[Clinical Nutrition 41 \(2022\) 1591](https://doi.org/10.1016/j.clnu.2022.05.018)-[1599](https://doi.org/10.1016/j.clnu.2022.05.018)

Contents lists available at ScienceDirect

# Clinical Nutrition

journal homepage: <http://www.elsevier.com/locate/clnu>

Original article

# Clinical evaluation of the new indirect calorimeter in canopy and face mask mode for energy expenditure measurement in spontaneously breathing patients



**CLINICAL NUTRITION** 

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## article info

Article history: Received 8 February 2022 Accepted 21 May 2022

Keywords: Indirect calorimetry Resting energy expenditure Canopy Face mask Nutritional assessment

## SUMMARY

Background  $&$  aims: The new indirect calorimeter developed in the framework of the ICALIC project was first evaluated in ventilation mode. This second phase aimed to compare its ease of use and precision with another commonly used device in spontaneously breathing adult patients using a canopy hood or a face mask.

Methods: The time required to measure resting energy expenditure (REE) with Q-NRG® in canopy and face mask mode was compared with Quark RMR® in canopy mode by sequential measurements in 45 and 40 spontaneously breathing adult patients, respectively. Their precision was assessed at different time intervals, using coefficients of variation (CV%) and repeated measures one-way ANOVA. Agreement between the two devices was evaluated by correlation coefficients, Bland-Altman plots, and paired ttest. Patients' characteristics potentially affecting the measurement were assessed using linear regression analysis.

Results: REE measurement with Q-NRG® was faster than Quark RMR® (19.7  $\pm$  2.9 min vs 24.5  $\pm$  4.3 min,  $P < 0.001$ ). In canopy mode, Q-NRG® gave values similar to Quark RMR®, with 73% of patients achieving a steady state (CV% <10%) within the 5-15 min interval. In face mask mode, Q-NRG® was less stable than Quark RMR® in canopy mode, and steady state was achieved in only 40% of the patients within the 5  $-15$  min interval. Correlation between the two devices was stronger when Q-NRG® was used in canopy than in face mask mode, with Pearson coefficients of 0.96 and 0.86, respectively. Compared to Quark RMR® in canopy mode, systematic bias $\pm$ 1.96\*SD with Q-NRG® was  $-14 \pm 236$  kcal/day in canopy and 73  $\pm$  484 kcal/day in face mask mode. Q-NRG® in face mask mode overestimated REE by 150  $\pm$  51 kcal/ day in men compared to Quark RMR® in canopy mode.

Conclusions: Q-NRG® in canopy mode made it possible to save at least 5 min compared to Quark RMR® while maintaining the same measurement precision. However, its use in face mask mode could lead to REE overestimation in men and, therefore, should not be recommended in the clinical setting. Trial registration: ClinicalTrials.gov no. NCT03947294.

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<https://doi.org/10.1016/j.clnu.2022.05.018>

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Abbreviations: BMI, body mass index; CV%, coefficient of variation; GFC, galvanic fuel cell; ICU, intensive care unit; NDIR, nondispersive digital infrared; REE, resting energy expenditure; RQ, respiratory quotient; VCO<sub>2</sub>, volume of carbon dioxide production; VO<sub>2</sub>, volume of oxygen consumption.

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### 1. Introduction

Accurate measurement of resting energy expenditure (REE) is essential to adequately determine patients' nutritional needs [\[1\]](#page-7-0). The use of predictive equations, such as Harris-Benedict [[2\]](#page-7-1), is often not relevant in patients as they do not take into account several disease-related factors that influence REE, such as inflammatory state, muscle wasting associated with immobilization, and medical interventions [[3\]](#page-7-2). The only way to accurately measure REE in the clinical setting is the use of an indirect calorimeter [[4](#page-7-3)]. However, most of the indirect calorimeters available on the market are expensive, cumbersome, tedious to use, time-consuming and/or not precise enough to be recommended in clinical practice [\[5](#page-7-4)[,6\]](#page-7-5). This is the reason why a new generation indirect calorimeter, Q-NRG® (COSMED, Italy), was developed within the framework of the ICALIC project with the support of the European Society of Clinical Nutrition and Metabolism (ESPEN) and the European Society of Intensive Care Medicine (ESICM) [\[7](#page-7-6)]. Q-NRG® was designed and validated according to clinicians' specifications to meet their needs [[8](#page-8-0)]. A comparative multicenter study confirmed that Q-NRG® can quickly and accurately measure REE in intensive care unit (ICU) patients requiring intubation and mechanical ventilation [\[9\]](#page-8-1). Q-NRG® can be used not only in ventilation mode, but also in spontaneously breathing patients using a canopy hood or a face mask. We previously demonstrated in vitro and in healthy volunteers that Q-NRG® is very precise and accurate in canopy mode compared to mass spectrometry measurement [[10\]](#page-8-2). However, its ease of use and precision had yet to be demonstrated in patients with clinical conditions that may affect their ability to breathe uniformly under a canopy hood or a face mask.

