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Gut motility, transit and pH: How different are we?

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Small intestine (SI) motility, transit times and pH can have implications on the absorption of poorly soluble drugs. Utilizing novel approaches, we investigated these physiological parameters in humans. The small bowel video capsule endoscope (VCE) allows visualization of the entire SI and the wireless motility capsule (SmartPill™, Medtronic, Minneapolis, MN) houses sensors that provide real-time measurements of temperature, pressure and pH of the immediate gastrointestinal (GI) luminal environment. Our findings illustrate that in some healthy subjects, pH in the proximal SI does not rise uniformly but is characterized by large fluctuations. In a third of healthy subjects, the pHmedian was 6.0 (5th, 95th percentiles 3.09, 7.06) and fluctuated over a mean period of 28 min. These pH changes can have implications on the supersaturation and precipitation of weakly basic drugs. Large inter-individual variability in the frequency of pressure activity (Ct) and area under the pressure curve (AUC) is observed in the proximal SI of healthy subjects and patients with constipation. Median AUC was 3996 mmHg s−1 (5th, 95th percentiles 948, 16866 mmHg s−1) in these two populations combined. An inverse correlation was observed between AUC and small intestinal transit times (SITT) at r=−0.49, $p < 1\times10-6$, that is a moderate correlation suggesting longer SITT with lower pressure activity. The inter-individual variations in SI pressure activity may have implications on the disintegration/dissolution of oral modified release (MR) dosage forms. The median SITT of human subjects as determined using VCE was 208 min, with times ranging from 50 to 460 min. This large inter-subject variability in transit times may explain the variability in bioavailability observed from some MR preparations. Our improved understanding of GI transit times, pH and pressure activities can be utilized in in silico and in vitro drug release and absorption models for oral drug delivery systems.

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