DOI: 10.14744/DAJPNS.2026.00314
Dusunen Adam J Psychiatr Neurol Sci
2026;39:52-58

RESEARCH ARTICLE

Evaluation of brexpiprazole as adjunctive therapy in treatment-resistant depression: Real-world data

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ABSTRACT

Objective: Brexpiprazole (BRX) is an antipsychotic used as an adjunctive agent in the treatment of major depressive disorder. We aimed to evaluate the effectiveness of BRX in treatment-resistant depression (TRD).

Method: This study was conducted between May 1, 2024 and January 1, 2025. Medical records of patients who were started on BRX as adjunctive treatment for TRD were retrospectively reviewed. Patient files containing sociodemographic data and scores from the Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), and Global Assessment Scale (GAS) were included in the analysis.

Results: A total of 30 patients were included in the study. The mean age was 32.50±11.38 years (range: 18–63), and 63.3% (n=19) were female. The median BRX dose was 2 mg/day. Of the 30 patients, 20 (66.7%) continued treatment regularly. Among those who discontinued treatment, three patients stopped due to akathisia, two due to sedation, and two due to an urgent need for electroconvulsive therapy. For the 20 patients who continued treatment, scale scores were reassessed during follow-up visits between weeks 4 and 8. A significant improvement was observed in both BDI scores (32.05±8.96 vs. 12.45±9.74; p<0.001) and BAI scores (28.00±10.07 vs. 12.75±10.83; p=0.001) after treatment. Meanwhile, no significant change was observed in body weight (73.05±20.93 kg vs. 75.30±20.32 kg; p=0.123). Among patients whose GAS scores indicated moderate functioning before BRX treatment, 80% (n=16) achieved good functioning after treatment.

Conclusion: BRX may be an effective adjunctive treatment option for patients with TRD, with potential benefits for anxiety symptoms and overall functioning. Although some patients experienced weight gain, this effect did not appear to be clinically significant in our sample.

Keywords: Brexpiprazole, depression, treatment-resistant depression, anxiety, functioning

INTRODUCTION

Brexpiprazole (BRX) is a newer-generation psychotropic medication approved by the United States Food and Drug Administration (FDA) in 2015. In addition to its efficacy in treating the negative symptoms of schizophrenia, it is also used as an adjunctive agent in the treatment of major depressive disorder (MDD). In 2023, the FDA also approved its use for the treatment of agitation associated with dementia due to Alzheimer's disease (1, 2). BRX acts as a partial agonist at dopamine D2 and serotonin

How to cite this article: Kara H, Erdogan A. Evaluation of brexpiprazole as adjunctive therapy in treatment-resistant depression: Real-world data. Dusunen Adam J Psychiatr Neurol Sci 2026;39:52-58.

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Received: January 15, 2026; **Revised:** February 20, 2026; **Accepted:** March 06, 2026

5-HT1A receptors. It also demonstrates strong antagonistic activity at serotonin 5-HT2A and α1B/2C adrenergic receptors. Compared with aripiprazole, it has a higher binding affinity for these receptors, particularly 5-HT2A, 5-HT1A, and α1B receptors (3).

Experimental studies have shown that brexpiprazole prevents dextran sulphate sodium-induced depressive-like behaviors and demyelination in the prefrontal cortex of mice (4). Following adjunctive therapy with BRX, patients treated for MDD have been reported to feel calmer and less anxious or irritable. Adjunctive BRX therapy has also been associated with improvements in overall mood and increased participation in daily activities (5). Moreover, case reports suggest a potential role for BRX in reducing suicidality, aggression, and substance misuse in some patients (6).

A study conducted in Japan suggested that 1 mg/day BRX is an appropriate initial dose, with both 1 mg/day and 2 mg/day doses being effective and well tolerated in patients with an inadequate response to antidepressant therapy (7). In another randomized double-blind study, BRX doses of 1 mg/day and 3 mg/day were well tolerated, with the 3 mg/day dose demonstrating effectiveness in treatment-resistant MDD compared to placebo (8). BRX has been shown to improve symptom clusters including anhedonia, dysphoria, psychomotor retardation, vegetative symptoms, loss of interest, and lassitude beginning as early as the first week of treatment (9). Adjunctive BRX therapy has also been shown to improve overall functioning and reduce anxiety symptoms (10). In addition to alleviating depressive and anxiety symptoms in patients with MDD, adjunctive BRX therapy has demonstrated favorable effects on sleep disturbances, impulsivity, and sexual dysfunction. Furthermore, it has been reported to improve academic and occupational functioning and enhance quality of life in young adult patients (11-15).

