A0239

Impact of Systemic Dipeptidyl Peptidase-4 (DPP-4) Inhibitors on Treatment Outcomes for Diabetic Macular Edema (DME) in the VISTA and VIVID trials

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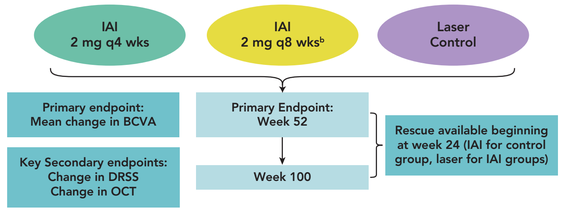
BACKGROUND

Randomized, multicenter, double-masked trials in patients with clinically significant DME with central involvement and ETDRS BCVA 20/40 to 20/320
Randomized and Treated N=404 (VIVID[a]) N=461 (VISTA[a])



[a]The VISTA and VIVID studies were funded by Regeneron Pharmaceuticals, Inc., Tarrytown, NY, and Bayer HealthCare, Berlin, Germany.
[b]Following 5 initial monthly doses
BCVA = best-corrected visual acuity; DRSS = Diabetic Retinopathy Severity Score; ETDRS = Early Treatment Diabetic Retinopathy Study; IAI = intravitreal aflibercept injection; OCT = optical coherence tomography

- IAI given q4 weeks or q8 weeks (following 5 monthly doses) significantly improved visual and anatomic outcomes over laser at week 52. These improvements were sustained through week 100 with both IAI regimens.
- In an integrated safety analysis, the most frequent serious ocular adverse event at week 100 was cataract (2.4%, 1.0%, and 0.3% for 2q4, 2q8, and control).

OBJECTIVE

- Recent evidence suggests that systemic dipeptidyl peptidase-4 (DPP-4) inhibitor use in diabetics may be protective against the progression of DR[1]
- This post hoc analysis examined whether DME patients taking systemic DPP-4 inhibitors differed in baseline characteristics and/or treatment outcomes in the VISTA and VIVID studies

1 Chung YR1, Park SW, Kim JW, Kim JH, Lee K. Protective effects of dipeptidyl peptidase-4 inhibitors on progression of diabetic retinopathy in patients with type 2 diabetes. *Retina*. 2016;36(12):2357-2363.

METHODS

- Post hoc analysis of integrated data from VISTA and VIVID
- Patients were categorized into two groups according to reported concomitant medication use at baseline:
  - Patients taking a DPP-4 inhibitor (+DPP-4 inhibitor group)
  - Patients NOT taking a DPP-4 inhibitor (–DPP-4 inhibitor group)
- Analyses of baseline characteristics and treatment outcomes were conducted within each treatment group (laser, IAI 2q4, IAI 2q8)
- In patients receiving rescue treatment, data were censored from the time rescue treatment was given

DPP-4 inhibitors included in this analysis

1. Januvia (sitagliptin)
2. Onglyza (saxagliptin)
3. Tradjenta (linagliptin)
4. Nesina (alogliptin)
5. Janumet (combination of sitagliptin and metformin)
6. Jentadueto (combination of linagliptin and metformin)
7. Kazano (combination of alogliptin and metformin)
8. Komboglyze (combination of saxagliptin and metformin)
9. Oseni (combination of alogliptin and pioglitazone)
10. Juvisync (combination of sitagliptin and simvastatin)

