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A Pacemaker AutoSense Algorithm with Dual Thresholds

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Abstract : A pacemaker autosense algorithm with dual thresholds, one for noise or tachyarrhythmia detection (noise threshold, NT) and the other for intrinsic beat detection (sensing threshold, ST), was developed to improve the sensing performance in single pass VDD electrograms, unipolar electrograms, or atrial fibrillation detection. When a deflection in an electrogram exceeds the NT (defined as 50% of ST), the autosense algorithm with dual thresholds checks if the deflection also exceeds the ST. If it does, the autosense algorithm calculates the signal to noise ratio (SNR) of the deflection to the highest deflection detected by NT but lower than ST during the last cardiac cycle. If the SNR 2, the autosense algorithm declares an intrinsic beat detection and calculates the next ST based on the three most recent intrinsic peaks. If the SNR ≥ 2, the autosense algorithm checks the number of deflections detected by NT during the last cardiac cycle in order to determine if it is a noise detection or tachyarrhythmia detection. Usually the autosense algorithm tries to set the ST at 37.5% of the average of the three intrinsic beats, although it changes the percentage according to event classifications. The autosense algorithm was tested through computer simulation of atrial electrograms from 5 patients obtained during EP study, to simulate a worst sensing situation. The result showed that the ST levels for autosense algorithm tracked the electrogram amplitudes properly, providing more noise immunity whenever necessary. Also, the autosense algorithm with dual thresholds achieved sensing performance as good as the conventional fixed sensitivity method that was optimized retrospectively.

Key words : Autosense, Automatic pacemaker sensing, Sensitivity

INTRODUCTION

The pacemaker autosense algorithms have been introduced in an attempt to improve sensing performance without repeated programming to optimize sensitivity level [1-7]. Although the algorithms have shown acceptable sensing performance, they are still at the stage of progress. The major advantage of autosense algorithm is to achieve sensing performance comparable to a conventional fixed-sensitivity method with an optimal threshold without human intervention, by reducing the duration during which the pacemaker system operates at high sensitivities by increasing sensitivities only when necessary [4, 6].

There are several study results that suggest using a high or highest sensitivity particularly for atrial bipolar electrograms to sense low amplitude p-waves such as atrial fibrillation or single lead VDD electrograms [8-12]. The idea might be a good solution for pacemaker sensing because we could simply choose a maximum sensitivity without further consideration. However, there are contradicting study results reporting oversensing or undersensing problems at a high sensitivity in atrial electrograms [9,11,13-15], so that the practice of choosing a high sensitivity should be carefully reviewed before overspreading acceptance.

Although the bipolar lead is less prone to myopotentials and shows a better sensing capability, a considerable percentage of ventricular leads is still unipolar due to the advantages of thinner diameter, easier to place, less expensive, and less susceptible to insulation defects [15-20]. For example, the unipolar ventricular electrodes were implanted in almost 60% and 79% of pacemaker recipients in Germany and Denmark, respectively, in 1998 [21]. For unipolar lead pacemaker system, it is expected that the autosense algortihm will reduce the myopotential oversense, because of its behavior of reducing the duration during which the pacemaker system operates at high sensitivities.

Most autosense algorithms introduced so far are based on simple mechanism based on only intrinsic beat amplitude. After an intrinsic beat detection, the algorithms

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set the next sensing threshold by considering several previously detected intrinsic peaks. Since such algorithms for pacemaker or ICD sensing depend only on intrinsic amplitudes, not on noise levels, maximum sensitivity should be restricted to avoid myopotential oversense or electromagnetic interferences, thereby compromising clinical performance when low amplitude signals are encountered. The maximum sensitivities differ from device to device, depending on electrogram characteristics and device type.

In this study, we introduce an autosense algorithm with dual thresholds, one for noise or tachyarrhythmia detection(noise threshold, NT) and the other for intrinsic beat detection(sensing threshold, ST), developed to improve the sensing performance in single lead VDD electrograms, unipolar electrograms, or atrial fibrillation detection. The algorithm adjusts the sensing threhsold between intrinsic peaks and noise level, and is able to use a higher maximum sensitivity than that of simple autosense algorithm without noise level measurement capability.

