

Efektivitas Deksametason pada Pasien yang Menjalani Operasi Off-pump Coronary Artery Bypass Grafting : Sebuah Uji Klinis Tersamar Ganda = Effectivity of Dexamethasone in Patients Undergoing Off-pump Coronary Artery Bypass Grafting Surgery : A Randomized Double Blind Controlled Clinical Trial

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Abstrak

Latar belakang: Berdasarkan pilot study di divisi Bedah Jantung Dewasa Rumah Sakit Pusat Jantung dan Pembuluh Darah Harapan Kita, SIRS lebih sering terjadi pada OPCAB dibandingkan dengan on-pump CABG, 67% vs 33% (30 sampel, 2017). Berangkat dari hal tersebut, peneliti melakukan uji klinis memberikan deksametason pada pasien yang menjalani operasi OPCAB. Metode: Pengumpulan sampel dilakukan secara konsekutif di divisi Bedah Jantung Dewasa Rumah Sakit Pusat Jantung dan Pembuluh Darah Harapan Kita antara Agustus 2018 - Januari 2019. Sampel yang memenuhi kriteria inklusi dan eksklusi dirandomisasi menjadi grup deksametason (n=30) dan grup plasebo (n=30). Intervensi deksametason intravena dosis 1 mg/KgBB (maksimal 100 mg) atau plasebo menggunakan normal salin (NaCl 0,9%). Analisis statistik digunakan independent t-test, Mann-Whitney test, fisher exact test dan AUC. Hasil: Insiden MACE pada grup deksametason dibandingkan grup plasebo (RR 0,385, CI 95%: 0,157-0,945, p = 0,024). Keluaran klinis lebih baik ditemukan pada grup deksametason dibandingkan grup plasebo untuk durasi ventilasi mekanik (6 (5-16) jam vs 8 (5-72) jam, p = 0,029), lama rawat ICU (17,5 (12-32) jam vs 19 (13-168) jam, p = 0,028), lama rawat rumah sakit (5 (5-8) hari vs 6,5 (5-30) hari, p = 0,04) dan VIS (0 (0-15) vs 5 (0-100), p = 0,045). Hasil penanda inflamasi, terdapat perbedaan rata-rata yang bermakna antara grup deksametason dibandingkan grup plasebo pada IL-6 (217,4 pg/mL, CI 95%: 107,9-326,8, p = 0,0001), PCT (3,41 µg/L, CI 95%: 2,1-4,71, p = 0,0001) dan CRP (52,3 mg/L, CI 95%: 28,8-75,8, p = 0,0001). Pada analisis AUC terdapat hubungan signifikan antara penanda inflamasi dengan insiden MACE pada IL-6 (AUC 0,728, CI 95%: 0,585-0,871, p = 0,005) dan PCT (AUC 0,723, CI 95%: 0,578-0,868, p = 0,007). Kesimpulan: Pemberian deksametason praoperasi OPCAB, efektif memperbaiki keluaran klinis dan mengendalikan reaksi inflamasi pascaoperasi dibandingkan plasebo.

.....Background: Based on a pilot study in the Adult Heart Surgery division of Harapan Kita Heart and Vascular Center Hospital, SIRS is more common in OPCAB compared to on-pump CABG, 67% vs 33% (30 samples, 2017). Based from this result, this research conducted a clinical trial to provide dexamethasone in patients undergoing OPCAB surgery. Methods: Samples were collected consecutively in the Adult Heart Surgery division of Harapan Kita Heart and Vascular Center Hospital between August 2018 - January 2019. Samples that fulfill inclusion and exclusion criteria were randomized to dexamethasone group (n=30) and placebo group (n=30). Intervention using intravenous dexamethasone dose of 1 mg/KgBB (maximum 100 mg) or placebo using normal saline (0.9% NaCl). Statistical analysis were used independent t-test, Mann-Whitney test, fisher exact test and AUC. Results: MACE incidence in dexamethasone group compared to placebo group (RR 0.385, 95% CI: 0.157-0.945, p = 0.024). Clinical output of dexamethasone group was better than placebo group in duration of mechanical ventilation (6 (5-16) hours vs 8 (5-72) hours, p = 0.029), ICU length of stay (17.5 (12-32) hours vs 19 (13-168) hours, p = 0.028), hospital length of stay (5

(5-8) days vs 6.5 (5-30) days, $p = 0.04$) and VIS (0 (0-15) vs 5 (0-100), $p = 0.045$). As a result of the inflammatory markers, there was a significant average difference between dexamethasone group compared to the placebo group in IL-6 (217.4 pg/mL, 95% CI: 107.9-326.8, $p = 0.0001$), PCT (3.41 $\mu\text{g/L}$, 95% CI: 2.1-4.71, $p = 0.0001$) and CRP (52.3 mg/L, 95% CI: 28.8-75.8, $p = 0.0001$) In the AUC analysis there was a significant association between inflammatory markers with the incidence of MACE in IL-6 (AUC 0.728, 95% CI: 0.585-0.871, $p = 0.005$) and PCT (AUC 0.723, 95% CI: 0.578-0.868, $p = 0.007$). Conclusion: Preoperative dexamethasone OPCAB is effective to improving clinical output and controlling postoperative inflammatory reactions compared to placebo.