Despite being approved by the FDA in 2015, BRX was introduced into clinical practice in Turkiye in May 2024. Accordingly, data regarding its effectiveness and tolerability in the Turkish population remain limited. Furthermore, real-world studies reflecting routine clinical practice are still scarce. Therefore, this study aimed to evaluate the real-world effectiveness of BRX as an adjunctive treatment in patients with treatment-resistant depression (TRD). We hypothesized that adjunctive BRX treatment would be associated with significant improvements in depressive symptoms, anxiety symptoms, and overall functioning.

METHODS

Sample and Procedure

This retrospective study was conducted in the Psychiatry Polyclinic of Akdeniz University and the Psychiatry Polyclinic of Specialized Dr. Huseyin Kara between May 1, 2024 and January 1, 2025. Medical records of patients diagnosed with treatment-resistant depression who were started on BRX as adjunctive therapy were retrospectively reviewed. TRD is defined as the failure to respond to at least two antidepressants administered at adequate doses and durations (16). In our study, TRD was determined through clinical evaluation. Patients who had not responded to at least two antidepressants during their treatment history were included. Specifically, patients who failed to respond to adequate doses of antidepressants (fluoxetine 20 mg/day, venlafaxine 150 mg/day, duloxetine 60 mg/day, sertraline 50 mg/day, escitalopram 10 mg/day, or paroxetine 20 mg/day) within an average treatment duration of four weeks were eligible for inclusion. Patients' sociodemographic and clinical characteristics were obtained from their medical records. BRX dosing followed routine clinical practice. Consistent with standard augmentation strategies, all patients were initially started on BRX 1 mg/day, with planned titration to 2 mg/day after one week, which represents the commonly recommended target dose. Dose adjustments were individualized based on clinical response, tolerability, and adverse effects. Patients demonstrating adequate clinical improvement or sensitivity to side effects were maintained at 1 mg/day, whereas others were titrated to 2 mg/day to optimize therapeutic benefit. This approach reflects naturalistic prescribing patterns in real-world clinical settings. Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), and Global Assessment Scale (GAS) scores obtained before treatment and at the first follow-up visit were evaluated. Follow-up assessments were conducted between weeks 4 and 8 after treatment initiation. Thus, evaluations were performed at the time of BRX initiation and at the subsequent follow-up visit (4-8 weeks). The median evaluation period was four weeks. During the study period, all patients diagnosed with TRD and prescribed BRX as augmentation therapy were screened.

Inclusion Criteria

- Patients aged between 18 and 65 years
- Diagnosis of TRD according to the Diagnostic and

Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) and initiation of BRX as adjunctive therapy
- Availability of scale scores in the patient file.

Exclusion Criteria
- Diagnosis of a neurological disorder
- Presence of an additional psychiatric disorder (e.g., obsessive-compulsive disorder, bipolar disorder, substance use disorder, etc.) other than anxiety disorders
- Use of adjunctive therapies other than BRX
- Use of additional antipsychotic or mood-stabilizing medications besides antidepressants
- Intellectual disability
- Electroconvulsive therapy within the preceding year.

Global Assessment Scale (GAS)
The Global Assessment Scale was developed by Endicott et al. (17) in 1976. The scale can be administered to both patient and healthy populations and ranges from 0 to 100 points, with higher scores indicating better functioning. Scores between 61-100 indicate good functioning, scores between 31-60 indicate moderate functioning, and scores below 30 indicate poor functioning.

Beck Depression Inventory (BDI)
The Beck Depression Inventory was developed by Beck et al. in 1961 to assess the severity of depressive symptoms. A validity and reliability study of the Turkish version has been conducted. The BDI consists of 21 items, each scored from 0 to 3, resulting in a total score range of 0-63. The inventory has been shown to have a sensitivity above 90% for detecting depression requiring treatment when a cutoff score of 17 or higher is used. However, some studies consider remission to be defined as a score below 10 (18, 19).

Beck Anxiety Inventory (BAI)
The Beck Anxiety Inventory was developed by Aaron T. Beck et al. in 1988 and was adapted into Turkish by Ulusoy et al. in 1998 with demonstrated validity and reliability. The inventory consists of 21 items, including 13 items assessing subjective anxiety and 8 items assessing somatic symptoms. Each item is scored from 0 to 3, yielding a maximum possible score of 63. The severity ranges are defined as follows:
- 0-7 points: No anxiety symptoms,
- 8-15 points: Mild anxiety,
- 16-25 points: Moderate anxiety,
- 26-63 points: Severe anxiety (20, 21).

