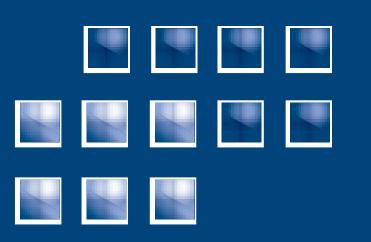


Effectiveness and Tolerability of Vortioxetine in the Treatment of Major Depressive Episodes Under Real-world Conditions in Switzerland



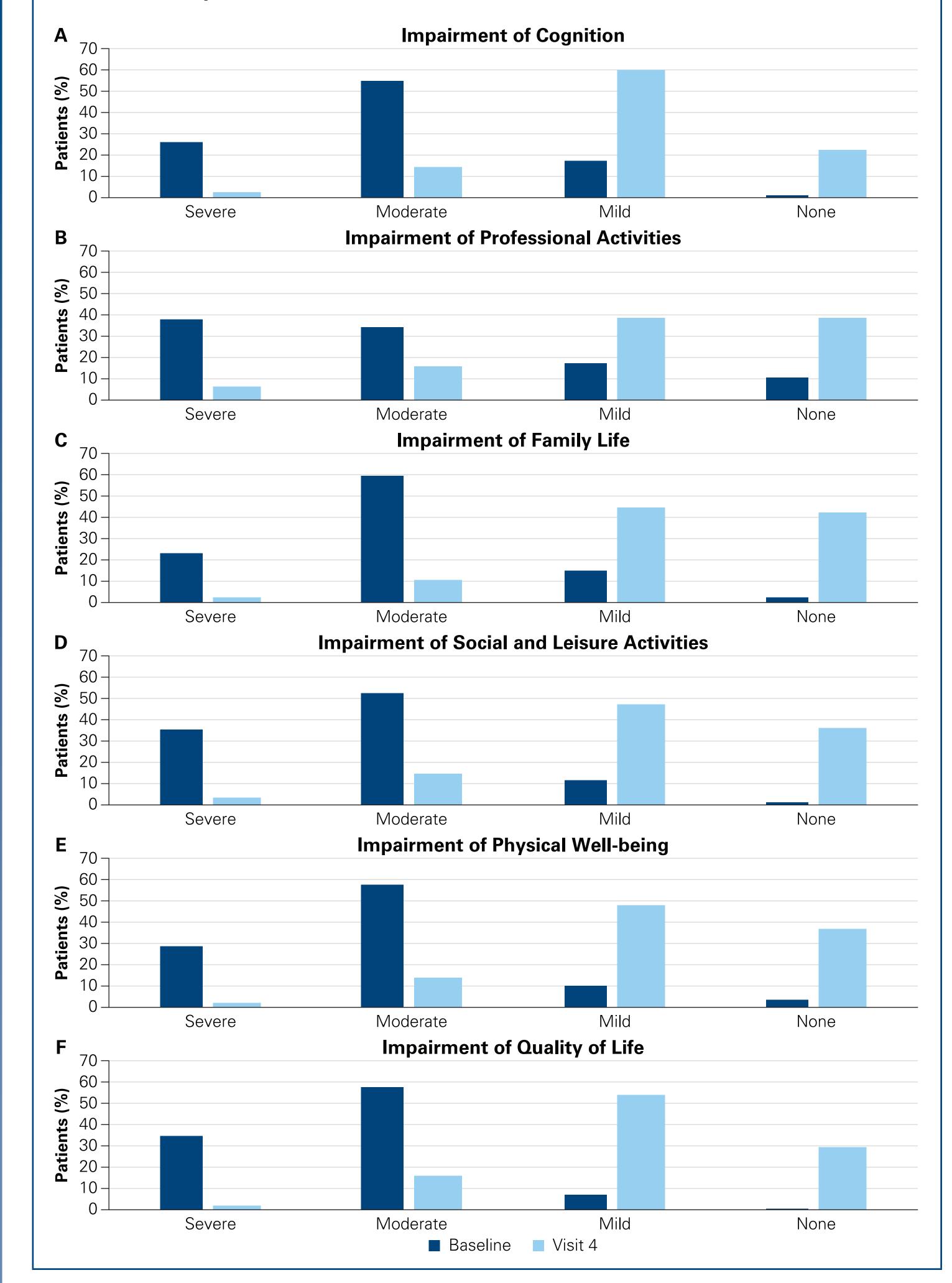
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BACKGROUND

Vortioxetine has been available in Switzerland since 2016 for the treatment of major depressive episodes and relapse prevention after satisfactory response. Efficacy, safety, and tolerability of vortioxetine have been demonstrated in numerous controlled clinical trials.¹ So far, systematically collected data on the treatment with vortioxetine under routine conditions have not been available for Switzerland. The rationale for this practice experience report is to document the effectiveness and tolerability of vortioxetine under everyday treatment conditions in Switzerland to add real-world evidence to the overall data set.

