

Učinak balona koji izlučuje lijek paklitaksel u liječenju aterosklerotskih lezija površinske bedrene arterije – pregled metode i privremeni rezultati

The effect of paclitaxel drug coated balloons in the treatment of atherosclerotic lesions of the superficial femoral artery – method review and interim results

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Cilj: Prikazati metodu i tehniku angioplastike aterosklerotskih lezija površinske bedrene arterije (AFS) primjenom balona koji izlučuje lijek (DCB) paklitaksel¹ i privremene rezultate liječenja.

Pacijenti i metode: U razdoblju od rujna 2015. godine do kolovoza 2016. godine u studiju je uključeno 20 bolesnika (8 žena i 12 muškaraca) sa simptomatskim aterosklerotskim lezijama AFS (Rutherford klasifikacija 2-4) liječenih primjenom DCB paklitaksel (Inpact Admiral, Medtronic, USA). Lezije AFS su kategorizirane prema TASC klasifikaciji. Svim bolesnicima je učinjen klinički pregled, mjerenje AB indeksa, digitalna pletizmografija i obojani Doppler (CD) prije, 24 sata nakon provedenog endovaskularnog liječenja i u redovitim kontrolnim pregledima (1, 3, 6 i 12 mjeseci). Prije endovaskularne revaskularizacije svim bolesnicima je učinjena DSA arterija donjih ekstremiteta. Glavni cilj analize je bio primarna prohodnost liječenih lezija AFS i vrijednost AB indeksa nakon intervencije.

Rezultati: Liječena je 21 AFS u 20 bolesnika, a tehnička uspješnost endovaskularne revaskularizacije je bila 100 % (21/21). Lezije AFS su kategorizirane prema TASC II: TASC A 10, TASC B 6, TASC C 4 i TASC D 1. Prosječna dužina lezija je bila 71 ± 54 mm, 7/21 (33,3 %) su bile stenotske lezije, a prosječan stupanj stenoze je bio 83 ± 10 %. Okluzija je zabilježena u 14/21 (66,7 %) lezije. Srednja vrijednost ABI prije intervencije je bila 0,62 ± 0,13. Prosječno razdoblje praćenja bolesnika je bio 7,9 ± 3,3 mjeseca. Nakon intervencije srednja vrijednost ABI je bila 0,92 ± 0,18. U kontrolnom razdoblju na CD-u su zabilježeni dvije restenoze AFS bez kliničkog značenja. Primarna prohodnost je bila 90 % (19/21 lezija). Nije bilo velikih komplikacija i reintervencija u kontrolnom intervalu.

Zaključci: Privremeni rezultati pokazuju da je primjena DCB koji izlučuje paklitaksel u liječenju simptomatskih aterosklerotskih lezija AFS izvediva i učinkovita uz visok stupanj primarne prohodnosti i značajno poboljšanje ABI u kratkom kontrolnom intervalu.

Objective: To describe the method and technique of paclitaxel drug coated balloon (DCB) angioplasty for atherosclerotic lesions of superficial femoral artery (SFA)¹ and interim results of treatment.

Patients and Methods: Our study included 20 patients (8 women and 12 men) with symptomatic atherosclerotic lesions of SFA (Rutherford Classification 2-4), treated using paclitaxel DCB (Inpact Admiral, Medtronic, USA), in period from September 2015 to August 2016. Lesions of SFA were categorized according to TASC classification. All patients made a clinical examination, measurement of ankle-brachial index (ABI), digital plethysmography and Color Doppler (CD), before, 24 hours after completion of the endovascular treatment and in regular control follow up (1, 3, 6 and 12 months). Before endovascular revascularization all patients underwent DSA of arteries of the lower extremities. The main objective of the analysis was the primary patency of treated AFS lesions and the value of ABI after the intervention.

Results: We treated 21 SFA in 20 patients, and technical success of endovascular revascularization was 100% (21/21). Lesions of SFA were categorized according to TASC II classification: TASC A 10, TASC B 6, TASC C 4 and TASC D 1 lesions. Average length of lesions was 71±54 mm and 7/21 (33.3%) were stenotic lesions with average degree of stenosis 83±10%. Occlusion was observed in 14/21 (66.7%) lesions. Mean ABI before intervention was 0.62±0.13. The average follow-up period was 7.9±3.3 months. After the intervention mean ABI was 0.92±0.18. In the control period we recorded two SFA restenoses on CD ultrasound, without clinical significance. Primary patency was 90% (19/21 lesions). There were no major complications or reinterventions in the control interval.

Conclusions: Interim results show that the use of paclitaxel DCB in the treatment of symptomatic atherosclerotic SFA lesions is feasible and effective with a high degree of primary patency and significant improvement of ABI in a short-term period.

LITERATURE

1. Laird JR, Schneider PA, Tepe G, Brodmann M, Zeller T, Metzger C, et al; IN.PACT SFA Trial Investigators. Durability of Treatment Effect Using a Drug-Coated Balloon for Femoropopliteal Lesions: 24-Month Results of IN.PACT SFA. *J Am Coll Cardiol.* 2015;66(21):2329-38.

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