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## 控制呼吸持续性监护仪临床应用的可行性和有效性

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**[摘要]** **目的:** 观察利用人工气道内温度节律性变化原理设计的控制呼吸持续性监护仪在不同人群和不同人工气道内的应用, 探讨其监测控制呼吸持续性的可行性和有效性, 为临床呼吸监测提供新方法。**方法:** 选择择期行全身麻醉术的成人患者60例, 1~3岁幼儿患者30例, 美国麻醉师协会(ASA)分级I-II级; 60例成人患者随机分为成人气管插管组(ATI组)和成人喉罩组(ALM组), 每组30例, 1~3岁幼儿患者30例设为幼儿气管插管组(CTI组)。全麻诱导后, CTI组和ATI组患者行气管插管, ALM组患者置入喉罩, 连接麻醉机行机械通气, 连接控制呼吸持续性监护仪, 观察监护仪是否能探测出各组患者呼吸频率(RR), 比较各组监护仪探测的RR和麻醉机设定频率; 3组患者均于手术开始前模拟呼吸回路断开、麻醉机手控未转换为机控和呼吸回路缓慢漏气3种临床常见控制呼吸持续性改变场景, 比较各组间监护仪发出报警方式和报警时间。**结果:** 3组患者应用控制呼吸持续性监护仪均能检测出RR, 各组内患者RR和麻醉机设定频率比较差异无统计学意义( $P>0.05$ )。在模拟3种常见呼吸持续性改变的场景中, 3组患者呼吸持续性监护仪均发出内容为“注意, 呼吸停止”的人工语音报警信号, 报警信号均被注意到, ATI组和ALM组控制呼吸持续性监护仪开始报警时间比较差异无统计学意义( $P>0.05$ )。与回路缓慢漏气比较, 同一组患者呼吸回路断开和手控未转换为机控场景时开始报警时间缩短( $P<0.05$ )。**结论:** 在不同人群和不同人工气道内利用探测人工气道内温度节律性升降变化原理设计的控制呼吸持续性监护仪临床应用具有可行性及有效性, 可为术中呼吸持续性监测和保障呼吸安全提供新方法。

**[关键词]** 全身麻醉; 呼吸频率; 控制呼吸持续性; 监护仪; 呼吸气流温度

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## Feasibility and efficacy of controlled respiratory persistence monitor in clinical application

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**ABSTRACT** **Objective:** To observe the application of the controlled respiratory persistence monitor designed based on the principle of rhythmic temperature variations in artificial airways among different populations and in various artificial airways, and to discuss the feasibility and efficacy of monitoring controlled respiration persistence, and to provide a new method for the clinical respiratory monitoring. **Methods:** A total of 60 adult patients scheduled for general anesthesia, and 30 pediatric patients aged from 1 to 3 years old, classified as American Society of Anesthesiologists (ASA) I-II, were selected. A total of 60 adult patients were randomly divided into adult tracheal intubation (ATI) group and adult laryngeal

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mask(ALM) group, and there were 30 cases in each group. Additionally, 30 pediatric patients aged from 1 to 3 years old were regarded as pediatric tracheal intubation (CTI) group. After induction of general anesthesia, the patients in CTI and ATI groups were underwent tracheal intubation, while the patients in ALM group were given a laryngeal mask inserted and were connected to the anesthesia machine for mechanical ventilation. Whether or not the device could detect the respiratory rate (RR) of the patients in various groups was observed; the RR detected by the device and the frequency set on the anesthesia machine in various groups were compared. All the patients in three groups were simulated three common clinical scenarios of continuous respiration changes before surgery: disconnection of the breathing circuit, failure to switch from manual to mechanical control on the anesthesia machine, and slow air leakage in the breathing circuit. The ways to report the alert and start time of the alarm by the monitors were compared. **Results:** The controlled respiratory persistence monitor was able to detect the RR of the patients in three groups, and there was no significantly difference between the RR detected by the device and the frequency set on the anesthesia machine ( $P>0.05$ ). In the simulated scenarios of common respiratory persistence changes, all the patients in three groups received an artificial voice alarm signaling "Attention, breathing has stopped.", which was acknowledged. There was no significant difference in the start time of alarm of the controlled respiratory persistence monitor between ATI group and ALM group ( $P>0.05$ ). Compared with the start time of alarm of the patients in the same group across different scenarios, compared with slow air leakage in the breathing circuit, the start time to alarm for circuit disconnection and failure to switch from manual to mechanical control was shorter ( $P<0.05$ ). **Conclusion:** The clinical application of the controlled respiratory persistence monitor device designed based on the principle of detecting rhythmic temperature variations within artificial airways is feasible and effective in different populations and artificial airways. This device offers a new method for monitoring the respiratory continuity and ensuring the respiratory safety during surgery.

