	2	90	90
3.	31	3	3	yes	30	30	5	1	62	79
4.	22	5	4	yes	23	25	4	1	41	85
5.	8	15	13	no 6 week observation	28	29	2	3	71	71
6.	30	10	9	yes	29	30	5	2	49	64
7.	10	25	11	yes	–	–	2	2	25	55
8.	30	9	–	yes 6 week observation	21	24	6	2	30	–
9.	13	–	–	–	27	–	2	–	35	–

I, result at the beginning of observation; II, result after 24 weeks of observation; MADRS, Montgomery-Asberg Depression Rating Scale; MMSE, Mini-Mental State Examination; CGI-S, Clinical Global Impression – Severity scale; PSP, Personal and Social Performance Scale

and 76 years and the comorbidity index in most patients was over 4 points. (Table 1).

During the observation two patients resigned from the follow up and one received kidney transplantation. Five patients receiving sertraline achieved remission according to MADRS, CGI-S and clinical evaluation. However, two patients required treatment modification and switching to vortioxetine (10–15 mg). Patients treated with agomelatine had no remission during the observation (one person was observed for 24 weeks and the other for 6 weeks, since the treatment was started during the study). Both required the agomelatine dose augmentation. One

had quetiapine and the other vortioxetine added to the treatment. In the sertraline group the dose of 50 mg was the minimal one to achieve remission, one patient required 100 mg dose. One person receiving agomelatine reported dizziness after 12 weeks of observation, but the treatment was continued. One patient treated with sertraline reported headaches after 6 weeks; the effect was transient and disappeared after splitting the dose into twice a day regimen. In the other individuals we observed no side effects. All patients that agreed to perform dementia screening using MMSE in the end of observation improved or had the equal test result. In the

Table 3. Laboratory parameters over the course of observation in patients receiving antidepressant treatment.

No.	I CaxPi mg/dl <79	II CaxPi mg/dl <79	I Kt/V >1.2	II Kt/V >1.2	I Hb g/dl 11.5–16.5 (F), 13–18 (M)	II Hb g/dl 11.5–16.5 (F), 13–18 (M)	I WBC G/l 4.0–11.0	II WBC G/l 4.0–11.0	I PLT G/l 150–400	II PLT G/l 150–400	I ALT U/l <41	II ALT U/l <41	Albumin g/l 35–52
1	68	70	1.6	1.6	9.7	10	5.8	4.8	167	180	6	8	44
2	54	44	1.2	1.1	11.4	8.7	8.6	6.3	555	656	7	3	43
3.	85	66	1.3	–	11.1	10.8	8.5	7.5	285	292	22	21	40
4.	57	35	3.1	1.7	12.7	9.2	8.9	5.6	135	248	10	10	39
5.	56	49	1.6	1.4	12.1	10.3	11.9	9.1	221	221	15	13	43
6.	37	27	1.4	1.2	11.8	11.6	6.1	5.4	222	221	17	15	40
7.	41	69	1.4	1.5	11.7	10.6	7.8	6.8	139	155	15	11	37
8.	18	39	1.7	1.5	9.3	10.1	4.7	3.9	231	189	20	7	46
9.	50	33	–	–	13.3	9.3	6	5.3	177	181	7	3	44

I, result at the beginning of observation; II, result after 24 weeks of observation; Kt/V (K, dialyzer clearance of urea; t, dialysis time; V, volume of distribution of urea; approximately equal to patient's total body water). Ca x Pi, calcium phosphate index; Hb, haemoglobin; F, female; M, male; WBC, white blood cells; PLT, platelet count; ALT, aminotransferase

patient that refused undertaking the test no clinical features of cognitive decline were observed (Table 2).

The laboratory results were also monitored during observation (Table 3). No abnormalities in liver transaminase levels were observed and the albumin level remained within the normal range in all the patients. In all individuals either no significant changes or the decrease in Kt/V were observed. White blood cells count decreased during the antidepressant treatment but remained within or slightly below the norm. The platelet count stayed within or above the normal range. We noticed the decrease of the haemoglobin level (above 1 g/dl) in five cases- in both patients treated with agomelatine and three patients receiving sertraline in the daily dose of 50 mg. No bleedings were reported in the study group.

DISCUSSION

The prevalence of depressive symptoms and cognitive impairment in the observed group of hemodialysis patients was significant. However, when the gold standard methodological tools in diagnosing major depressive disorder are used and age, coexisting diseases, dementia screening are taken into consideration, it is similar to other elderly populations with high comorbidity rate (Luppa *et al.*, 2012; Wang *et al.*, 2017). It is important while analysing the effectiveness of self-reported questionnaires, which may over-diagnose depressive symptoms. Thus, the psychiatrist examination remains a crucial point in diagnosing depression in a dialysis centre. Increasing its availability for the dialysis patients might have a positive impact on their quality of life and compliance. Moreover, it could upgrade the motivation to proceed in kidney transplantation process.

Taking into consideration the small study group, the number of patients that refused antidepressant treatment or resigned from the follow up was high. The results are consistent with the National Kidney Foundation survey, referring that half of the hemodialysis patients do not adhere to the dialysis regimen (Estrella *et al.*, 2013). Hemodialysis patients suffer from numerous comorbidities and often require polypharmacy, which may be one of the reasons of the incompliance. It might be the group of patients that would agree to psychotherapy or other nonpharmacological approach.

All patients treated with antidepressants that agreed to perform MMSE in the end of observation improved the cognitive functions or achieved the equal test result. It may indicate that some of the observed cognitive disorders in dialysis patients are functional, related to mood disorders. During the treatment, the regular laboratory testing is needed. The decrease of haemoglobin level might be triggered among others by the platelet dysfunction and bleeding caused by the antidepressant agent. The decrease of white blood cells count might be connected with the potential anti-inflammatory effect of antidepressants suggested in previous studies (Taraz *et al.*, 2013). Kt/V is used to evaluate dialysis adequacy; however, its interpretation should be individual due to its limitations as a single parameter (Jones *et al.*, 2018).

The treatment tolerance was good, and the adverse effects of the antidepressants were mild and transient. The antidepressant effect of sertraline in the observed group was satisfactory, however two patients required treatment with vortioxetine. Sertraline is known to be safe to use in the end-stage kidney disease population, but its effectiveness requires further research. Individuals that received treatment with agomelatine did not achieve re-

mission according to psychiatrist evaluation. More studies considering newer antidepressant agents, causing less adverse effects (Cipriani *et al.*, 2018), including agomelatine and vortioxetine, are needed.

CONCLUSIONS

In patients receiving sertraline the antidepressant effect was satisfactory. No remission of depressive symptoms was observed in individuals treated with agomelatine. The side effects of used medications were mild and transient. All patients treated with antidepressants improved or had equal cognitive performance at the end of the follow-up. Further research on depression treatment in hemodialysis patients is needed, including the newer antidepressant agents.

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