The present study received ethical approval from the Akdeniz University Medical Scientific Research Ethics Committee on January 2, 2025 (decision number TBAEK-43). All stages of this study were conducted in accordance with the principles of the Declaration of Helsinki. This study was a retrospective file review, and all analyzed data were obtained from assessment scale results collected during routine clinical practice. The data used in the study were derived exclusively from standard clinical evaluations performed as part of patients' diagnosis, follow-up, and treatment monitoring. No additional contact was established with the patients, no new assessments were conducted, and no interventions outside routine clinical practice were undertaken for research purposes. Therefore, in accordance with the evaluation of the local ethics committee and considering the retrospective design of the study, obtaining informed consent from the patients was not deemed necessary.

Statistical Analysis
Data analysis was performed using IBM SPSS version 23.0. Continuous variables were presented as mean±standard deviation, median, minimum, and maximum values. Categorical variables were presented as frequencies and percentages. The normality of continuous variables was assessed using the Shapiro–Wilk test and visual inspection of histograms and Q–Q plots. Post-treatment Beck Depression Inventory scores, post-treatment Beck Anxiety Inventory scores, and both pre- and post-treatment Global Assessment Scale scores did not meet normality assumptions. Therefore, comparisons involving these variables were performed using the Wilcoxon signed-rank test. Pre-treatment BDI and BAI scores and body weight measurements met normality assumptions. Although nonparametric tests were used for variables that did not meet normality assumptions, these variables are presented as mean±standard deviation for ease of clinical interpretation. Effect sizes for Wilcoxon signed-rank test comparisons were calculated using the r statistic ($r=|Z|/\sqrt{N}$). Statistical significance was set at $p<0.05$.

RESULTS

This study included a total of 30 participants, of whom 20 (66.7%) continued treatment regularly. The antidepressants used prior to BRX augmentation, along with their dose ranges and durations of use, were as follows: escitalopram (10 mg for 4 weeks),

sertraline (50 mg for 4 weeks), paroxetine (20-30 mg for 4-6 weeks), fluoxetine (20 mg for 4 weeks), and venlafaxine (150-300 mg for 4-8 weeks). The recommended target dose of BRX in TRD is 2 mg/day (7). Accordingly, all patients were initially started on 1 mg/day and were instructed to increase the dose to 2 mg/day after one week. However, five patients reported that they continued treatment at the same dose (1 mg/day). Upon comorbid physical conditions were evaluated, four patients were found to have essential hypertension and one patient had diabetes mellitus. No other medical conditions were identified. Sociodemographic and clinical characteristics of the participants are summarized in Table 1.

In our study, five participants discontinued medication due to side effects. Three individuals discontinued treatment due to akathisia and two due to sedation. Two additional patients required urgent electroconvulsive therapy and discontinued medication for this reason. Three patients did not attend follow-up after the initial visit and were considered to have discontinued treatment. Overall, 20 of the 30 patients (66.7%) continued treatment regularly. For these 20 patients, comparisons of scale scores before and after BRX treatment are summarized in Table 2.

A comparative analysis was conducted to determine whether patients who continued treatment (n=20) differed from those who discontinued treatment (n=10) in terms of sociodemographic variables. The analyses revealed no statistically significant differences between the groups in terms of age, sex, weight, marital status, education level, or employment status (all p>0.05).

Treatment response and remission were evaluated separately for depressive and anxiety symptoms among the 20 patients who continued treatment. According to the BDI, treatment response, defined as a ≥50% reduction from baseline scores, was observed in 70% of patients (14/20), while complete remission (BDI<10) was achieved in 50% (10/20).

Anxiety outcomes were assessed using the BAI. A treatment response, defined as a ≥50% reduction in BAI scores, was observed in 50% of patients (10/20), and complete remission of anxiety symptoms (BAI≤7) was achieved in 45% of patients (9/20).

Of the 20 patients who continued treatment, 14 were receiving selective serotonin reuptake inhibitors (SSRIs) and six were receiving serotonin–norepinephrine reuptake inhibitors (SNRIs). Separate analyses were conducted for these subgroups. BDI and BAI scores decreased significantly in the SSRI group (p=0.001 and p=0.009, respectively) and in the SNRI group (p=0.027 and p=0.028, respectively), as assessed using the Wilcoxon signed-rank test.

