

minipig as an alternative is comparable to dog in cardiovascular safety pharmacology. **METHODS** Beagle dogs and Chinese Miniature Experiment Pigs were implanted with telemetry transmitters and the influences of the procedures of gavage administration, feeding and circadian cycle on ECG signal quality, blood pressure, heart rate, body temperature and locomotor activity were investigated during a 12-h light/12-h dark recording period. **RESULTS** The ECG signal quality from telemetry minipig was superior to dog. Decreased ECG signal quality, elevated HR, BP and locomotor activity were associated with the procedure of gavage administration and feeding in both species. The ECG signal quality, BP and locomotor activity were recovered much faster in minipigs than in dogs both after gavage and feeding. A residual elevation of HR was found in minipigs lasting about 4 h post-feeding. There was a clear circadian rhythm of locomotor activity in both species and the minipig was less active during the light period compared to dogs. A significant increased body temperature during the dark period not associated with feeding was observed in minipigs. **CONCLUSION** Our results indicate that the telemetry freely-moving Chinese experimental minipig is a valuable alternative to beagle dog for cardiovascular safety pharmacology studies.

**Foundation item:** The project supported by the National Key Project on Drug Development from the Ministry of Science and Technology of China (2009ZX09501-034)

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## T4 食品安全与营养

### T4.1 营养素可耐受最高摄入量的制定与相关研究进展

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**摘要:** 营养素可耐受最高摄入量是指特定人群平均每日摄入某种营养素的最高限量。即只要摄入量低于“可耐受最高摄入量(UL)”, 对该人群中的几乎所有的健康个体都不至于产生有害效应。美国食品营养委员会(US FNB)对营养素的需要量和可耐受量进行大量评价后采用了“可耐受最高摄入量(UL)”这一术语。英国维生素矿物质专家委员会(UK EVM)则对维生素和矿物质采用“最高安全限量(Safe Upper Limit, SUL)”的术语。营养素 UL 的特殊性 营养素 UL 值的制定与其他外源性物质限量制定的区别: 因营养素摄入较高和摄入较低时均可能存在风险, 即存在两条不同的摄入-反应曲线, 且相互独立、具有不同的机制和通路, 而外源性物质低于界值的摄入一般不造成危害; 营养素 UL 随着年龄、生理特点和特定人群的不同而变化; 对于外源性化学物质, 一般采用比较保守的不确定系数(即 10 倍种属差异, 10 倍个体变异), 而营养素不确定系数的设定需考虑多方面的因素综合决定。营养素 UL 的制定原则与步骤 UL 的制定应基于人体在不同暴露情况下发生变化的特征进行评估的结果, 即应遵循风险评估的原则和步骤: 即危害识别、危害特征描述(剂量反应评估)、暴露评估(包括不确定性的确定)、风险特征描述。营养素 UL 的制定的局限 上述风险评估法不适用于尚未发现有不良健康作用的营养素; 尚未发现有“无风险摄入量水平”的营养素; 现有资料表明, 导致风险的摄入量水平与生物所需或对健康有益的摄入量水平有重叠的营养素。营养素 UL 制定的方法进展 针对上述局限性, 目前各国制定 UL 值采用了未发现不良健康效应营养素-OSL/HOI 法。此方法较适用于尚未发现有不良健康作用的营养素及“非传统性营养素”的 UL 值制定。

**基金项目:** 国家自然科学基金重点项目(81030053)

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