**KEYWORDS** General anesthesia; Respiratory rate; Controlled respiratory persistence; Monitor; Respiratory airflow temperature

控制呼吸持续性是指暂时或长期丧失自主呼吸需要由呼吸机供氧的持续状态,是确保患者生命安全的重要措施。但临床工作中存在许多因素产生呼吸持续性中断的风险<sup>[1]</sup>。针对呼吸持续性的监测是防止发生供氧中断的必要措施<sup>[2]</sup>。虽然现有的监测项目(脉搏血氧饱和度和呼吸末二氧化碳分压等)包含着与呼吸有关的内容<sup>[3-5]</sup>,但针对呼吸持续性监测存在敏感度和警示度不足的问题。呼吸频率(respiratory rate, RR)是重要的生命体征,监测RR是判断人生命体征状态的重要路径,也是睡眠呼吸暂停综合征等疾病诊断的重要依据<sup>[6-9]</sup>,目前有多种方法监测RR<sup>[10-11]</sup>。HAKIMI等<sup>[12]</sup>在新生儿近红外光谱信号中通过监测系统同步记录不同生理来源的脑灌注和呼吸信息,同时综合分析呼吸对大脑血流动力学的影响;ADDISON等<sup>[13]</sup>基于深度传感器系统对RR进行精确的非接触监测;NUNZIA等<sup>[14]</sup>利用数码相机识别胸壁运动的呼吸模式对神经肌肉疾病患者进行呼吸监测;YOO等<sup>[15]</sup>应用光纤传感器在磁共振成像

(magnetic resonance imaging, MRI)检查中监测呼吸;BAI等<sup>[16]</sup>应用纱线温度传感器和普通织物口罩制备了可以监测人体呼吸信号的传感器口罩,能够准确区分正常呼吸、深呼吸和说话时快速呼吸等不同呼吸状态。健康人体温约为37℃,呼出气体温度约为31℃~35℃,肺泡气温度和呼出气体温度之间存在2℃~6℃的差异<sup>[17]</sup>。研究<sup>[18]</sup>显示:吸入空气和呼出空气之间的温差可高达15℃。本文作者研发了控制呼吸持续性监护仪,利用人工气道内呼吸气流温度节律性升降的原理计算RR,通过观察RR对控制呼吸持续性进行监测,探讨该监护仪临床应用的可行性和有效性,为临床控制呼吸持续性监测提供新方法。