Table 1: Sociodemographic and clinical characteristics of participants (n=30)

	n	%
Gender		
Female	19	63.3
Male	11	36.7
Marital status		
Single	15	50.0
Married	13	43.3
Divorced/other	2	6.77
Education level		
Elementary school	3	10.0
High school	7	23.3
University	20	66.7
Employment status		
Employed	14	46.7
Unemployed	16	53.3
Current antidepressant treatment		
Escitalopram	5	16.7
Sertraline	2	6.7
Paroxetine	5	16.7
Fluoxetine	7	23.3
Venlafaxine	11	36.7
Age (years) (mean±SD) (min-max)	32.50±11.38 (18-63)	
Brexpiprazole dose (mg/day) (n=20), mean±SD	1.75±0.44	
Median (min-max)	2.00 (1.00-2.00)	

SD: Standard deviation; Min: Minimum; Max: Maximum.

Functioning was evaluated based on GAS scores. According to GAS scores, all patients demonstrated moderate functioning before BRX treatment. After receiving BRX, 80% (n=16) of the patients were classified as having good functioning, whereas 20% (n=4) continued to demonstrate moderate functioning.

DISCUSSION

This study represents one of the first investigations evaluating the effectiveness of BRX as adjunctive therapy in patients with TRD in our country. Our results demonstrate that the use of BRX as an adjunct to antidepressants in the treatment of depression

Table 2: Comparison of scale scores before and after brexpiprazole treatment

	Before brexpiprazole (n=20)	After brexpiprazole (n=20)	p
Beck Depression Inventory (mean±SD)	32.05±8.96	12.45±9.74	**<0.001** (effect size r=0.877)
Beck Anxiety Inventory (mean±SD)	28.00±10.07	12.75±10.83	**0.001** (effect size r=0.768)
Weight (kg) (mean±SD)	73.05±20.93	75.30±20.32	0.141
Global Assessment Scale (mean±SD)	48.00±6.95	78.50±10.89	**<0.001** (effect size r=0.885)

Body weight before and after treatment was compared using the paired-samples t-test. Beck Depression Inventory, Beck Anxiety Inventory, and Global Assessment Scale scores were compared using the Wilcoxon signed-rank test. Effect size was calculated as $r=Z/\sqrt{n}$. SD: Standard deviation.

leads to significant clinical improvement. Both BDI and BAI scores showed significant reductions following treatment, and overall patient functioning improved. Although patients experienced an average weight gain of 2.25 kg, this increase was not statistically significant.

Our findings regarding the effectiveness of BRX as adjunctive therapy in patients with TRD are consistent with previous literature. Our findings suggest that BRX is effective in patients with TRD. As an adjunctive treatment, BRX has been reported to alleviate core depressive symptoms, improve sleep and appetite disturbances, and enhance functioning (22). A study conducted in elderly patients aged 65 years and older reported improvements in depressive symptoms, social functioning, and quality of life (23). Doses of 1-2 mg/day have generally been found to be effective for adjunctive BRX therapy (24). In a randomized controlled study conducted in Japan, BRX at a dose of 3 mg/day demonstrated significant improvement compared to placebo (8). Adjunctive BRX therapy at doses between 0.5 and 3 mg/day has also been shown to be generally safe and well tolerated for up to 52 weeks (25). Consistent with these findings, our study showed that a median dose of 2 mg/day of BRX was associated with reductions in depressive symptoms and improvements in patient functioning. Therefore, a dose of 2 mg/day may be considered an effective target dose for reducing depressive symptoms. More than 50% of patients receiving adjunctive BRX therapy demonstrated improved participation in daily life, with significant positive changes reported as early as one month after treatment initiation. Among indicators of life participation, the most prominent improvements were observed in the emotional and social domains (26). In the present study, inventory scores improved significantly within 4-8 weeks after adjunctive BRX treatment. These findings support previous evidence suggesting that the therapeutic effects of BRX in treatment-resistant depression may emerge within a relatively short period.

In addition to improving depressive symptoms and functioning, BRX may also help patients achieve significant improvements in emotional, physical, social, and cognitive domains (22, 27). A 52-week open-label, multicenter study reported that, following adjunctive BRX therapy at a dose of 2 mg/day in patients with depression, clinicians tended to focus more on depressive symptom severity, whereas patients prioritized improvements in functioning and daily life activities (28). In the present study, functioning improved from moderate to good in 80% of patients according to GAS scores, suggesting that the functional benefits of BRX may represent a significant clinical advantage.

