of Sun Yat-sen University. Additionally, all participants (or their guardians when necessary) provided written informed consent.

The genotype-specific risks were estimated as ORs with associated 95% CIs using Pearson $x^2$ test. A trend test of ORs was used to assess an allele dose-dependent effect. As shown in Table 1, genotypes GC, AG, and AA are not associated with NSCLC risk, but the distribution trend of genotype shows some significance ($P_{\text{trend}} = 0.035$). These data show that rs430397 is still not a risk factor of NSCLC. In addition to our previous results, we infer that intronic rs430397 mutation is still a controversial and indecisive contributing factor during the occurrence of disease stress.

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Monitoring Noninvasive Ventilation of Home Bilevel Ventilators

Are Bench Studies More Necessary and Familiar?

To the Editor:

Noninvasive bilevel positive-pressure ventilators provide physicians with software that records parameters important for patient monitoring, although the validity of this information has not yet been independently assessed. In an article in CHEST (February 2012), Contal et al developed a bench test system to assess the performance of seven home bilevel ventilators and compared leaks and tidal volume (VT) from bench test data with results retrieved from the ventilator software. Testing was performed on a bench model adapted to simulate noninvasive ventilation and generate unintentional leaks. Five levels of leaks were simulated using a computer-driven solenoid valve at different levels of pressure.

Interestingly, these investigators found that three of the devices (Trilogy [Philips Respironics], VPAP III ST and VPAP IV ST-A [ResMed]) provided highly reliable estimates of leak flow, with a small bias and narrow limits of agreement, and high correlations between ventilator software and bench results. Moreover, as leaks increased, ventilator auto-triggering occurred in two of these devices (Ventimotion [Weinmann Medical Technology GmBH & Co KG] with maximal respiratory rate [RR] recorded at 25 cycles/min, and Vivo 40 [Breas Medical AB] with a maximal RR recorded at 19 cycles/min). VT was underestimated by all devices, and bias increased (range, 66-236 mL) with higher inspiratory pressures. Synchrony (Philips Respironics) and Trilogy demonstrated consistently low VT bias of < 100 mL in all test conditions. The relationship between ΔVT and leaks was not significant for Mnomal T30 (Air Liquide), Trilogy; and Ventimotion; was positive in Vivo 40; and was inversely related in the Synchrony, VPAP III ST, and VPAP IV ST-A. These results led Contal et al to suggest that considerable variability may be encountered in estimates of respiratory parameters from data obtained with software in seven commonly used domiciliary ventilators.

We consider and support that despite considerable evidence to suggest that monitoring can significantly impact noninvasive ventilation effectiveness, the current study provides long-needed objective data to establish the reliability of leak and VT estimates from different ventilators. In monitoring home noninvasive...
ventilation, we usually use information provided by the ventilators' software (eg, Vt, RR, minute ventilation, residual events index), pulse oximetry, capnography, and telemedicine devices. Thus, Contal et al provide important insight, suggesting that differences in equipment and pressure profiles can influence leaks and Vt estimates significantly. Resulting inaccuracies can contribute to variability in patient tolerance, adherence, and effectiveness and ultimately influence long-term outcomes, such as quality of life and survival. It is incumbent upon the clinician to become familiar with performance characteristics of those ventilators best suited to address the specific needs of patients.

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Response

To the Editor:

We agree with the conclusions of Dr Esquinas and colleagues. There is a substantial variability in reliability of ventilator software, in modes of data reporting as detailed in our study, and also in ventilator pressurization capabilities. For these reasons, clinicians must become familiar with the performance and the limitations of the devices they choose among those that are commercially available for home noninvasive ventilation (NIV). This is, however, a problem, since independent testing and validation of ventilator software or new ventilator modes are either not always available or not necessarily conclusive. For instance, ventilators proposing volume-targeted bilevel pressure support have been commercialized for several years, yet the evidence concerning the clinical relevance of this mode remains inconclusive. Although volume targeting may improve nocturnal transcutaneous Pco2 by a few mm Hg, it may be at the expense of a decrease in quality of sleep; furthermore, the short- or long-term clinical benefit in adults is not established. In sleep-disordered breathing, the option of auto-CPAP is present in most or all CPAP devices on the market, without having shown its superiority in terms of efficiency or compliance. Another example concerns interfaces for NIV. Borel et al showed that the type of mask chosen by the clinician has a direct and significant impact on volume delivered to the patient as well as on the effective pressurization by home ventilators.

One could also argue that this type of study shows that it is crucial to have an independent evaluation of home ventilators and their performance before their commercialization. This evaluation should include not only basic functioning and safety but also reliability of built-in software for monitoring and relevance of new ventilator modes or “gadgets” proposed. Commercial competition puts conceivers of medical devices under enormous pressure to propose new and attractive options, and the ingenuity and creativity of conceptors and technicians in this field is remarkable. However, a new medication must prove not only its safety but also its efficacy and its benefit compared with already existing treatments. Similarly, new ventilators, ventilator modes, or ventilator software should be subjected to premarketing testing based on recommendations made by scientific societies in this field. Moreover, pivotal studies should demonstrate the interest of these innovations not only on surrogate markers, such as sleep quality or nocturnal transcutaneous PaCO2 but also in terms of long-term outcomes (ie, morbidity, mortality, and quality of life).

We also agree with Dr Esquinas and colleagues on the point that monitoring can significantly impact NIV effectiveness. We need comparative effectiveness studies that include cost effectiveness as an outcome to allow decision-makers to develop healthcare policies regarding the clinical application of NIV monitoring for the ambulatory management of patients on long-term NIV. Until this is implemented, we must, as clinicians, keep in mind that among the ingenious options offered by ventilator conceivers, all that glitters is not gold.

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