## 1 资料与方法

### 1.1 控制呼吸持续性监护仪的设计原理和研制

在临床麻醉中观察到控制呼吸条件下人工气道中每个呼吸周期存在规律性的温度变化,而呼吸持续性丧失(气流中断)后,气管插管内温度变化规律



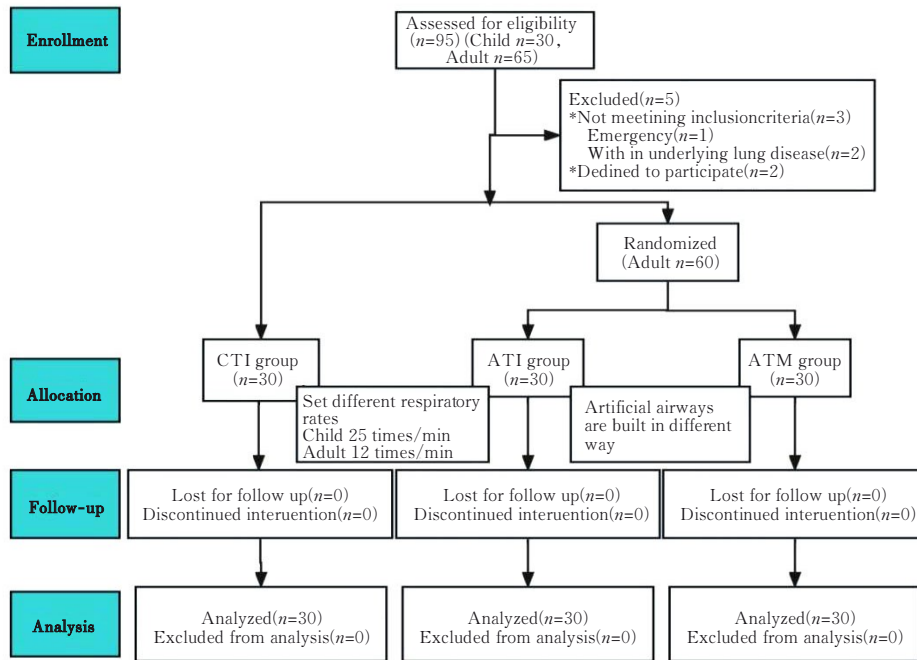
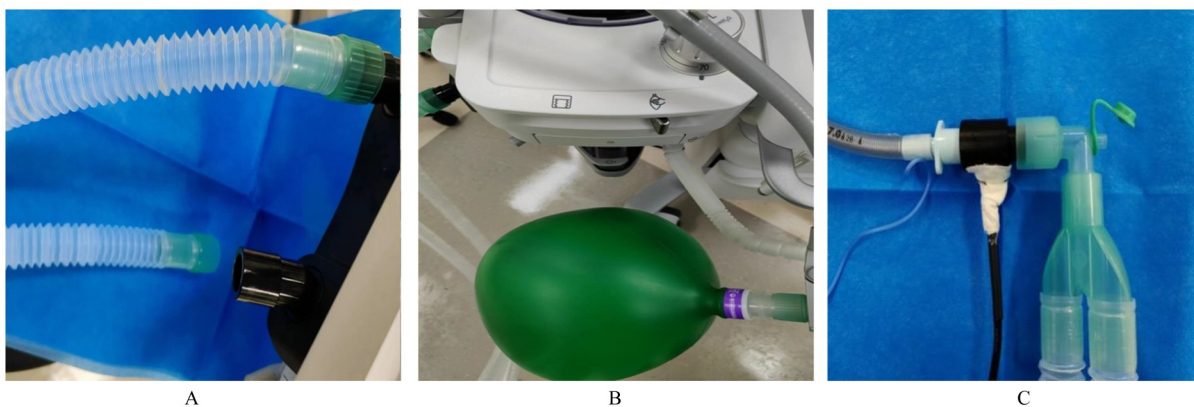


图4 临床试验流程图

Fig. 4 Flow diagram of clinical experiment



A: Breathing circuit disconnected; B: Manual control not converted to mechanical control; C: Slowly air leakage in breathing circuit.

图5 各组患者术前模拟3种呼吸持续性改变场景

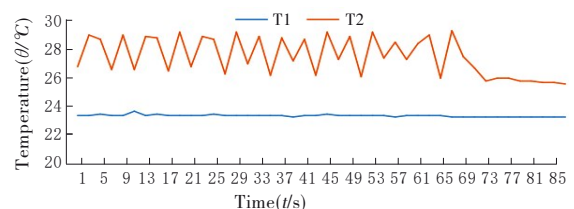
Fig. 5 Three simulated forms of respiratory persistence change of patients before surgery

学意义。

## 2 结果

**2.1 监护仪设计原理验证** 控制呼吸条件下人工气道中每个呼吸周期存在温度的规律性变化, 而呼吸持续性丧失(气流中断)后, 气管插管内温度变化规律也即刻丧失。见图6。

ATI组30例患者, 口腔温度 $36.2\text{ }^{\circ}\text{C}\sim 36.8\text{ }^{\circ}\text{C}$ , 气管导管开口处气体最高温度( $29.84\text{ }^{\circ}\text{C}\pm 0.70\text{ }^{\circ}\text{C}$ )与最低温度( $26.92\text{ }^{\circ}\text{C}\pm 0.70\text{ }^{\circ}\text{C}$ )的差值



Curve T1 represented input gas temperature of anesthesia machine; Curve T2 represented fluctuation pattern of gas temperature in artificial airway.

