A Novel System and Methodology for Continuous Ambulatory Monitoring of Gastric Slow Waves

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Introduction

Gastric contractions are initiated and coordinated by an underlying bioelectrical activity, termed slow waves (SWs). Dysrhythmias of SWs have been associated with gastroparesis (Gp). Gastric electrical stimulation (GES) is an option to alleviate the Gp symptoms. However, various researchers have reported conflicting therapeutic effects, and the mechanisms of action are not fully understood. As a result a novel methodology to objectively document the GES effect is required. We have developed a system and methodology to chronically monitor SWs.

System Architecture

The system consists of a portable front-end module, which directly connects to SW acquiring electrodes, and can wirelessly transmit data to a back-end receiver, through an ISM RF transceiver; and a back-end module connected to a PC to display real-time data and store for off-line analysis. The portable module has four input channels where low-amplitude and low-frequency SWs propagate through the lead electrodes from the stomach to the battery-powered front-end module. Besides, the module also operates independently by logging data into a micro SD memory card.

Experimental Procedure

5 patients who received a temporary GES device via endoscopy—prior to having a permanent stimulator—participated in this study. During endoscopy, 2 electrodes and leads were placed- a proximal and distal. The electrodes were secured to the gastric mucosa with clips and the leads exited via the nose. One of the leads connected to the GES and the other one was connected to the recording system. The SWs were recorded wirelessly in the recovery room for short periods (approximately 10 min) before and after turning on the stimulator. Then each patient received a portable module (placed in a plastic pouch) that was set in the data-logging mode. Patients returned in ~ 5 days later.

Acknowledgements

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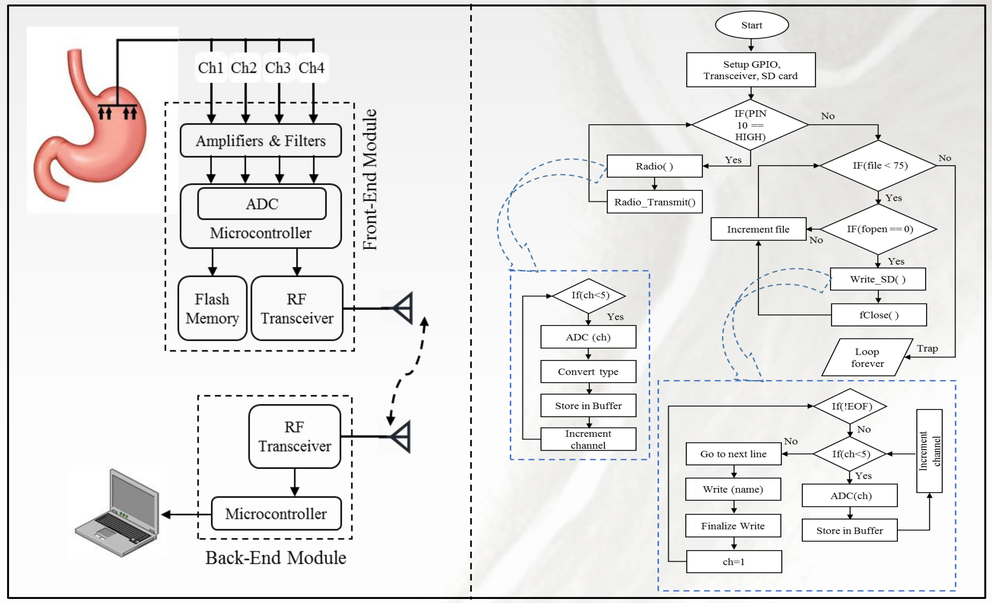

Fig. 1. Left: The block diagram of the system is composed of a front-end, back-end, and a computer. The system can record gastric slow waves from 3 channels, and stimulate the stomach through one channel. Right: The flow chart shows the front-end function, consisting of wireless data transmission to the back-end module, as well as storing data to a micro SD memory card for off-line analysis.

Results

The encased portable system measures 8×6×4 cm^3 and has the sampling rate of 58 and 24 in the wireless and data-logging modes, respectively. Signals from 4 patients were recorded and analyzed successfully in terms of frequency and amplitudes. The signal from the fifth patient was not representative, because the impedance of the implanted electrode breached the allowed threshold. The average frequency of the SWs measured as 3.1±0.2 cpm when the patients were in the recovery room, and before the GES was turned on. This frequency did not change in 3 of the patients after the GES was turned on. The frequency, amplitude, and shape of the SWs varied between the patients, and for each patient, depending on fed and fast states. Figure 3 shows the recorded signals from one of the patients for approximately 12 hours. The arrows show the feeding time based on the patient diary, and the inset shows the selected period for 7 minutes prior to feeding with the frequency of 3.1 cpm.

Conclusions

❖**A multi-channel low-power wireless device for monitoring the gastric SWs has been developed and validated in clinical settings. The developed system and methodology enables physicians to document the SWs during the temporary GES.**

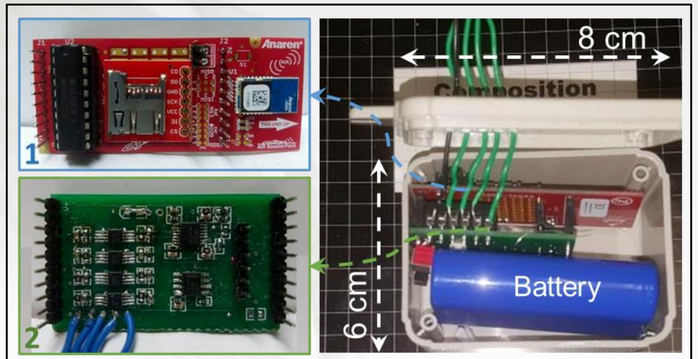

Fig. 2. The Front-end Module: Consisting of (1) Microcontroller and Transceiver board and (2) Signal conditioning board

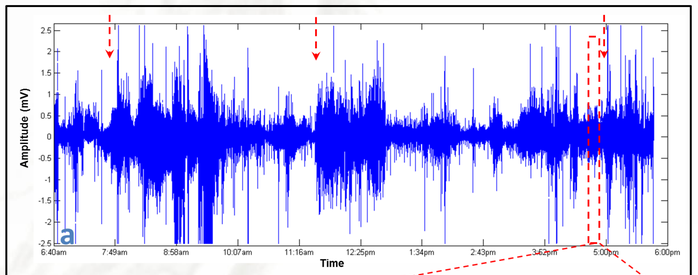

Fig. 3. Slow waves recorded from patient #3: (a) 12 hours of slow waves. Red arrow shows the feeding times, corresponding to breakfast, lunch & dinner, respectively. (b) A selected 7 minutes period before dinner. 21 peaks can be seen corresponding to 3 cpm.

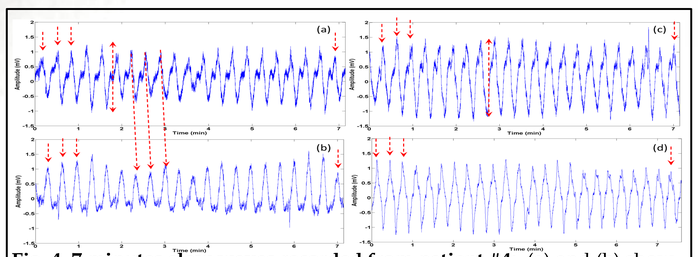

Fig. 4. 7 minutes slow waves recorded from patient #4: (a) and (b) show recordings from proximal and distal electrodes while the reference electrode was outside the body. (c) and (d) show the signal from the proximal electrode, before and after turning on the stimulator, respectively, while the reference electrode was inside the stomach.