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Lurasidone and Sexual Dysfunction: Post-HOC Analysis of Pooled Data

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Introduction/Objectives/Aims

Antipsychotic-induced hyperprolactinaemia is associated with sexual dysfunction.[1] In pivotal schizophrenia studies, lurasidone was associated with limited elevation of prolactin.[2] This post-hoc analysis substantiates the clinical relevance by evaluating the incidence of treatment-emergent adverse events related to sexual dysfunction (SD-TEAEs) in patients with schizophrenia treated with lurasidone compared with active controls or placebo.

Methods

22 clinical studies were stratified into short-term, long-term and all Phase 2/3 lurasidone study pools. SD-TEAEs were defined as any adverse events related to sexual dysfunction starting on/after the first dose date and within 7 days of treatment discontinuation.

Results

All reported SD-TEAEs were mild or moderate in severity.

	Short-term controlled studies		Long-term controlled studies		All Phase 2/3 lurasidone studies[a]	
	N	SD-TEAEs (%)	N	SD-TEAEs (%)	N	SD-TEAEs (%)
Lurasidone	1508	0.5[b]	624	2.2[c]	3202	1.2
Placebo	708	0.6[d]	N/A		N/A	
Haloperidol	72	0				
Olanzapine	122	0.8[e]				
Quetiapine XR	119	0.8[f]	85	0		
Risperidone	65	1.5[g]	199	6.5[c]		

[a]Short-term and long-term studies, including ≤22-month open-label extension studies of lurasidone with no controls; [b]erectile dysfunction, amenorrhoea, irregular menstruation, sexual dysfunction; [c]decreased libido, erectile dysfunction, amenorrhoea, galactorrhoea; [d]erectile dysfunction, delayed menstruation; [e]breast pain; [f]irregular menstruation; [g]galactorrhoea.

Conclusion

The incidence of SD-TEAEs with lurasidone treatment was comparable to placebo in short-term studies and lower than for risperidone in both short-term and long-term trials. Future studies utilising formal sexual functioning rating scales on a prospective basis should be considered to further examine this issue.

References

1. Ahl et al. Ann NY AcadSci 2004;1032:289–90
2. Kantrowitz JT, Citrome L. ExpertRevNeurother 2012;12:265–73

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