

Efektifitas hidrasi agresif sebagai pencegahan pankreatitis pasca endoscopic retrograde cholangiopancreatography: uji klinis acak tersamar ganda = Comparison between aggressive hydration and standar hydration in preventing pancreatitis post endoscopic retrograde cholangio pancreatography: double blind randomized clinical trial

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Abstrak

Latar Belakang : Pankreatitis pasca ERCP adalah komplikasi tersering dan menyebabkan peningkatan morbiditas dan mortalitas. Hidrasi agresif sebagai terapi pencegahan pankreatitis belum diteliti lebih lanjut. Tujuan : Mengetahui perbandingan efektivitas pencegahan pankreatitis pasca ERCP antara hidrasi agresif dengan hidrasi standar.

Metode : Uji Klinis Acak tersamar ganda, satu sentral penelitian di Pusat Endoskopi Saluran Cerna (PESC) RS Cipto Mangunkusumo pada pasien usia antara 18-60 tahun yang menjalani tindakan ERCP periode Agustus-Oktober 2018. Randomisasi manual, Teknik sampling konsekutif dilakukan untuk mengalokasikan kelompok hidrasi agresif dan hidrasi standar. Pankreatitis ditegakkan dengan kriteria Atlanta.

Hasil : Didapatkan 92 pasien yang dirandomisasi kedalam dua kelompok. Didapatkan nilai Control Event Rate (CER) sebesar 15,2%, Experiment Event Rate (EER) sebesar 4,3% Absolute Risk Reduction (ARR) 10,9% Relative Risk (RR) 0,28 Relative Risk Reduction (RRR) 71,7% Number Needed to Treat (NNT) 9.

Tidak didapatkan efek samping pada kedua kelompok. Hidrasi agresif lebih efektif dalam mencegah pankreatitis pasca ERCP walaupun secara statistik tidak bermakna.

.....Pancreatitis post ERCP is a common complication and increased morbidity and mortality. Aggressive hydration as prevention of post ERCP pancreatitis has not been fully research.

Aims : To compare effectivity between aggressive hydration and standard hydration in preventing pancreatitis post ERCP.

Design and Methods : A double blind randomized clinical trial in one center at gastrointestinal endoscopy center RSCM was conducted on patients aged between 18-60 years old that had endoscopic retrograde cholangiopancreatography in the period from August to October 2018. Consecutive manual randomization was performed to allocate aggressive hydration and standard hydration. Pancreatitis diagnosed using Atlanta criteria.

Results : Two groups with total 92 subject was randomized equally. Analyzed resulted Control Event Rate (CER) 15,2%, Experiment Event Rate (EER) 4,3%, Absolute Risk Reduction (ARR) 10,9%, Relative Risk (RR) 0,28, Relative Risk Reduction (RRR) 71,7%, Number Needed to Treat (NNT) 9. No side effect reported in this trial. Aggressive hydration more effective in perventing post ERCP pancreatitis although statistically not significant.