Pacemaker autosense algorithm with dual thresholds

The design requirements of the pacemaker autosense algorithm with dual thresholds include that 1) the algorithm should be fully automatic, 2) the sensing performance should be as good as or better than that of conventional fixed-sensitivity methods regardless of electrogram state, and 3) the algorithm performance should be unaffected by lead type.

To meet the above requirements, we developed an autosense algorithm with dual thresholds as shown in Figure 1. In the figure, a series of three rectified intrinsic depolarization beats, A, B, and C are shown, and both sensing threshold ST and noise threshold NT are tracking the electrogram. Usually, the autosense algorithm tries to set the ST at 37.5% of the average of three most recent intrinsic peaks and sets the NT at 50% of the ST, although it changes the percentages according to event classifications.

The autosense algorithm with dual thresholds declares an intrinsic beat detection when a deflection satisfies two conditions; its amplitude exceeds the ST and the signal to noise ratio (SNR), which is defined as intrinsic beat amplitude divided by the highest deflection detected by NT but lower than ST during the last cardiac cycle, is higher than or equal to 2.

The autosense algorithm monitors the electrogram and checks if a deflection exceeds NT or ST. When deflections exceed the NT only, the number of deflections after the last intrinsic beat is counted and their highest peak is determined, continuously. When a deflection exceeds the ST, the algorithm starts the following main procedure:

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Step 1. Determine the amplitude of the deflection higher than ST
Step 2. Determine the average noise rate and the highest noise level
Step 3. Calculate SNR
  If SNR ≥ 2,
        Accept the deflection higher than ST as an intrinsic beat, and set the sensing threshold between intrinsic beat and noise
  If SNR < 2,
        If noise rate ≥500bpm or ≤URL,
              Classify the current beat as noise
        If noise rate is between URL and 500bpm,
              Classify the current beat as a tachyarrhythmia
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In step 1, the autosense algorithm determines the amplitude of the deflection that is higher than ST. In step 2, the autosense algorithm converts the number of deflections, that are higher than NT but lower than ST during the last cardiac cycle, to average noise rate in the unit of bpm(beat per minute), and determines the highest noise level as the amplitude of the highest deflection. In step 3, the autosense algorithm calculates the SNR by the amplitudes obtained in step 1 and the highest noise level determined in step 2. If the SNR is at least 2 or higher, the deflection higher than ST is accepted as an intrinsic beat. However, if the SNR is less than 2, the algorithm refers to the average noise rate, and determines if current deflections are noise or tachyarrhythmia. If the average noise rate is higher than 500bpm or lower than upper rate limit(URL), the algorithm classifies the current electrogram as noise. If the noise rate is between URL and 500bpm, the algorithm classifies the current electrogram as a tachyarrhythmia. In the autosense algorithm with dual thresholds, the 500bpm is the boundary rate to discriminate noise and tachyarrhythmia. The main procedure of the autosense algorithm is shown as a flow chart in Figure 2.

Although the algorithm tries to set the sensing level at 37.5% of the three most recent intrinsic peaks, there are 6 possible percentages of sensing level as shown in Table I. The sensing percentages are chosen for fast calculation in device hardware. The algorithm chooses the percentage

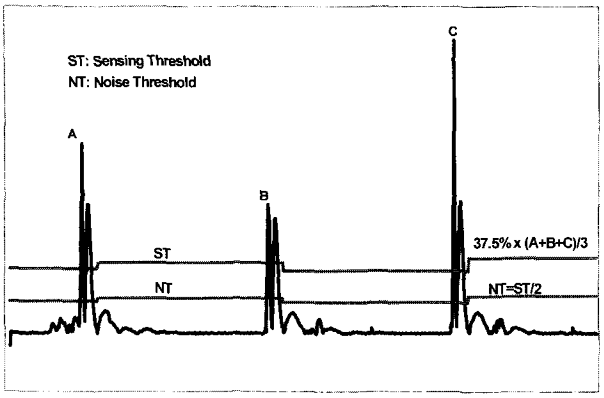

Fig. 1. The autosense algorithm sets the next sensing threshold(ST) at 37.5% of the average of three most recent intrinsic peaks and the noise threshold(NT) at 50% of ST after it determines an intrinsic beat

