

Perbandingan Hasil Pengobatan dan Efek Samping Obat Antituberkulosis Kategori I antara Paduan menggunakan Dosis Harian dengan Paduan menggunakan Dosis Berselang Sebagian pada Tuberkulosis Paru = Comparison of Treatment Outcomes and Adverse Effects of Antituberculosis Drugs Category I between Daily Dose Combination and Part Daily Dose Combination in Pulmonary Tuberculosis

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Abstrak

Pendahuluan: Tuberkulosis (TB) adalah penyebab utama kematian akibat infeksi di dunia. Sejak tahun 2008 - 2017 terdapat penurunan angka keberhasilan pengobatan TB di Indonesia (< 90%). Rekomendasi pengobatan TB di Indonesia adalah paduan obat antituberkulosis (OAT) dosis berselang sebagian (2RHZE/4R3H3) atau harian (2RHZE/4RH). Menurut WHO, paduan OAT RHZE/R3H3 mempunyai angka kegagalan dan kekambuhan yang lebih tinggi. Namun, penelitian meta-analisis RCT menyatakan bahwa kedua paduan OAT mempunyai angka kegagalan dan kekambuhan yang sama. Oleh karena itu, dilakukan penelitian untuk membandingkan hasil pengobatan dan efek samping antara paduan OAT 2RHZE/2RH dengan 2RHZE/4R3H3.

Metode: Penelitian ini merupakan studi analitik observasional dengan desain cross sectional yang membandingkan hasil pengobatan dan efek samping antara paduan OAT 2RHZE/4RH dengan 2RHZE/4R3H3 pada pasien TB paru kategori I di RSUP Persahabatan periode Januari 2015 sampai Juni 2018. Data sekunder diambil dari rekam medik. Hasil pengobatan dinilai sesuai definisi dalam pedoman nasional penanggulangan TB di Indonesia dan WHO. Efek samping dinilai dari seluruh efek samping terkait OAT yang tercatat dalam rekam medik.

Hasil: Terdapat 175 pasien pada masing-masing kelompok. Pada kelompok paduan OAT 2RHZE/4RH terdapat 89.1% pasien berhasil, 13.1% sembuh, 76.0% pengobatan lengkap, 10.6% putus berobat, 0.6% gagal, dan tidak ada yang meninggal. Pada kelompok paduan OAT 2RHZE/4R3H3 terdapat 91.4% pasien berhasil, 39.4% sembuh, 52.0% lengkap, 8% putus berobat, tidak ada yang gagal, dan 0.6% meninggal. Tidak ada perbedaan bermakna untuk keberhasilan pengobatan ($p=0.470$, $OR=1.299$, $IK95\%;0.637-2.648$), putus berobat ($p=0.659$, $OR=0.758$, $IK95\%;0.365-1.577$), gagal ($p=1.000$), dan meninggal ($p=1.000$) di antara kedua kelompok. Namun, terdapat perbedaan bermakna untuk kesembuhan ($p=0.003$, $OR=2.358$, $IK95\%;1.375-5.206$) dan pengobatan lengkap ($p<0.001$, $OR=0.342$, $IK95\%;0.217-0.540$). Sebagian besar pasien mengalami efek samping pengobatan (51.1%) terutama di tahap intensif (73.2%). Pada tahap lanjutan tidak ada perbedaan bermakna kejadian efek samping antara kedua kelompok ($p=0.324$, $OR=1.386$, $IK95\%;0.723-2.657$).

Kesimpulan: Kesembuhan kelompok paduan OAT 2RHZE/4R3H3 lebih baik daripada 2RHZE/4RH, sedangkan pengobatan lengkap sebaliknya. Tidak ada perbedaan bermakna untuk keberhasilan pengobatan, putus berobat, kegagalan, meninggal, dan kejadian efek samping pada tahap lanjutan di antara kedua kelompok.

.....Introduction: Tuberculosis (TB) is the main cause of death for infectious disease in the world. Since

2008 - 2017, there was a decline of TB success rate ($< 90\%$) in Indonesia. Treatment of TB in Indonesia are using antituberculosis drugs with part daily dose combination (2RHZE/4R3H3) or daily dose combination (2RHZE/4RH). WHO concluded that 2RHZE/4R3H3 combination had higher failure and recurrence rate. However, a meta-analysis study showed that both combinations had same failure and recurrence rate. Therefore, this study is conducted to compare treatment outcomes and adverse effects between 2RHZE/4RH combination and 2RHZE/4R3H3 combination.

Method: This was an observational analytic study with cross sectional design which compared treatment outcomes and adverse effects between 2RHZE/4RH combination and 2RHZE/4R3H3 combination in pulmonary tuberculosis patient at RSUP Persahabatan period January 2015 until June 2018. Secondary data was taken from medical record. Treatment outcomes were assessed using definition in Indonesia National Guideline of TB and WHO. Adverse effects were assessed from all adverse effects that written in medical record.

Result: There are 175 patients in each group. In 2RHZE/4RH combination group, there were 89.1% patients succeed, 13.1% cured, 76.0% completed treatment, 10.6% lost to follow up, 0.6% failed and no one died. In 2RHZE/4R3H3 combination group, there were 91.4% patients succeed, 39.4% cured, 52.0% completed treatment, 8% lost to follow up, no one failed, and 0.6% died. There was no significant difference for success ($p=0.470$, $OR=1.299$, $IK_{95\%};0.637-2.648$), loss to follow up ($p=0.659$, $OR=0.758$, $IK_{95\%};0.365-1.577$), failure ($p=1.000$), and death rate ($p=1.000$) between two groups. However, there was a significant difference for cure ($p=0.003$, $OR=2.358$, $IK_{95\%};1.375-5.206$) and complete treatment rate ($p<0.001$, $OR=0.342$, $IK_{95\%};0.217-0.540$) between two groups. Most patients had adverse effects (51,5%), especially in intensive phase (73,2%). In continuation phase, there was no significant difference of adverse effects event between two groups ($p = 0.324$, $OR= 1.386$, $IK_{95\%}; 0.723-2.657$).

Conclusion: Cure rate was better in 2RHZE/4R3H3 group than 2RHZE/4RH group, for completed treatment on the contrary. There was no significant difference for success rate, loss to follow up rate, failure rate, death rate, and adverse effects event in continuation phase between two groups.