Effectiveness and tolerability of Vortioxetine in the treatment of major depressive episodes under real-world conditions in Switzerland

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Background: Vortioxetine is available in Switzerland since 4 years 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 (Koesters 2017). Systematically collected data on the application of Vortioxetine under routine conditions are not yet available for Switzerland. The rationale for this practice experience report is to document the effectiveness and tolerability of Vortioxetine as real-world-evidence.

Methods: Data of effectiveness and tolerability of Vortioxetine in the treatment of patients with a current major depressive episode with or without comorbidities are collected in a non-interventional, multicentric, prospective, open observation. Vortioxetine is used in accordance with the summary of product characteristics, observations follow the usual therapeutic procedure in Switzerland. Only data of patients, for whom treatment with Vortioxetine was decided independently of the observation, are collected. The course of disease is documented at 4 visits over approximately 8 weeks. Here the results of an interim analysis are presented.

Table 1. Patient disposition

Patient disposition (n=101)	
Age	40,8 years (mean)
Females	62 %
BMI	24,4 (mean)
Duration of current depressive episode	4,8 months (mean)

Figure 1. Patient disposition: depressive episode

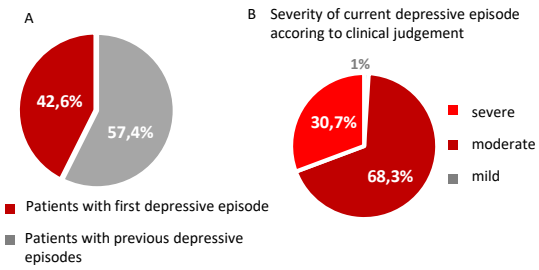


Figure 2. Galenic form at treatment

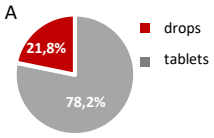
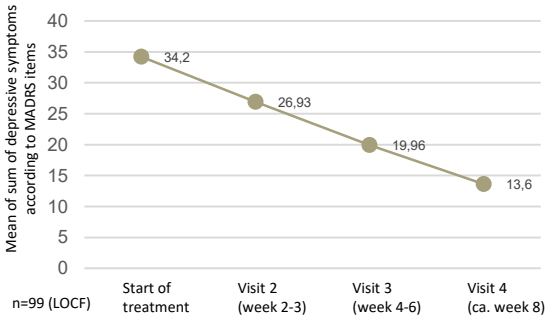


Figure 3: Severity of depression according to sum of MADRS items*



*according to MADRS-Items: symptoms during the last 7 days: 0= none / 1 = almost none/ 2 = mild / 3 = moderate / 4 = marked / 5 = intense / 6 = extreme

Figure 4: Depressive symptoms according MADRS items*

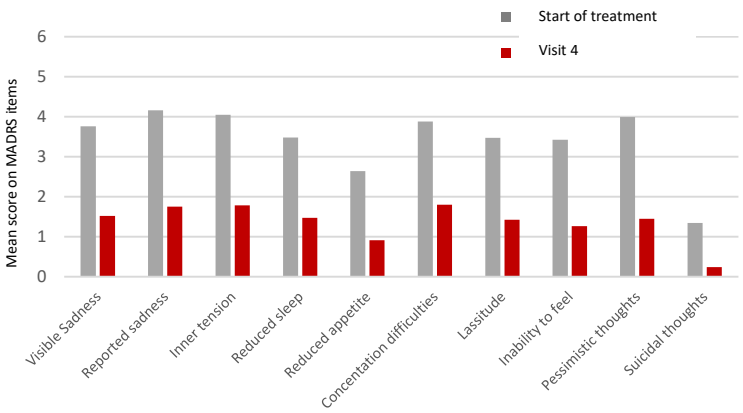


Figure 5: Impact of current depressive episode on domains of everyday functioning (A-F)

