



Terapijski profil amlodipin maleata (Tenox[®], Krka)

Therapeutic profile of Krka's Tenox[®] (amlodipine maleate)

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SAŽETAK: Amlodipin je priznata tvar koja posjeduje antihipertenzivni učinak. U odnosu na druge dihidropiridinske blokatore kalcijevih kanala amlodipin ima i dodatne terapijske učinke zahvaljujući pozitivnom naboju svojih molekula. Lijek također smanjuje rizik kardiovaskularnih bolesti. Sigurnost i učinkovitost amlodipin maleata (Tenox[®], Krka) testiran je u kliničkim ispitivanjima. Ispitivanja su pokazala da je terapijski profil jednak originatoru. Krkin amlodipin je učinkovit u monoterapiji kao i u kombinaciji s drugim antihipertenzivima u pacijenata svih dobnih skupina.

KLJUČNE RIJEČI: arterijski tlak, kardiovaskularne bolesti, blokatori kalcijevih kanala, amlodipin.

ABSTRACT: Amlodipine is a recognised substance with antihypertensive effect. In comparison with other dihydropyridine calcium channel blockers it possesses additional therapeutic effects due to a positive charge of its molecules. Amlodipine also reduce the risk of cardiovascular events. Safety and efficacy of Krka's amlodipine (amlodipine maleate) was tested in clinical trials. They have showed that therapeutic profile is equivalent to originator. Krka's amlodipine is effective in monotherapy as well as in combination with other antihypertensives and for patients of all age groups.

KEYWORDS: blood pressure, cardiovascular events, calcium channel blockers, amlodipine.

Za liječenje hipertenzije postoji pet skupina raspoloživih lijekova čija je sigurnost dokazana kliničkim ispitivanjima (tiazidni diuretici, beta-blokatori, ACE inhibitori, angiotenzin II receptor blokatori i blokatori kalcijevih kanala). Tvrtka Krka u svojoj paleti antihipertenziva ima lijekove iz svih prethodno navedenih skupina. Jedan od njih je Tenox[®] (amlodipin maleat) iz skupine dihidropiridinskih blokatora kalcijevih kanala (DHP CCBs). Veza uz način djelovanja i farmakodinamiku, amlodipin je sličan drugim tvarima iz ove skupine, ali ima različita fizikalno-kemijska svojstva. To je jedini DHP CCB koji se nalazi u ioniziranom obliku sa pozitivnim molekularnim nabojem pri pH 7,4¹. Zbog toga su njegova dodatna terapijska djelovanja (antioksidativno, antiagregacijsko, antiaterogeno) naglašenija u usporedbi sa drugim DHP CCB-ima. Krkin amlodipin je lijek sa ispitanim terapijskim djelovanjem. Njegova učinkovitost i sigurnost su dokazane u kliničkim ispitivanjima koja su obuhvatila gotovo 6.000 pacijenata²⁻⁶.

Učinkovitost i sigurnost Krkinog amlodipina odgovaraju originalnom lijeku što je dokazano u izravnom komparativnom kliničkom ispitivanju². Usporedba smanjenja arterijskog tlaka (AT) za oba lijeka je prikazana na **slici 1**.

Sukladno kliničkoj praksi, zadovoljavajuća kontrola AT uključuje kombinaciju dva, tri ili više antihipertenziva lijeka. U studiji koja je uključivala 827 pacijenata, liječenjem amlodipinskom monoterapijom je za 6 tjedana snižen je AT sa 165 ± 17/ 92 ± 10 na 139 ± 16/83 ± 7 mm Hg, a ciljani AT (<140/90 mm Hg) postignut je kod 57% pacijenata. Drugim ispitanicima koji nisu postigli ciljani AT, dodani su drugi antihipertenzivi prema izboru liječnika. Kombiniranim liječenjem pospješila se učinkovitost te su ciljane vrijednosti AT-a postignute kod 70% do 90% bolesnika. Rezultati su prikazani na **slici 2**.

