

Uji Klinik Crossover Acak Tersamar Ganda pada Pemberian Antiaritmia Bisoprolol berdasarkan Tipe Sirkadian Kontraksi Ventrikel Prematur terhadap Beban Kontraksi Ventrikel Prematur dan Variabilitas Beban Kontraksi Ventrikel Prematur = Efficacy of Morning vs Evening Bisoprolol Intake towards PVC Burden and PVC Burden Variability: A Double-blind Randomized Crossover Trial

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Abstrak

Latar belakang: F-HR-PVC merupakan KVP yang kemunculannya berbanding lurus dengan peningkatan laju nadi. Mekanisme yang mendasarinya adalah adanya variasi sirkadian sistem saraf autonom dan kadar katekolamin darah. Adanya variasi sirkadian tersebut membuka peluang untuk intervensi KVP secara kronoterapi.

Tujuan: Meneliti efektivitas kronoterapi bisoprolol pada pasien KVP idiopatik terhadap beban KVP dan variabilitas beban KVP selama 24 jam.

Metode: Penelitian ini merupakan uji klinik crossover acak tersamar ganda dengan total subjek 23 pasien dengan tipe F-HR-PVC (beban KVP 24 jam 5% dan variabilitas beban KVP >35%). Subjek penelitian dibagi menjadi dua kelompok. Kelompok sekuens 1 diberikan bisoprolol pagi hari (1 minggu pertama), dilakukan crossover, dilanjutkan pemberian bisoprolol malam hari (1 minggu kedua) sedangkan kelompok sekuens 2 menerima perlakuan sebaliknya. Evaluasi Holter 24 jam dilakukan pada akhir minggu pertama dan kedua dan dianalisis untuk membandingkan efektivitas pemberian bisoprolol sesuai kronoterapi terhadap beban KVP dan variabilitas beban KVP selama 24 jam.

Hasil: Pemberian bisoprolol baik pagi hari ($p=0,018$) maupun malam hari ($p=0,014$) dapat menurunkan beban KVP secara signifikan. Namun hanya pemberian bisoprolol pagi hari yang dapat meningkatkan variabilitas beban KVP selama 24 jam ($p=0,028$). Tidak ada perbedaan penurunan beban KVP antara pemberian bisoprolol pagi hari atau malam hari (treatment effect $-0,06 [-4,12 - 4,00]$; IK 95%, $p = 0,976$). Selain itu, variabilitas beban KVP juga tidak berbeda antara kedua kelompok perlakuan (treatment effect $6,34 [-10,41 - 23,08]$; IK 95%, $p = 0,439$).

Kesimpulan: Tidak ada perbedaan efektivitas pemberian bisoprolol pada pagi hari dibanding malam hari terhadap beban KVP maupun variabilitas beban KVP selama 24 jam

.....Background: F-HR-PVC is one of PVC circadian variation which occurrence increases linearly with baseline heart rate. The mechanism involved is considered related to the circadian mechanism which includes autonomic nerve system and catecholamine levels. The presence of circadian variation in PVC raise the potential of chronotherapeutic approach in treating PVC.

Methods: This is a double-blind randomized crossover trial with a total subject of 23 patients who have F-HR-PVC with 24-hr PVC burden 5% and PVC burden variability >35%. Subjects were divided into two sequences. Those in sequence 1 were given bisoprolol in the morning in the first week, crossed over then followed by the administration of evening bisoprolol in the second week. Meanwhile, those in sequence 2 received alternate treatment. 24-hour holter evaluation was done and analyzed to compare the efficacy of bisoprolol administration with chronotherapeutic approach toward PVC burden and its variability in 24-hr.

Results: Either morning or evening administration of bisoprolol significantly reduced the PVC burden (morning vs. evening; $p=0,018$ vs. $p=0,014$). However, only morning administration which increases the PVC burden variability in 24-hr ($p=0,028$). There is no significant difference between morning and evening administration of bisoprolol on both PVC burden (treatment effect $-0,06$ [$-4,12 - 4,00$]; CI 95%, $p = 0,976$) and PVC burden variability (treatment effect $6,34$ [$-10,41 - 23,08$]; CI 95%, $p = 0,439$) for 24 hours.

Conclusion: There was no difference in the efficacy of giving bisoprolol in the morning compared to the evening dosing on the PVC burden and the variability of PVC burden for 24 hours.