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Results Of The ROSA Trial: A Randomised Controlled Trial Of The Effect Of CPAP On Diabetic Macular Oedema In People With Concurrent Obstructive Sleep Apnoea

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Abstract:
The ROSA trial (Retinopathy and Obstructive Sleep Apnoea) is a multi-centre randomised controlled trial conducted in the United Kingdom.
Methods
Patients of 23 UK Eye Hospitals with diabetic macular oedema and type 2 diabetes were offered home sleep studies. Those with severe OSA (ODI>20 or AHI >30), plus visual impairment due to diabetic macular oedema, were randomised to usual ophthalmic care (control) or usual ophthalmic care plus CPAP for one year. Exclusion criteria included respiratory failure, excessive daytime sleepiness requiring urgent

treatment or cataract precluding ophthalmic assessment. Follow up occurred at three, six and twelve months with measures of visual acuity (LogMAR), optical coherence tomography (OCT), retinal photography, all performed by investigators blinded to treatment group, plus sleepiness and health-related quality of life. The primary outcome was the change in LogMAR score at 12 months. Ongoing support was provided to the CPAP group to optimise use.

Results There were 131 patients randomised: 64 to CPAP, 67 to control, of whom 57 and 61 respectively completed follow up. The groups were well matched at baseline. There was no significant difference in LogMAR at 12 months between the patients in the CPAP group and those in the control group after adjusting for the minimisation factors, neither was there at 3 months or 6 months. There was no change in central macular thickness measured by OCT at any time point nor the progression of Diabetic Retinopathy at 12 months, determined by retinal photography grading. The mean number of ocular interventions including anti-VEGF, laser, surgery was not significantly different between the groups. Mean (SD) CPAP use was 2.43 (2.04) hours at 3 months, 2.53 (2.28) at 6 months and 2.21 (2.22) at 12 months. There was no significant difference between the groups in the change in Epworth Sleepiness Score at any time point. There was no significant correlation of CPAP use with changes in LogMAR. There was no significant difference in the Visual Function Questionnaire 25 between groups at 3, 6 and 12 months, nor in any domain of the Short Form 36.

Conclusions This randomised controlled trial shows that CPAP used for 12 months had no effect on any measures of visual function in patients with type 2 diabetes with impaired vision due to diabetic macular oedema and newly diagnosed severe OSA.

Results of the ROSA trial, shown as mean (95% CI)

	CPAP, n=57	Control, n=61	Mean difference	p value
LogMAR BCVA at 12 months	0.34 (0.29 to 0.38)	0.31 (0.27 to 0.35)	0.03 (-0.03 to 0.09)	0.31
Central macular thickness	320.4 (298.2, 342.6)	309.2 (286.5, 331.9)	11.2 (-20.8, 43.2)	0.49
Mean number of ocular interventions during study period	5.2 (3.6 to 6.8)	3.6 (2.5 to 4.8)	1.4 (0.9 to 2.3)	0.125

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