Clinical evaluation of a pacemaker algorithm that adjusts the pacing rate during sleep using activity variance

F Duru, K E Bloch, Daniel Weilenmann & R Candinas

Even though rate responsive pacemakers are able to regulate pacing rates based on sensor activity, they are set with a minimum rate that is not adjusted to provide rate decreases during sleep. The aim of this study was to evaluate the performance of the "Sleep Rate" feature, as compared to patient diaries and a validated method that identifies sleep from wrist actigraphy. In 19 patients (15 men; age 69 +/- 8 years) with Pacesetter Trilogy DR+ pacemakers, the base rate and the sleep rate were set to 80 and 50 ppm, respectively. When the patients returned 2 days later, data recorded by the pacemaker and wrist actigraph were analyzed to find the agreement in corresponding sleep/wake periods. In 17 (89%) patients, the pacemaker went into the sleep mode. The total sleep time derived from actigraphy significantly exceeded the time during which the pacemaker was in sleep mode (1156.8 +/- 83.4 vs 307.3 +/- 77.2 minutes). Frequent reversions out of the sleep mode limited the total sleep time derived from the pacemaker. Cumulative analysis of the pacemaker data showed that the maximum time in the sleep mode was 78 minutes, and exceeded 1 hour in six instances, 30 minutes in 32 instances, and 15 minutes in 83 instances. Epoch by epoch comparisons revealed a good agreement (93.6 +/- 1.8%) during wakefulness between the corresponding actigraph and pacemaker epochs. However, only 24.6 +/- 3.7% of the corresponding epochs during sleep were identical, and the overall agreement was 54.4 +/- 3.7%. Except for one patient who reported palpitations, patients did not suffer from a pacemaker rate change. The Sleep Rate feature provides rate reduction during sleep, while assuring rapid frequency response during physical activity. However, the current algorithm does not allow long periods of slow pacing rate during continuous sleep, possibly due to its conservative design and the presence of movement arousals, which has to be improved in future generation algorithms.

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