Table I. The percentages of sensing level in the autosense algorithm with dual thresholds. The autosense algorithm sets the sensing threshold at one of the sensing percentage of the average of three most recent intrinsic peaks according to event classification

Level	ST	NT
ST-1	75.0 %	37.50 %
ST-2	62.5 %	31.25 %
ST-3	50.0 %	25.00 %
ST-4	37.5 %	18.75 %
ST-5	25.0 %	12.50 %
ST-6	12.5 %	6.25 %

automatically based on electrogram characteristics such as noise level, tachyarrhythmia, or asystole. If deflections higher than NT but lower than ST are classified as noise, the algorithm chooses one step higher percentage of sensing level to provide more noise immunity. After choosing a higher percentage of sensing level, if no more noise is detected, the algorithm chooses a one step lower sensing level percentage until it reaches the nominal 37.5%. If the algorithm does not detect an intrinsic beat and, thereby, the pacemaker generates a pacing pulse, the algorithm chooses one step lower sensing level of 25% in order to detect low amplitude intrinsic beats, if they exist. When the algorithm classifies tachyarrhythmia, it lowers the sensing level percentage one step for effective tracking of the fast rhythm.

The detailed behavior of the autosense algorithm with dual thresholds is explained as following for different sensing situations.

1. Behavior of the autosense algorithm with dual thresholds after an intrinsic beat detection

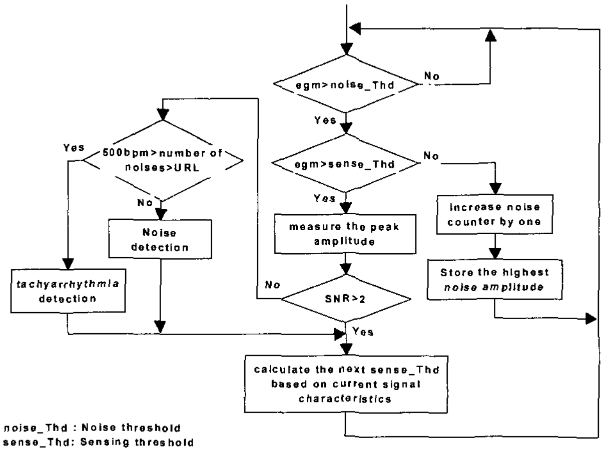

Fig. 2. Flow chart of the main procedure of autosense algorithm

The algorithm procedure after intrinsic beat detection is explained with Figure 3. After the intrinsic beat A is detected, the algorithm sets the next ST at 37.5% of the average of three most recent intrinsic peaks, as mentioned above. However, in the next interval between beats A and B, the NT detects a deflection N, that is higher than the NT but lower than ST, and the SNR (B/N) is higher than 2. Because the beat B satisfies both conditions of being an intrinsic beat, the beat B is accepted as an intrinsic beat, but the autosense algorithm sets the next sensing level at 50% of the average of three most recent intrinsic peaks, that is one step higher percentage as shown in Table I, to provide more noise immunity. Since the NT does not detect any deflection during the next interval of beats B and C, the algorithm brings the next sensing level back at 37.5%. If a deflection were detected again by NT only during beats B and C interval, the algorithm would choose one step higher sensing level of 62.5%.

2. Behavior of the autosense algorithm with dual thresholds after pacing event

The algorithm behavior after pacing event is explained with Figure 4. In the figure, the algorithm sets the sensing threshold at 37.5% after intrinsic beat detection. However, no intrinsic beat is detected within a lower rate limit(LRL), and the pacemaker generates a pacing pulse. After the pacing pulse generation, the algorithm chooses one step lower sensing percentage of 25% to find a possible low amplitude intrinsic beat and keeps it during pacing. If noises were determined during pacing, the algorithm would choose one step higher sensing level.