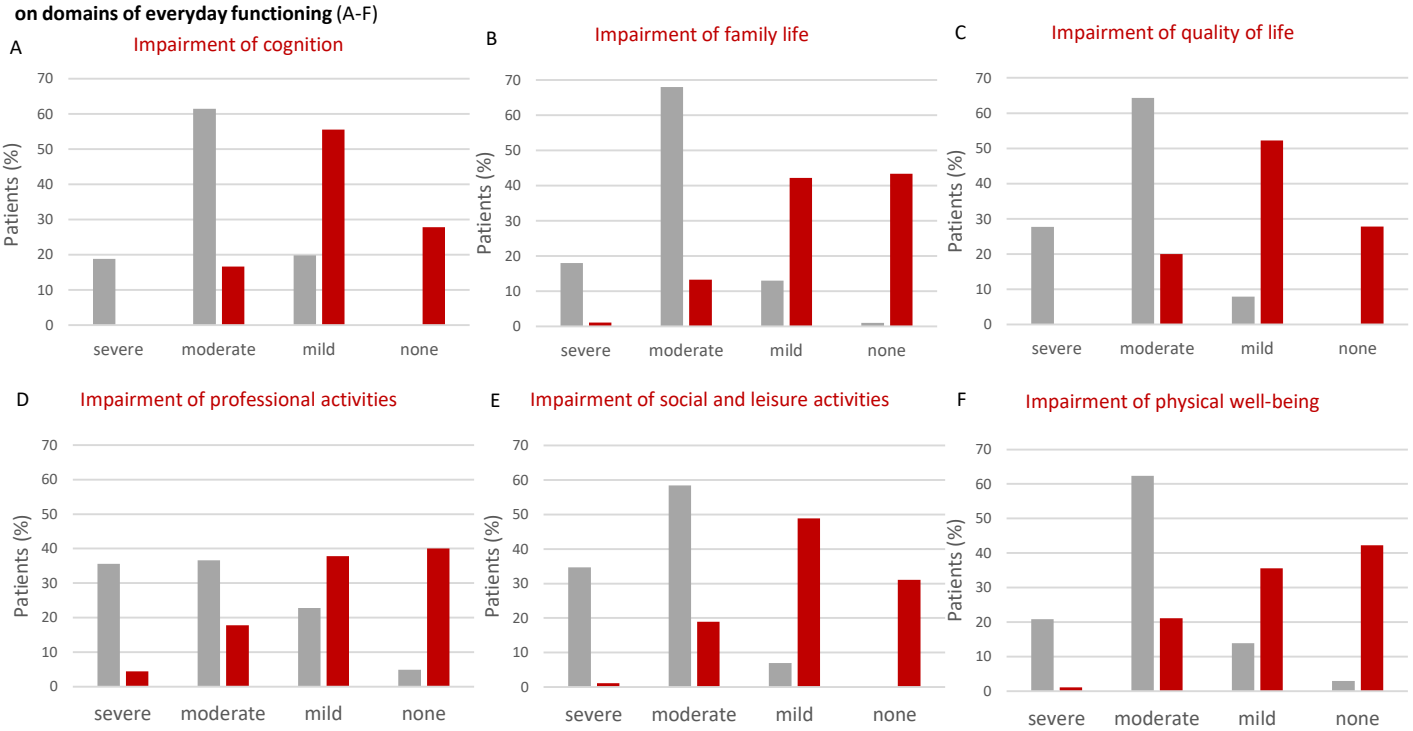


Table 2. Adverse drug reactions

Adverse drug reactions ≥ 2%	% (n)
Nausea	7,8 (8)
Dizziness	3,9 (4)
Headache	3,9 (4)

Conclusion: According to this interim evaluation, treatment of depressive episodes with Vortioxetine under real-world-conditions in Switzerland leads to reduction of depressive symptoms as well as improvement of functionality and quality of life while being well tolerated.

Results: Data of 101 patients have been analysed. 92 patients (91.1%) completed the observation period of approx. 8 weeks - mean observation period was 9 weeks. Patient disposition is described in Table 1 and Fig. 1.

21.8% of patients started treatment with Vortioxetine drops (Fig.2), dose titration was planned for 20% of patients. Vortioxetine dosage was flexible within the limits of the Swiss summary of product characteristic – i.e. maximum dose 20mg/day - and at the discretion of the treating psychiatrist.

Mean severity of depression at start of treatment was 34.2 according to the sum of MADRS items, the mean change over 8 weeks is -20.6 (LOCF) (Fig 3 & 4). The impairment of functionality due to depression improved in the domains cognition, professional, family and social activities, physical well-being as well as quality of life (Fig. 5 A-F).

The most frequent adverse drug reaction (ADR) was nausea (7.8%). Further ADR ≥ 2% were dizziness and headache (3.9 % each) (Table 2). 83% of psychiatrists and 82% of patients evaluated the overall efficacy as good or very good. 87% of psychiatrists and 86% of patients evaluated the overall tolerability as good or very good. 82% of patients did continue treatment with Vortioxetine.

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