Furthermore, adjunctive BRX is not only effective for depressive symptoms but also for anxiety symptoms. This finding was demonstrated in our study by improvements in BAI scores and is consistent with previous reports. Earlier studies have shown BRX to have anxiolytic effects (1, 10, 24). These results highlight the multifaceted effect profile of the drug and its potential to improve overall patient quality of life. In addition, our study found BRX to be well-tolerated, with no serious adverse effects observed in the majority of patients. Treatment with BRX was tolerated for up to three months with a low rate of discontinuation due to side effects, consistent with previous studies (10).

The present study did not observe a statistically significant change in body weight among participants; however, a mean increase of approximately 2 kg was noted. The rate of weight gain associated with adjunctive BRX was reported as 8.3% in a study by Lepola et al. (23) and 33.2% in a study by Kato et al. (7) A study involving 2,944 patients reported the rate of weight gain associated with BRX therapy to be 17.7%, with a mean increase of 2.7 kg by week 26 and 3.2 kg by week 52 (25). In the present study, a mean weight gain of 2.25 kg was observed during the 4-8-week follow-up period. Although this increase was not statistically

significant, a weight gain of 2.25 kg within such a short period may still be clinically relevant. The relatively rapid weight gain observed raised concerns regarding potential long-term effects. Therefore, even though the difference was not statistically significant in our study, we recommend that patients receiving BRX be carefully monitored for weight changes. Longer-term follow-up studies (e.g., 1–2 years) are clearly needed to evaluate the long-term impact of BRX on body weight.

This study has certain limitations. These include the difficulty of establishing cause-effect relationships due to its retrospective nature, the absence of a control group, the selection of the study sample from only two centers, and the limited sample size. The relatively small sample size should be considered when interpreting the findings, as it may limit the generalizability of the results. The absence of a control or comparison group makes causal inference difficult. The small sample size may also have limited our ability to detect domain-specific functional changes. In addition, relying solely on the GAS may not fully capture detailed aspects of functioning. The fact that GAS assessments were not blinded may have introduced potential observer bias. Another important limitation is that standard diagnostic tools, such as the Structured Clinical Interview for DSM-5 (SCID-5), were not used for diagnosis. Other limitations of the study include the short follow-up period, which did not allow for the assessment of long-term effects, selective attrition, and potential reporting bias in self-report measures. Because outcome scales could not be administered to patients who discontinued treatment, an intention-to-treat analysis could not be performed. This represents another limitation of the study and should be addressed in future research. Because our sample consisted predominantly of young female patients (mean age: 32.5 years), the generalizability of our study to broader populations (e.g., elderly patients or those with severe TRD) is limited.

The strengths of our study include that it is the first study conducted in our country examining BRX in patients with TRD and that it is based on real-world clinical data. We believe that real-world evidence regarding new pharmacological treatments is an important complement to findings from randomized controlled trials. Future studies with larger sample sizes and longer follow-up periods are needed to further evaluate the effectiveness of BRX in patients with TRD.

CONCLUSION

In this retrospective real-world study, adjunctive BRX treatment was associated with significant improvements in depressive symptoms, anxiety symptoms, and overall functioning in patients with TRD. BRX augmentation was generally well tolerated, and no statistically significant weight change was observed during the short-term follow-up period. These findings suggest that BRX may be an effective and feasible augmentation option in routine clinical practice for patients with TRD. Nevertheless, prospective studies with larger sample sizes and longer follow-up periods are needed to confirm these findings and to better evaluate long-term outcomes.

Ethical Approval: The Akdeniz University Medical Scientific Research Ethics Committee granted approval for this study (date: 02.01.2025, number: TBAEK-43).

Informed Consent: Informed consent was not required due to the retrospective nature of this study.

Conflict of Interest: The authors declare that there is no conflict of interest.

Financial Disclosure: The authors declared that this study has received no financial support.

Use of AI for Writing Assistance: Not declared.

Contribution Categories		Author Initials
Category 1	Concept/Design	H.K., A.E.
	Data acquisition	H.K., A.E.
	Data analysis/Interpretation	H.K., A.E.
Category 2	Drafting manuscript	H.K., A.E.
	Critical revision of manuscript	H.K., A.E.
Category 3	Final approval and accountability	H.K., A.E.
Other	Technical or material support	H.K., A.E.
	Supervision	H.K., A.E.

Peer-review: Externally peer-reviewed.

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