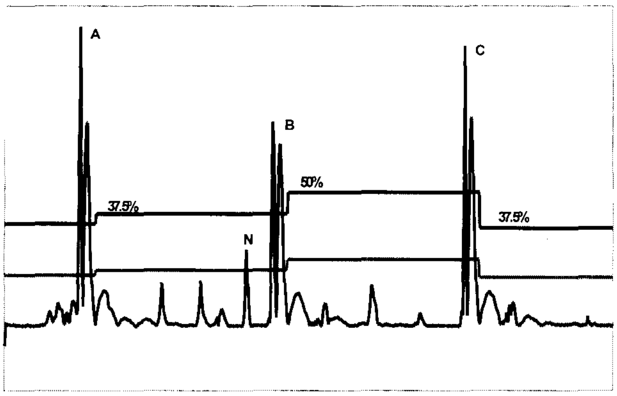

Fig. 3. Behavior of the autosense algorithm with dual thresholds after intrinsic beat detection. The algorithm sets the next ST at 37.5% of the average of three most recent intrinsic peaks. However, when the NT detects a deflection N, the autosense algorithm sets the next ST at 50% that is one step higher sensing level percentage to provide more noise immunity

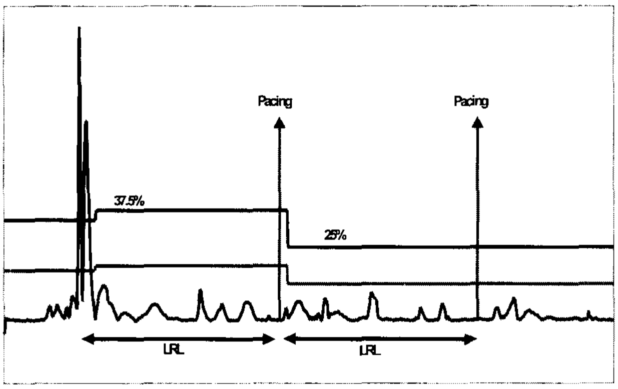

Fig. 4. Behavior of the autosense algorithm with dual thresholds after pacing event. After pacing pulse generation, the algorithm chooses one step lower sensing percentage of 25% to detect a possible low amplitude intrinsic beat and keeps

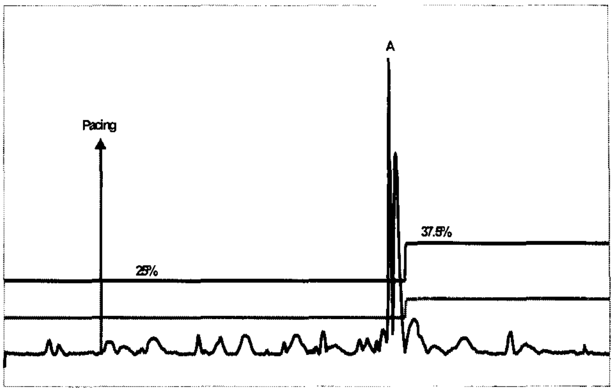

Fig. 5. Behavior of the autosense algorithm after an intrinsic beat detected after pacing event. Pacing event keeps the sensing level at 25%. After an intrinsic beat A detection, the algorithm sets the next sensing level at 37.5% of the average of three most recent intrinsic peaks

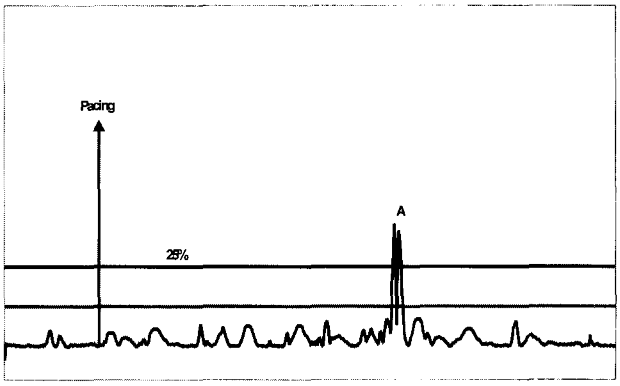

Fig. 6. Behavior of the autosense algorithm after an intrinsic beat detected after pacing event. In this case, the beat A is accepted as an intrinsic beat because it satisfies the conditions of intrinsic beat, higher than ST and SNR≥2, but the sensing level percentage does not increase because of the beat amplitude is still low, compared to previous intrinsic peaks