For treatment of hypertension there are five groups of substances available with their safety proven in clinical trials (thiazide diuretics, beta-blockers, ACE inhibitors, angiotensin II receptor blockers, and calcium channel blockers). The company Krka has in its antihypertensive portfolio medicines from all before mentioned groups. One of them is Tenox[®] (amlodipine maleate) from the group of dihydropyridine calcium channel blockers (DHP CCBs). Regarding mode of action and pharmacodynamics amlodipine is similar to other substances from this group but has distinctive physico-chemical characteristics. It is the only DHP CCB to be found in ionized form with a positive molecular charge at pH 7.4¹. Because of this its additional therapeutic effects (antioxidative, antiaggregational, antiatherogenic) are more pronounced in comparison with other DHP CCBs. Krka's amlodipine is a medicine with tested therapeutic effect. Its efficacy and safety were proven in clinical trials that included almost 6.000 patients²⁻⁶.

Efficacy and safety of Krka's amlodipine are equivalent to originator which was proven in a head-to-head comparative clinical trial². Comparison of blood pressure reduction for both medicines is shown in a **Figure 1**.

According to clinical practice satisfying control over blood pressure (BP) involves a combination of two, three or even more antihypertensive medicines. In a study, involving 827 patients, treatment with amlodipine monotherapy for 6 weeks reduced BP from 165 ± 17/ 92 ± 10 to 139 ± 16/83 ± 7 mm Hg and target BP (<140/90 mm Hg) was achieved by 57% of patients. To patients who did not achieve target BP other antihypertensive drugs were added by the choice of physicians. Combined treatment improved efficiency and target values of BP were achieved by 70% to 90% of patients. Results are presented in a **Figure 2**.

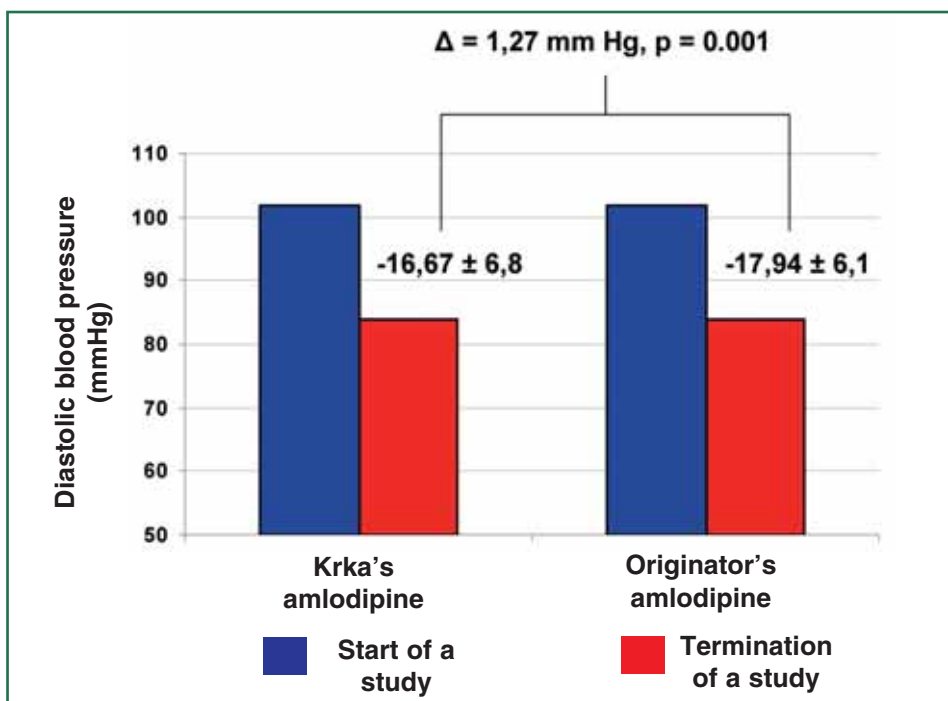


Figure 1. Diastolic blood pressure reduction comparison of Krka's amlodipine and originator's.