Figure 3. Impact of Current Depressive Episode on Domains of Everyday Functioning and Quality of Life (A-F)



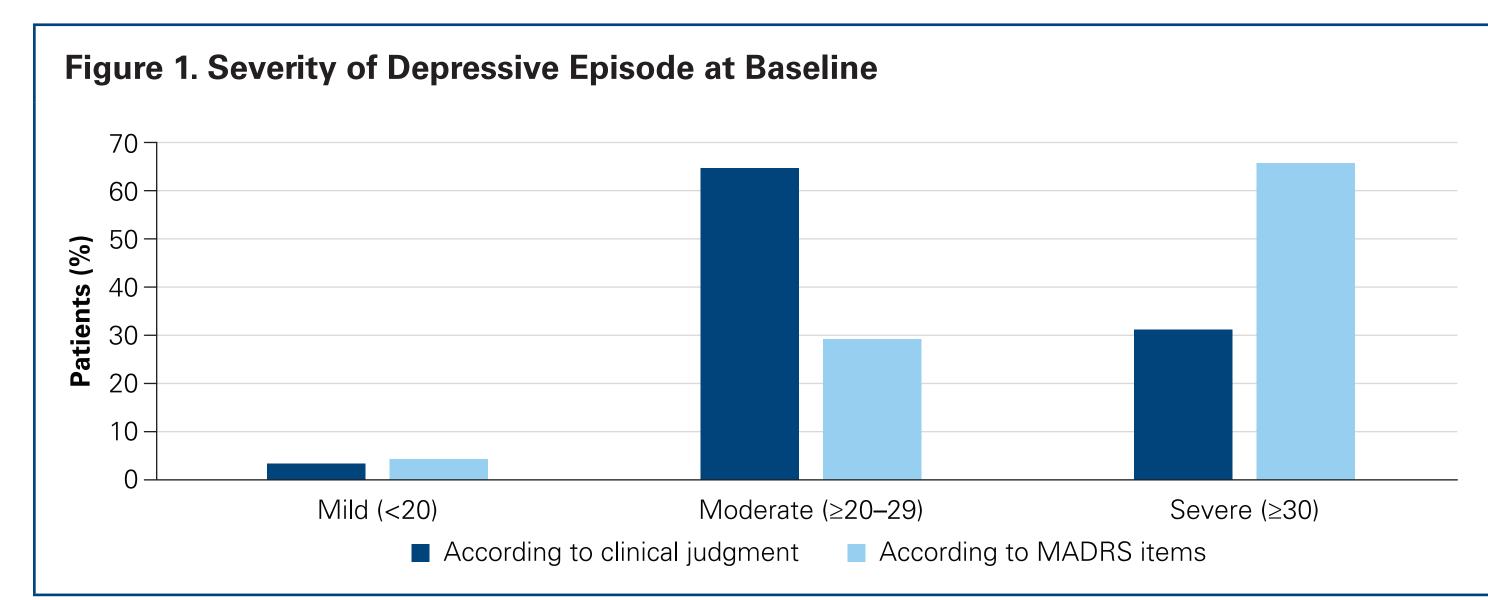
METHODS

Data on the effectiveness and tolerability of vortioxetine in the treatment of patients with a current major depressive episode were collected in a noninterventional (observational), multicentric, prospective study. Vortioxetine was prescribed in accordance with the summary of product characteristics with a maximum dose of 20 mg/day. The study was conducted according to usual therapeutic procedure in Switzerland. Psychiatrists recorded data from patients for whom treatment with vortioxetine was decided upon independently of and before inclusion in this study.

They documented the course of depressive symptoms and functionality at 4 visits over approximately 8 weeks. Key assessments included the unanchored items of the Montgomery-Åsberg Depression Rating Scale (MADRS), impact of depression on functional domains of everyday life assessed as on a 4-point scale, as well as subjective overall evaluation of effectiveness and tolerability by psychiatrist and patient on a 4-point scale. Pre-planned explorative descriptive statistics were applied, using last observation carried forward (LOCF) methods.