Figure 5 shows the algorithm behavior after an intrinsic beat detected after pacing event. After pacing pulse generation, the autosense algorithm keeps the sensing level at 25%. Before LRL is reached, an intrinsic beat A is detected and the algorithm sets the next sensing level at 37.5% of the average of three most recent intrinsic peaks. Figure 6 shows a similar situation with Figure 5, but with a lower amplitude deflection A. In this case, the beat A is accepted as an intrinsic beat because it satisfies the conditions of intrinsic beat, higher than ST and SNR≥2, but the sensing level percentage does not increase because of the beat amplitude is still low, compared to previous intrinsic peaks. The autosense algorithm requires at least two times higher amplitude than ST for bringing up the sensing level percentage at 37.5%.3. Behavior of autosense algorithm with dual thresholds in the presence of noise or tachyarrhythmia

In Figure 7, the algorithm behavior in the presence of noise is shown. After the detection of third intrinsic beat C, the algorithm sets the next sensing level at 37.5%. However, several deflections after intrinsic beat C, exceeds NT, and the deflection D exceeds ST. In this case, the deflection D is not accepted as an intrinsic beat although it exceeds ST, because the signal to noise ratio (D/N) is less than 2. After LRL, the algorithm converts the number of deflections to the average noise rate in bpm. Since the noise rate is higher than 500bpm, the

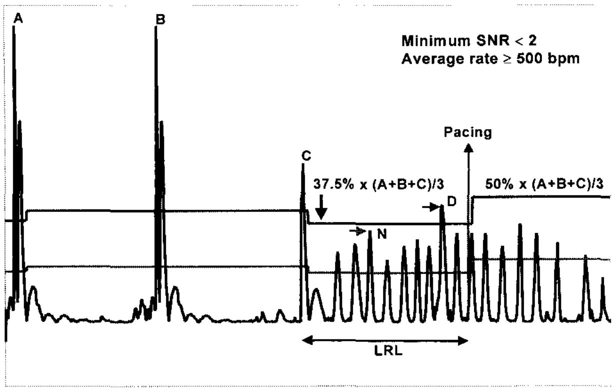

Fig. 7. Behavior of the autosense algorithm with dual thresholds in the presence of noise. The deflection D is not accepted as an intrinsic beat, because the signal to noise ratio (D/N) is less than 2. Since the average noise rate is higher than 500bpm, the algorithm considers the current deflections as noise and chooses one step higher sensing level at 50% to provide more noise immunity

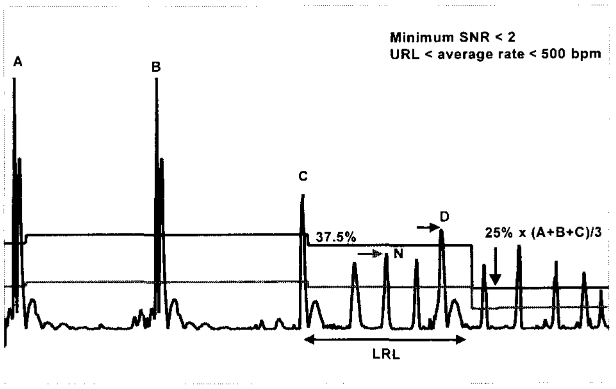

Fig. 8. Behavior of the autosense algorithm with dual thresholds in the presence of tachyarrhythmia. The average noise rate during LRL is between URL and 500bpm. Because the noise rate belongs to tachyarrhythmia rate, the algorithm declares tachyarrhythmia detection, and chooses one step lower sensing level of 25% for effective tachyarrhythmia tracking

algorithm considers the current deflections as noises and chooses one step higher sensing level at 50% to provide more noise immunity after pacing pulse generation.