Potrebna je posebna briga u liječenju pacijenata s povišenim rizikom od kardiovaskularnih bolesti što uključuje i osobe starije životne dobi. Krkin amlodipin je učinkovit i siguran lijek i za tu skupinu pacijenata. Pokazalo se da je liječenje sa Krkinim amlodipinom u kombinaciji drugim lijekovima iz različitih antihipertenzivskih skupina učinkovitije, a ciljani AT se postizao značajno češće u odnosu na kontrolno liječenje. Uočeno je učinkovito sniženje KT-a bez obzira na starosnu skupinu pacijenata^{4,5}.

Extra care is needed in the treatment of patients with higher risk for cardiovascular diseases which includes also elderly patients. Krka's amlodipine is efficient and safe medicine for such patients as well. The treatment with Krka's amlodipine in combination with other drugs from different antihypertensive groups proved to be more effective and the target BP reached significantly more often in comparison with control treatment. Efficient BP reduction was observed regardless of age group of patients^{4,5}.

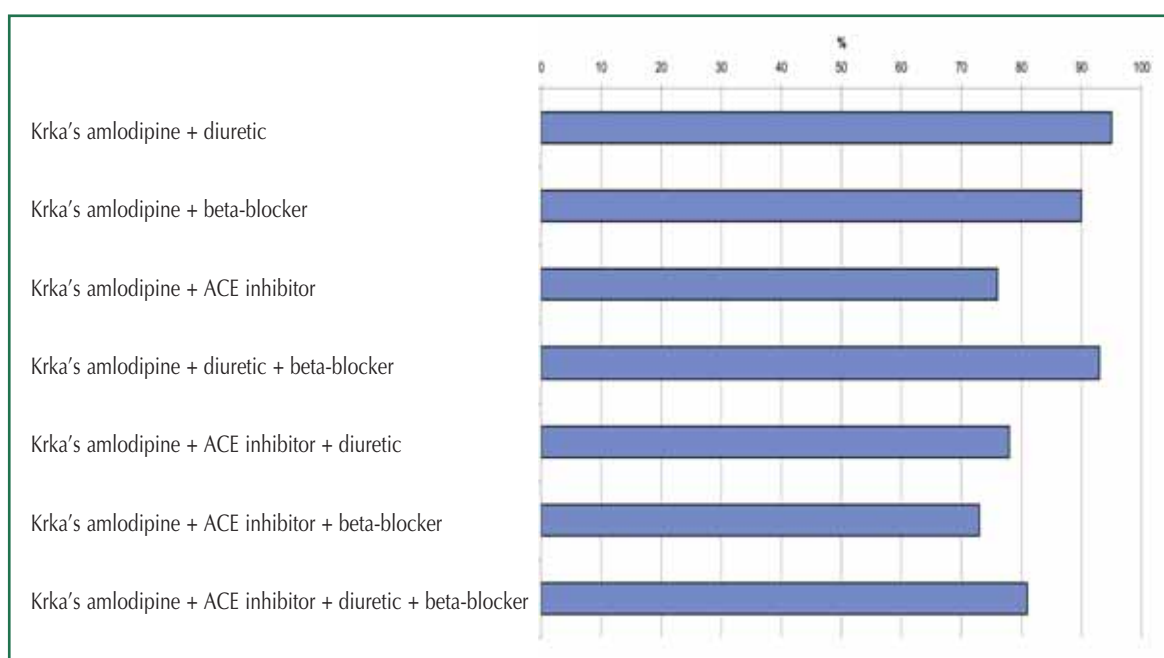


Figure 2. Percentage of patient achieving target blood pressure (<140/90 mm Hg).



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