图6 呼吸回路内温度变化折线图

Fig. 6 Line diagram of temperature change in breathing circuit

为  $2.92\text{ }^{\circ}\text{C}\pm 0.45\text{ }^{\circ}\text{C}$ 。

**2.2 监护仪准确性验证结果** 3组患者应用呼吸持续性监护仪均可检测出控制呼吸气流温度变化所形成的RR, 3组患者RR与麻醉机设定频率比较差异无统计学意义 ( $P>0.05$ )。见表1。

**2.3 监护仪有效性验证结果** 在模拟3种常见呼吸持续性改变的场景中, 3组患者呼吸持续性监护

仪均发出内容为“注意, 呼吸停止”的人工语音报警信号, 报警信号均被注意到。ATI组与ALM组患者应用的监护仪开始报警时间比较差异无统计学意义 ( $P>0.05$ )。在同一组内比较3种场景开始报警时间, 与回路缓慢漏气比较, 呼吸回路断开和手控未转换为机控开始报警时间缩短 ( $P<0.05$ )。见表2。

表1 3组患者控制呼吸持续性监护仪60s内测定RR和麻醉机设定频率

Tab.1 RR and frequencies set by anesthesia machine of patients in three groups within 60 s detected by controlled respiratory persistence monitor ( $n=30, \text{min}^{-1}$ )

Group	RR detected by monitor [M(P25, P75)]	Frequency set by anesthesia machine	Z	P
CTI	25.00(25.00, 25.00)	25	-0.460	0.646
ATI	12.00(12.00, 12.00)	12	-1.755	0.079
ALM	12.00(12.00, 12.00)	12	-1.572	0.110

表2 模拟3种呼吸持续性改变场景各组控制呼吸持续性监护仪开始报警时间

Tab.2 Start time of alarm of controlled respiratory persistence monitors in various groups during simulating three forms of respiratory persistence change ( $n=30, \bar{x}\pm s, t/s$ )

Group	Start time of alarm		
	Disconnection of breathing circuit	Failure to switch from manual to mechanical control	Slow air leakage in breathing circuit
CTI	7.739 $\pm$ 0.344*	9.223 $\pm$ 0.523*	16.409 $\pm$ 0.462
ATI	15.120 $\pm$ 1.285*	18.428 $\pm$ 0.995*	33.137 $\pm$ 0.980
ALM	15.295 $\pm$ 0.568*	18.126 $\pm$ 0.902*	33.306 $\pm$ 1.082

\* $P<0.05$  compared with slow air leakage in breathing circuit.

### 3 讨论

机械通气的有效实施可实现充分的气体交换, 同时减少对患者的不利影响<sup>[19]</sup>, 控制呼吸持续稳定对维护患者术中生命安全至关重要。呼吸持续性的本质是气体的周期性进出于肺泡和气管, 探测呼吸的传感器可感知气流中某种物理量, 如流量、声学、温度、湿度、光强度、应变和移动测量等<sup>[20]</sup>。上述物理量在气流进出人体时具有各自的特点, 如在呼吸过程中进出人体的气流有不同流量或速度<sup>[20]</sup>; 吸入空气的相对湿度为40%~80%, 而呼出的空气经蒸气饱和, 相对湿度为100%<sup>[21]</sup>, 吸入的空气中含有约21%O<sub>2</sub>, 而呼出的气体中含有约16%O<sub>2</sub>和5%CO<sub>2</sub><sup>[22]</sup>, 在呼吸过程中空气进入肺部导致胸部膨胀至7cm<sup>[23]</sup>。本文作者设计的监护仪应用高敏热量传感器探测呼吸气流中的温度变化,

由于人体恒温, 呼出气流携带相对稳定的热量, 吸入气流与呼出气流存在温度差<sup>[17-18]</sup>, 每个控制呼吸周期中温度会出现升降变化。所以呼吸气流温度变化规律可代表呼吸气流的持续性。研究<sup>[24]</sup>显示: 基于呼吸气流温差的传感器较少, 主要考虑吸入气流的温度受环境温度变化影响较大。本文作者研制的控制呼吸持续性监护仪的应用场景是在手术室内建立人工气道的全麻手术, 手术室温度相对恒定, 减轻了环境温度变化对监护仪准确性的影响, 高敏温度传感器将人工气道内温度变化电信号传输到中央处理器 (central processing unit, CPU) 处理器, 通过傅里叶变换公式计算出温度上升和下降的时间, 最后计算出RR。呼吸气流中的温度可以代表气流本身, 当某种因素导致呼吸气流中断或减小, 监护仪探测到的呼吸气流温差小于设定温差阈值, 即可判断控制呼吸持续性异常, 监护仪启动报警诊