In Figure 8, the algorithm behavior in the presence of tachyarrhythmia is shown. This is very similar with the case of noise as shown in Figure 7, but the average noise rate during LRL is between URL and 500bpm. Because the noise rate belongs to tachyarrhythmia rate, the algorithm declares tachyarrhythmia detection, and chooses one step lower sensing level of 25% for effective tachyarrhythmia tracking.

Simulation of the autosense algorithm with dual thresholds and the conventional fixed-sensitivity method with optimal sensing level

The autosense algorithms with dual thresholds have been tested on five human atrial electrograms obtained during EP study that were chosen to satisfy at least one of the following conditions to simulate a worst sensing situation: amplitude variation more than 60%, noticeable beat-to-beat interval variation, noise level comparable to signal level, or no synchronization between p- and r-waves. The total number of the p-waves in the five electrograms was 1978 beats.

The autosense algorithm was coded by C++ programming language and executed in a personal computer with the 5 electrograms. Also, a conventional fixed-sensitivity method with a retrospectively obtained optimal sensing threshold that minimized oversensed and undersensed beats was applied to the same electrograms.

Sensing performance of the autosense algorithm with dual thresholds and the conventional fixed-sensitivity method with optimal sensing threshold were then compared each other for each electrogram. One example of the used electrograms and its optimal sensing threshold obtained retrospectively is shown in Figure 9. The figure shows the amplitude histogram of any deflections higher than 0.58mV, and the intrinsic p-waves were identified by experienced persons with surface ECG recorded simultaneously. The optimal threshold is obtained to minimize oversensed and undersensed beats, by examining the identified p-waves and artifacts, from the histogram. The optimal sensing threshold is then applied back to the electrogram, and the number of oversensed and undersensed beats were counted and compared to those of the autosense algorithm with dual thresholds.

In order to see the benefit of the autosense algorithm with dual thresholds compared to simple autosense algorithms without noise level measurement capability, two types of simulated noise, intermittent random(muscle) noise and continuous sinusoidal(EMI) noise with various amplitudes, were added to the 5 patients atrial electrograms. After that, the autosense algorithm with dual thresholds and a simple autosense algorithm that sets the next sensing threshold at 50% of the average of most recent three intrinsic beats without noise level measurement were applied to the electrograms.

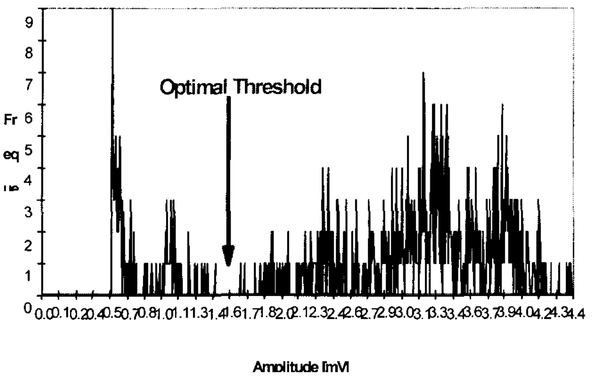

Fig. 9. Amplitude histogram of deflections in one patient electrogram used to test the autosense algorithm. The amplitudes of any deflections higher than 0.58mV including both noise and intrinsic p-waves were measured, and the optimal threshold is obtained to minimize oversensed and undersensed beats

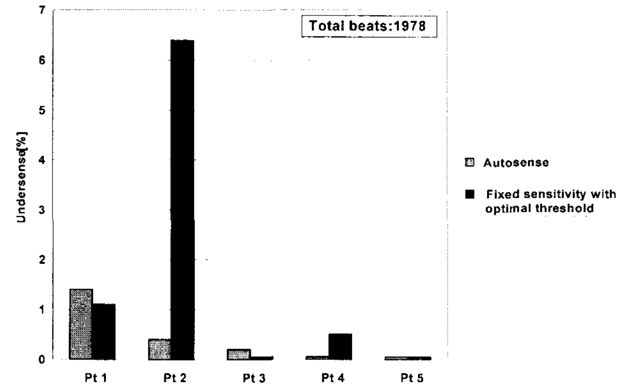

Fig. 10. Percentage of undersensed bits by the autosense algorithm with dual thresholds and conventional fixed-sensitivity method with optimal sensing threshold

