NEW CLINICAL EVIDENCE

BETTER BP LOWERING WITH COMBINATION THERAPY OF TELMISARTAN AND AMLODIPINE THAN AMLODIPINE ALONE

Recent data show that treatment with Twynsta – a single-pill combination of telmisartan, an angiotensin receptor blocker (ARB), and amlodipine, a calcium channel blocker (CCB) – results in significant reductions in blood pressure (BP) in patients with hypertension who do not respond to amlodipine therapy.[1,2,3] The data also demonstrate higher BP control and response rates are achieved with Twynsta in amlodipine non-responder patients compared to amlodipine monotherapy.

Evidence suggests that more than half of hypertensive patients do not have their BP adequately controlled with amlodipine 5mg (A5) alone. Up-titrating to amlodipine 10mg (A10) may improve response rates but also increases the incidence of side effects such as oedema (mainly peripheral oedema). These may lead to reduced compliance and treatment discontinuation. Alternatively, amlodipine non-responder patients may benefit from combination therapy by adding an antihypertensive agent with a complementary mechanism of action, such as the ARB telmisartan.

In this context, the telmisartan and amlodipine single-pill combination Twynsta was investigated in two studies to evaluate its antihypertensive efficacy and safety in hypertensive patients not responding adequately to treatment with amlodipine 5mg (TEAMSTA-5) or amlodipine 10mg (TEAMSTA-10) monotherapy.

Study Design

TEAMSTA-5 and TEAMSTA-10 were two 8 week, double-blind, randomised, active-controlled, parallel group, non-responder studies, done in patients with mild to severe hypertension who were not adequately controlled on A5 or on A10 respectively. Patients were randomised to receive Twynsta or amlodipine alone as follows:

- TEAMSTA-5 treatment arms: Twynsta 40mg/5mg or 80mg/5mg, A5 or A10 (n= 1,097);
- TEAMSTA-10 treatment arms: Twynsta 40mg/10mg or 80mg/10mg, or A10 (n=947).

Twynsta provides superior blood pressure reductions

The results of the TEAMSTA-5 study showed that after 8 weeks of treatment, both Twynsta doses (40mg/5mg and 80mg/5mg) were significantly superior to A5 mg monotherapy and A10 mg monotherapy in reducing SBP and DBP (see Table 1).[2]

Similarly, the results from the TEAMSTA-10 study showed that both Twynsta doses (40mg/10mg and 80mg/10mg) achieved significantly greater BP reductions than A10 monotherapy (see Table 2).[3]

Moreover, TEAMSTA-5 results showed that the proportion of patients achieving BP control was significantly greater for both Twynsta doses compared with A5 alone (see Table 1).[2] In the same way, TEAMSTA-10 results also showed that the proportion of patients achieving BP control was significantly higher with Twynsta 40mg/10mg or 80mg/10mg than with A10.[3]

All Twynsta doses were well tolerated. Oedema rates were significantly lower with Twynsta 40mg/5mg and 80mg/5mg compared to amlodipine 10mg in TEAMSTA-5 (5.1% and 3.6% versus 27.2%, respectively).[2]

Conclusion

These results demonstrate the efficacy and safety of the telmisartan and amlodipine fixed dose combinations in patients with hypertension not responding adequately to treatment with amlodipine. Dr Sarah Jarvis, General Practitioner and Fellow of the Royal College of General Practitioners and Women's Health in the UK, commented: "High blood pressure is a primary risk factor for a serious cardiovascular event such as a heart attack or stroke. Cardiovascular disease is the number one cause of death worldwide. Well-tolerated treatment options that reduce the pill burden for my patients will lead to better management of their hypertension and lead to better outcomes".

Telmisartan and amlodipine are the two longest acting components in their class providing reliable 24 hour reduction in blood pressure. Twynsta is indicated for essential hypertension in adults whose blood pressure is not adequately controlled on amlodipine and for replacement therapy for adults receiving telmisartan and amlodipine from separate tablets.

References:

1- Twynsta SmPC (www.medicines.ie)

2- Neldam, S, et al. J. Clin. Hypertens. 2009; 11 (Suppl s1):114(P279).

3- Neldam, S. et al. (2009) J. Hypertens. 27 (Suppl4) S277. Abstract P26 319

Table 1: Mean SBP and DBP reductions and control in non-responders to amlodipine 5mg

		A5mg	A10mg	Twynsta 40/5mg	Twynsta 80/5mg
Reduction from baseline (mmHg)†	SBP (SD)	-6.2 (0.7)	-11.1 (0.7)	-13.6 (0.7)***	-15.0 (0.7)***
	DBP (SD)	-5.7 (0.5)	-8.0 (0.5)	-9.4 (0.5)***	-10.6 (0.5)***
Patients with BP control (%)	SBP	39.2	54.4	60.0***	65.7***
	DBP	42.0	56.7	56.7***	63.8***

†Adjusted mean change from baseline; *** p< 0.001 to A5mg

Table 2: Mean SBP and DBP reductions and control in non-responders to amlodipine 10mg

		A10mg	Twynsta 40/10mg	Twynsta 80/10mg
Reduction from baseline (mmHg)†	SBP (SD)	-7.4 (0.7)	-11.1 (0.7)****	-11.3 (0.7) ****
	DBP (SD)	-6.5 (0.5)	-9.2 (0.5)****	-9.3 (0.5)****
Patients with BP control (%)	SBP	50.2	58.8*	60.3**
	DBP	51.1	63.7**	66.5**

†Adjusted mean change from baseline; *p<0.05; **p<0.01; ****p< 0.0001 (all *vs.* A10mg alone).

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