断功能,发出内容为“注意,呼吸停止”的人工语音报警信号,提高工作人员对报警的敏感性。清晰的语音报警方式简单明了且通俗易懂,适合用于最紧急情况,即紧急程度为“即刻”的报警实践中,报警提示情况紧急需要马上处理<sup>[25]</sup>。

QUATRARA等<sup>[26]</sup>研究表明:RR越慢,吸入气流与人体温度交换越充分,口腔呼出气流温度越高。考虑到RR对呼吸气流温度交换的影响,结合婴幼儿RR快和潮气量小的特点设置CTI组,结果显示:该监护仪在RR快且潮气量小的情况下仍然可以准确检测RR。本研究结果显示:各组麻醉机设定的频率与监护仪检测RR比较差异均无统计学意义,说明监护仪检测RR与麻醉机设定频率一致,其监测结果准确。因为呼吸气流温差存在于手术的全部时程,可见呼吸持续性监护仪工作原理的背景具有可靠性。

研究<sup>[27-29]</sup>显示:麻醉意外事故最常见的原因是缺氧和CO<sub>2</sub>蓄积,通气失败和缺氧严重者可导致患者死亡,所以呼吸持续性监测尤为重要。临床常见的导致控制呼吸持续性改变因素较多,如麻醉机故障、头颈部手术因术者操作导致麻醉机呼吸回路脱落、麻醉医生建立人工气道后常因故未及时将麻醉机手控状态转换为机控状态和呼吸回路连接气体分析的密闭帽脱离导致回路缓慢漏气等。本研究中,设计3种临床麻醉中常见的呼吸持续性中断的场景,即呼吸回路断开、麻醉机手控未转换为机控和回路缓慢漏气。本研究结果显示:在不同场景中,3组监护仪均发出人工语音警报,ATI组和ALM组开始报警时间比较差异无统计学意义,表明监护仪针对威胁患者生命安全的常见呼吸持续性中断的监测具有敏感性和有效性,且发出报警的敏感性不受人工气道种类的影响,可应用于临床麻醉监测控制呼吸意外中断。当麻醉机呼吸回路已与气管插管连接但未将手控模式及时转换到机控模式时,麻醉机供气持续灌入肺内,而没有呼出气流,气管插管中温度恒定,无升降变化的节律性。肺内高压导致右心阻力升高左心血流减少甚至中断,将引起严重心律失常或心脏骤停事件,而此时生命监护仪显示血氧饱和度正常,麻醉机无报警,表明现有监护项目存在监测盲区。在本研究模拟的该场景中,呼吸持续性监护仪在20s内报警,显示出该监护仪设计原理具有独特的优势,可弥补现有监护的不足。本研究中,3组监护仪在回路缓慢漏

气试验中启动报警时间明显长于呼吸回路断开和麻醉机手控未转换为机控,是因为在回路缓慢漏气时,仍有气流进出人工气道,监护仪仍可探测到呼吸气流的温度变化,随漏气累积量逐渐增大,人工气道开口处温差逐渐减小,当小于设定阈值,即可启动报警,提示控制呼吸持续性改变。本研究中控制呼吸持续性监护仪的设计首创性地采用呼吸气流温差,设定温差阈值,当温差小于阈值而不是呼吸气流完全消失时即开始报警,更有利于提高控制呼吸持续性监测的安全性。

受客观条件的限制,本试验存在观察的人工气道种类有限、单中心样本和各组样本量较少的局限性,为进一步验证该监护仪的可靠性、普适性和稳定性,今后应进行多中心和大样本的试验研究。另外,在无创通气和撤除人工气道后患者呼吸监测方面的有效性需要进一步验证。

综上所述,利用人工气道内温度节律性升降变化原理设计监测控制呼吸持续性的方法可行且有效,可为全麻手术中患者呼吸持续性监测和保障呼吸安全提供新方法。

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