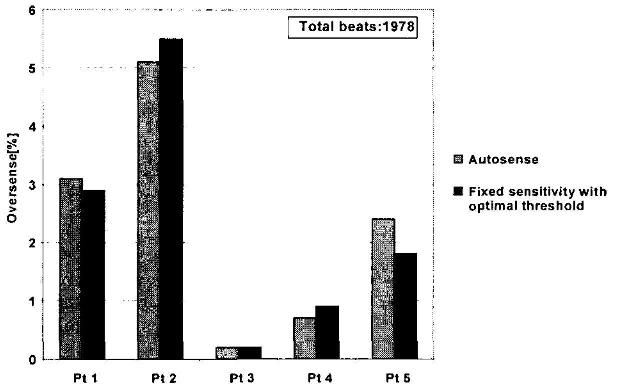

Fig. 11. Percentage of oversensed bits by the autosense algorithm with dual thresholds and conventional fixed-sensitivity method with optimal sensing threshold

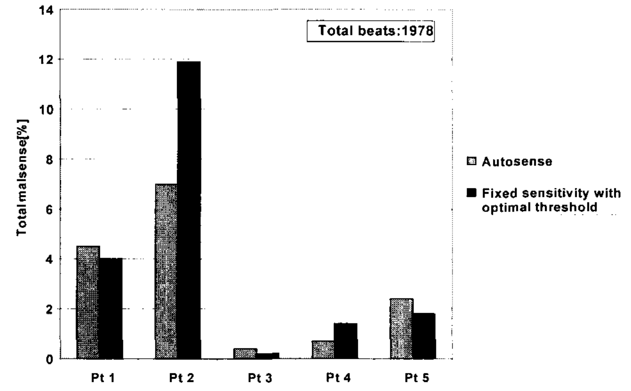

Fig. 12. Percentage of the sum of undersensed and oversensed bits by the autosense algorithm with dual thresholds and conventional fixed-sensitivity method with optimal sensing threshold

RESULTS

The sensing performance of the autosense algorithm with dual thresholds is compared to that of fixed-sensitivity method with optimal threshold in Figure 10, 11, and 12. In Figure 10, the percentage of undersensed bits by both methods is compared for each electrogram. In patient 2, the autosense algorithm reduces the undersensed beats greatly compared to the fixed-sensitivity method, while they are comparable in other patients. The electrogram characteristic of patient 2 includes severe p-wave amplitudes variation and high amplitude far-fields from ventricle without synchronization between p- and r-waves, which are higher than reduced p-wave amplitudes occasionally.

Figure 11 shows the percentage of oversensed beats for each patient. Although the fixed sensitivity method with optimal threshold performed slightly better in patient 1 and patient 5, the overall performance does not show significant difference. Figure 12 shows the percentage of the sum of undersensed and oversensed beats. As can be seen, there is no significant difference by both methods in 4 patients, while the autosense algorithm performed better clearly in patient 2.

Figure 13 and 14 show the behavior of the autosense algorithm with dual thresholds and a simple autosense algorithm that sets the sensing threshold at 50% of the average of most recent three intrinsic beats regardless of noise level. Figure 13 shows the case of simulated intermittent random(muscle) noise added to an electrogram and Figure 14 shows the case of continuous sinusoidal (EMI) noise added. In the figures, the dark line is the