RESULTS

Figure 1. Proportion of Patients by Baseline Concomitant Medication Class

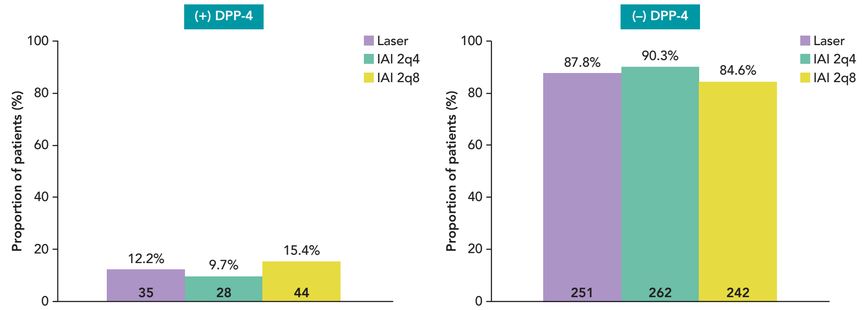


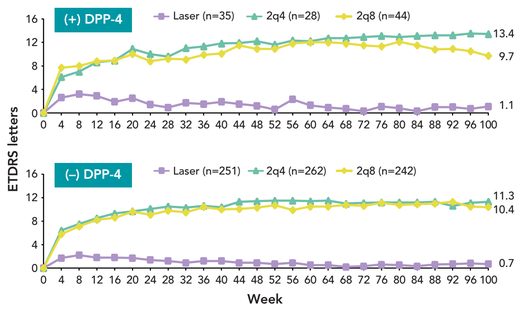
Table 1. Baseline Characteristics

	(+) DPP-4			(–) DPP-4		
	Laser	IAI 2q4	IAI 2q8	Laser	IAI 2q4	IAI 2q8
N (full analysis set)	35	28	44	251	262	242
Mean BCVA, ETDRS letters (SD)	62.3 (9.6)	59.5 (10.9)	62.0 (8.4)	60.0 (10.9)	59.8 (10.8)	58.6 (11.4)
Mean CRT, µm (SD)	502.5 (117.9)	507.8 (146.7)	476.6 (117.8)	510.7 (159.7)	491.6 (151.2)	501.4 (157.2)
DRSS score, n (%)						
Low risk (DRSS ≤43)	11 (31.4)	11 (39.3)	17 (38.6)	97 (38.6)	85 (32.4)	80 (33.1)
Moderate Risk (DRSS = 47)	5 (14.3)	4 (14.3)	8 (18.2)	45 (17.9)	40 (15.3)	51 (21.1)
High Risk (DRSS ≥53)	19 (54.3)	13 (46.4)	19 (43.2)	109 (43.4)	137 (52.3)	111 (45.9)

Integrated VISTA & VIVID
SD = standard deviation; CRT = central retinal thickness; DRSS = Diabetic Retinopathy Severity Scale

Figure 2. Visual Outcomes

(a) Mean BCVA Change



(b) Difference (-DPP4 vs +DPP4) in BCVA Change

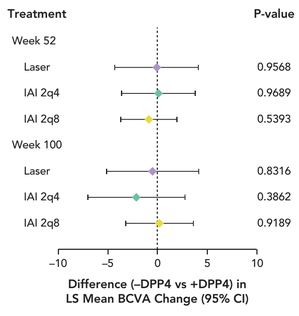
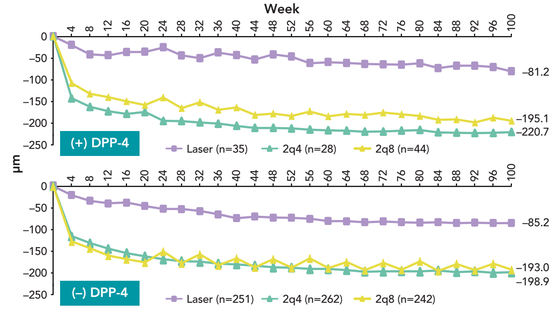


Figure 3. Anatomic Outcomes

(a) Mean CRT Change



(b) Difference (-DPP4 vs +DPP4) in CRT Change

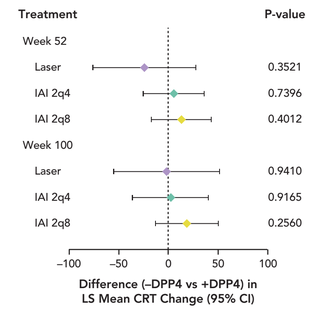
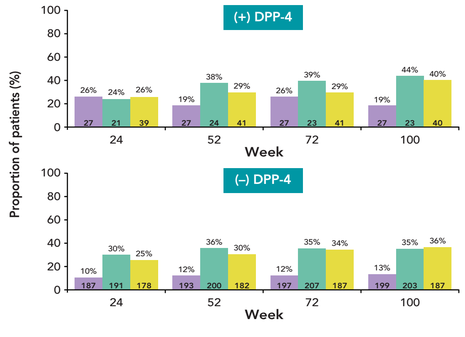
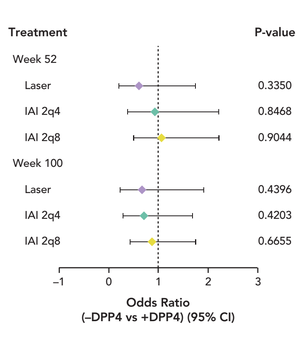


Figure 4. Diabetic Retinopathy Severity Outcomes

(a) ≥2-Step DRSS Score Improvement



(b) Odds Ratio (-DPP4 vs +DPP4) for ≥2-Step DRSS Score Improvement



CONCLUSIONS

- At baseline, 12.2%, 9.7%, and 15.4% of patients in laser, IAI 2q4, and IAI 2q8 groups were on DPP-4 inhibitors
- Baseline characteristics and BCVA, CRT, and DRSS outcomes in the baseline (+) DPP-4 inhibitor group do not appear to differ significantly from those patients not on DPP-4 inhibitors

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