Table 1. Patient Disposition at Baseline Patient disposition (n=226)	
Sex, female, %	55.3 (n=125)
BMI	24.7 (mean)
Duration of current depressive episode	4.3 months (mean)
First depressive episode, %	51.3 (n=116)
Sum of MADRS items	34.2 (mean)







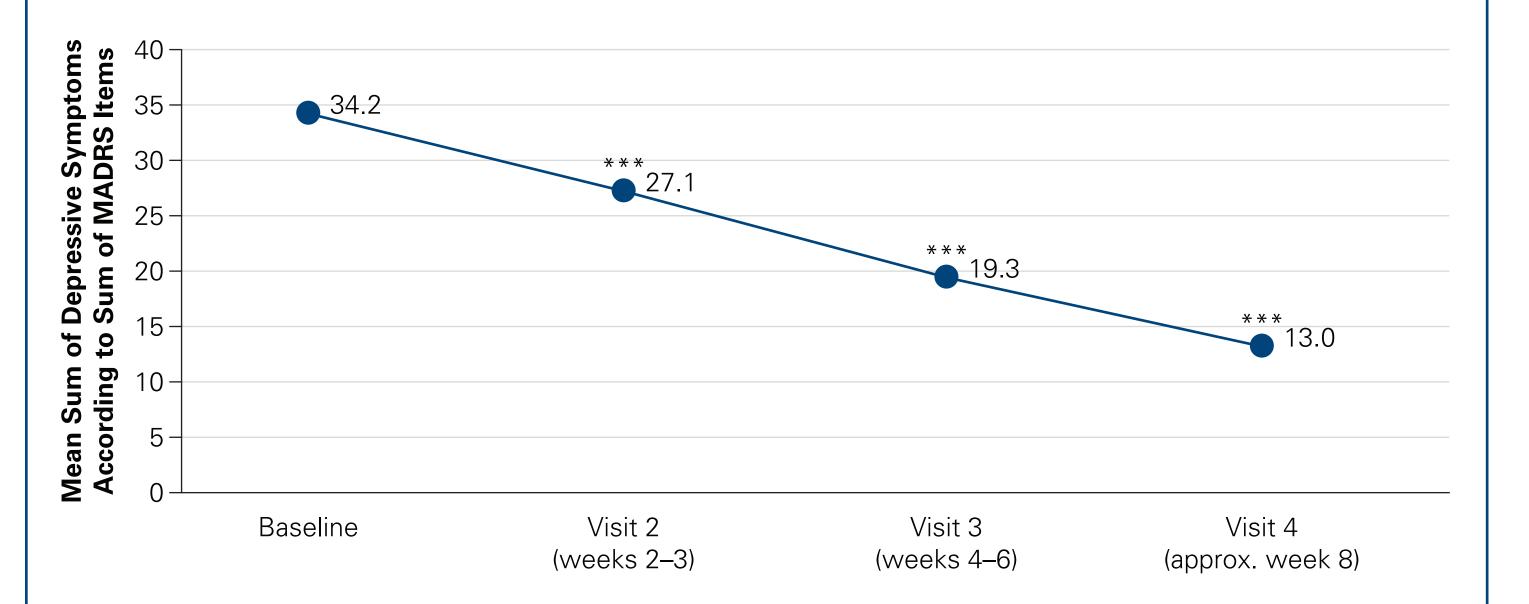


Table 2. Adverse Drug Reactions

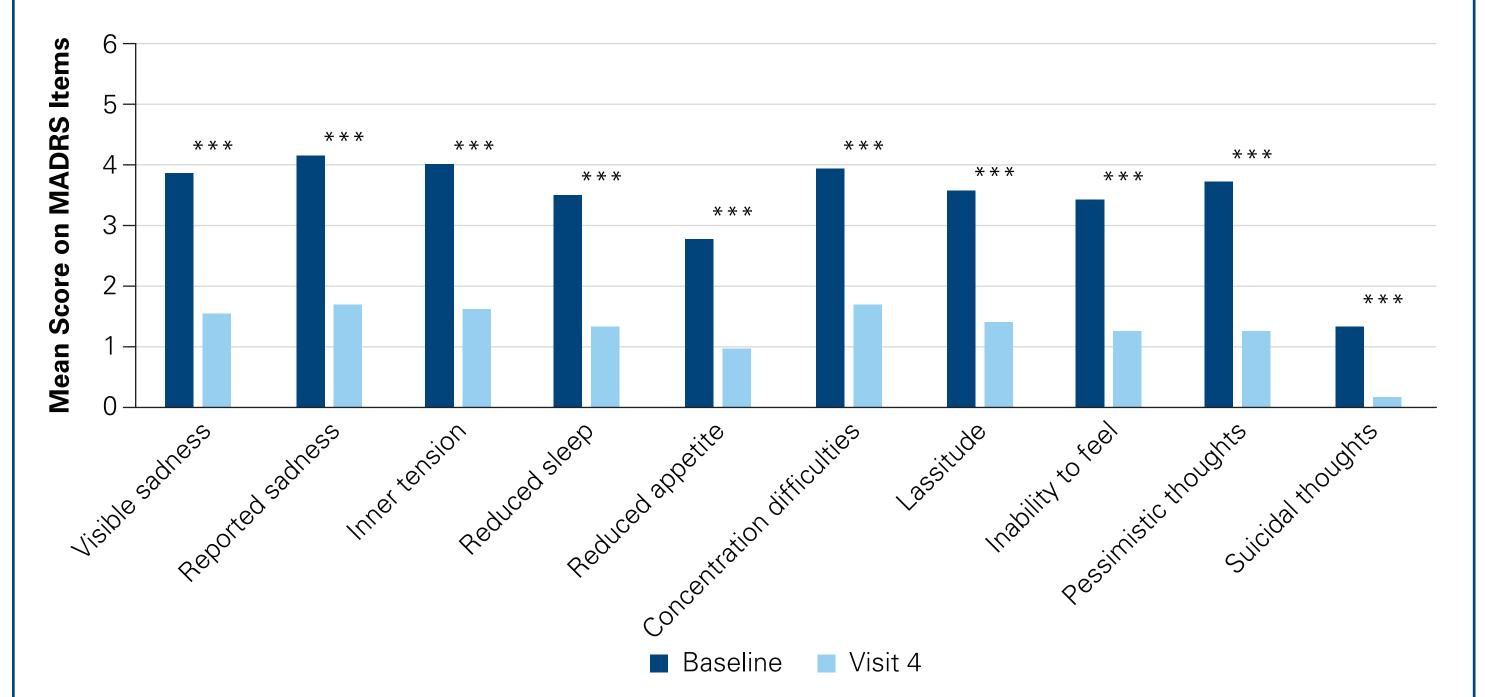
Adverse drug reactions ≥1%	% (n)
Nausea	3.5 (8)
Headache	1.8 (4)
Dizziness	1.3 (3)

RESULTS

Data from 226 patients were analysed. 208 patients (92%) completed the observation period of approx. 8 weeks; mean observation period was 9 weeks. Patient disposition is described in **Table 1** and **Figure 1**.

Severity of depression tended to be underestimated by clinical judgment compared to measurement-based assessment by unanchored MADRS items (**Figure 1**). Mean severity of depression at start of treatment was 34.2 according to the sum of MADRS items, 66% of patients were severely depressed (sum of MADRS items \geq 30). The mean change in the sum of unanchored MADRS items was –21.3 indicating a significant improvement (LOCF, *P*<0.001) in severity of depressive symptoms at 8 weeks (**Figures 2A & 2B**). The impairment of functionality due to depression improved in all the domains noted (**Figure 3 A-F**).

Figure 2B. Depressive Symptoms According to MADRS Single Items^a



^aAccording to MADRS items: symptoms during the last 7 days: 0=none, 1=almost none, 2=mild, 3=moderate, 4=marked, 5=intense, 6=extreme.

****P*<0.001 vs baseline (LOCF). LOCF, last observation carried forward; MADRS, Montgomery-Åsberg Depression Rating Scale.

The most frequent adverse drug reaction (ADR) was nausea (3.5%). Further ADRs \geq 1% were headache (1.8%) and dizziness (1.3%) (**Table 2**). 91% of psychiatrists and 89% of patients evaluated the overall effectiveness as good or very good. 92% of psychiatrists and patients evaluated the overall tolerability as good or very good. 85% of patients continued treatment with vortioxetine after the observation period.

CONCLUSION

According to this evaluation, treatment of depressive episodes with vortioxetine under real-world conditions in Switzerland was associated with reduction of depressive symptoms as well as improvement of functionality and quality of life and was well tolerated.

ACKNOWLEDGMENTS

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1. Cipriani A. et al. Comparative efficacy and acceptability of 21 antidepressant drugs for the acute treatment of adults with major depressive disorder: a systematic review and network meta-analysis. *Lancet*. 2018;391(10128):1357-1366.