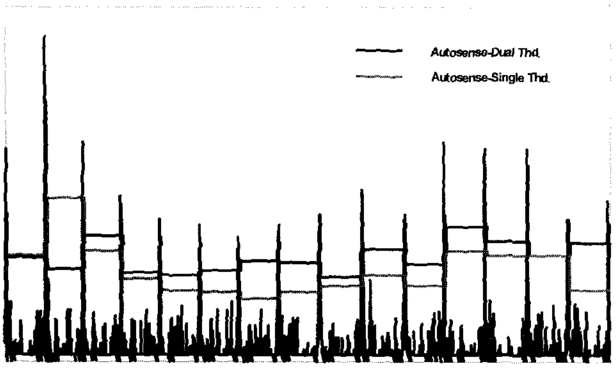

Fig. 13. Behaviors of the autosense algorithm with dual thresholds(dark-lines) and simple autosense algorithm without noise level measurement(light-lines) when simulated muscle noise is added to the electrogram

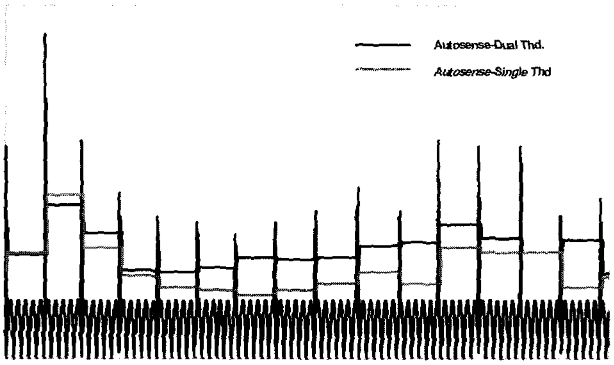

Fig. 14. Behaviors of the autosense algorithm with dual thresholds(dark-lines) and simple autosense algorithm without noise level measurement capability(light-lines) when simulated continuous sinusoidal EMI noise is added

sensing threshold determined by the autosense algorithm with dual thresholds and the light line is the threshold determined by simple autosense algorithm. As can be seen in the figures, the autosense algorithm with dual thresholds sets the sensing level(dark-lines) above the noise level to avoid noise oversenses, while the simple autosense algorithm without noise level measurement tracks the electrogram amplitudes blindly regardless of noise level. While the automatic sensing algorithm with dual thresholds maintained the sensing threshold at least 50% above the noise level, the simple autosense algorithm maintained it 10% in the electrograms.

DISCUSSION

Although the autosense algorithm with dual thresholds shows a comparable performance to the fixed sensitivity method with optimal threshold, the result means much more than that because the autosense algorithm operated fully automatically and the retrospectively obtained optimal sensing threshold in the fixed sensitivity method can hardly obtainable in practice from a couple of intrinsic amplitude measurement during pacemaker implantation or patient follow-ups.

At present, it is somewhat skeptical if autosense algorithm is really beneficial for pacemakers. However, if the sensing performance of automatic sensing algorithm is as good as or better than fixed-sensitivity method with optimal threshold, as we saw with the limited data set chosen to simulate a worst sensing situation, it will be a great benefit for both pacemaker patients and physicians. Patients will enjoy the best possible sensing performance comparable to an optimal sensing threshold that is hardly obtainable in conventional fixed sensitivity method. And for physicians, they can save time and remove the endeavor for selecting best sensing threshold based on a couple of intrinsic amplitude measurement. In addition, the good sensing will provide better operating environment for advanced features such as mode switching or antitachycardia pacing.

Because the autosense algorithm with dual thresholds has a capability to monitor the noise level, the maximum sensitivity of the algorithm can be higher than conventional fixed method or simple autosense algorithm without noise measurement capability, and it will be a great benefit particularly for atrial tachyarrhythmia detection or single-pass VDD sensing. Also, as we saw in Figure 13 and 14, the algorithm capability to provide more noise immunity for noisy electrograms will greatly reduce possible oversensing problems in unipolar lead ventricular electrograms.

Although the electrogram data set used in this study to test the autosense algorithm is limited in number, it has shown that the autosense algorithm with dual thresholds can be a beneficial pacemaker feature that provides an opportunity to improve sensing performance and operates without human intervention. Therefore, intense study with a large number of various clinical electrograms should be followed for this potentially valuable feature toward a better pacemaker.

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