#### 2. Materials and methods

#### 2.1. Study design and objectives

This observational prospective cross-sectional study was carried out at the Geneva University Hospitals after approval by the local Research Ethics Committee (Swissethics BASEC ID:2019-00106; ClinicalTrials.gov no. NCT03947294). The primary objective was to assess the minimum time required to perform REE measurement in canopy and face mask mode with Q-NRG® compared to Quark RMR® (COSMED, Italy), an indirect calorimeter commonly used in canopy mode in spontaneously breathing patients [\(Fig. 1\)](#page-2-0). The secondary objective was to compare the variability and precision of volume of oxygen consumption  $(VO<sub>2</sub>)$ , volume of carbon dioxide production (VCO<sub>2</sub>), respiratory quotient (RQ) and REE measurement between the two devices and to identify potential factors among patients' sex, body weight, height, body mass index (BMI), and age, which could have caused a difference of REE measurement between the two devices.

## 2.2. Study population

Spontaneously breathing in- and out-patients who were prescribed REE measurement for clinical purpose between May 2019 and June 2021 were considered eligible for this study. The exclusion criteria were age <18 years, intolerance or phobia to canopy hood or face mask, physical agitation or activity <1 h before REE measurement, or inability to follow the study procedures (e.g. communication problem, psychological disorders, dementia). As the estimated time required to perform REE measurement with Quark RMR® in our clinical practice was  $30 \pm 5$  min, a minimum of 36 patients were required for each measurement mode to be 80% sure that the limits of a two-sided 90% confidence interval excluded a difference in means of more than 5 min.

#### 2.3. Investigational products

Both indirect calorimeters are certified for medical device safety standards and were used according to the user manual instructions without interfering with patients' treatments ([Fig. 1](#page-2-0)). Q-NRG® (CE mark  $n^{\circ}$  MED 9811) has been designed to reduce maintenance operations, warm-up and measurement time [[7](#page-7-6)]. It is equipped with dynamic micro-mixing chamber, bidirectional digital turbine flowmeter, galvanic fuel cell (GFC)  $O<sub>2</sub>$  analyzer, and nondispersive digital infrared (NDIR)  $CO<sub>2</sub>$  sensor. Gas analyzers are automatically calibrated against room air during each indirect calorimetry measurement and require calibration against precision gas mixture only once a month. A warning message appears on the Q-NRG® screen when monthly calibration of the gas analyzers, the blower (canopy) or the turbine (face mask) is required. Software with touchscreen controls is used to perform data entry and acquisition. As comparator, Quark RMR® (COSMED, Italy) in canopy mode was used according to our clinical practice. It is equipped with paramagnetic  $O_2$  analyzer, NDIR  $CO_2$  sensor, and bidirectional turbine flowmeter. Data processing is performed by the Omnia 1.6.3 software. Quark RMR® is the only indirect calorimeter in the market that has been validated on the two gas exchange methods (breath by breath and mixing chamber), and on a wide range of exercise intensities  $[11-13]$  $[11-13]$  $[11-13]$  $[11-13]$ .

# 2.4. Procedure

Participants were included in the study after being screened for eligibility and signing an informed consent. REE measurement was performed after an overnight fast and a resting time of  $10-20$  min during which the patient's history record and installation was carried out according to our clinical practice. In out-patients, body weight and height were measured using a calibrated weight scale and stadiometer, respectively. REE measurement was then performed sequentially on a per patient basis with Q-NRG® and Quark RMR® according to the procedure stated in their respective user manual. Times to perform data input, gas analyzer, blower, and turbine calibration if required, installation of the canopy hood or the face mask, and REE measurement were measured with a chronometer and recorded in the case report form by one of the two investigators. Time required to reach a steady state [[14\]](#page-8-4), and measure REE was assessed from CV% of the raw data of the two devices, and from their comparison at different time intervals  $(0-5 \text{ min}, 5-10 \text{ min}, 10-15 \text{ min})$ . Time and reason for interruption, if any, due to technical problem, patient's care or discomfort, or other unexpected events was also recorded. The participants could withdraw at any time from the study if they felt discomfort during the measurement under canopy hood or face mask. After the measurement, disinfection of the reusable parts was carried out according to the user manual. Face mask and external turbine flowmeter were soaked in Deconex® Instrument Plus solution (Borer Chemie AG, Switzerand) at room temperature for 15 min and rinsed three times in a large volume of water for at least 3 min for each rinsing cycle.

### 2.5. Data handling and statistical analysis

All variables were expressed as proportions or means  $\pm$  standard deviation (SD). Agreement between the two devices were assessed by Pearson coefficients, Bland-Altman plots with limits of agreement (LoA, bias  $\pm$  1.96\*SD), and paired *t*-test. The precision of the two devices was assessed at different time intervals  $(0-5 \text{ min},$ 5–10 min; 10–15 min), using coefficients of variation (CV% =  $SD/$ mean\*100) and repeated measures one-way ANOVA followed by Bonferroni's correction for post hoc multiple comparison tests.

<span id="page-2-0"></span>

Fig. 1. Technical features of Q-NRG® and the Quark RMR® comparator. The listed features are according to the instruction manuals. Both systems are open-circuit devices.

Intra-class correlation coefficient (ICC) using two-way mixed effects with absolute agreement was used to assess the reliability of REE,  $VO<sub>2</sub>$ ,  $VCO<sub>2</sub>$ , and RQ measurement between the two devives. The reliability was considered as poor for ICC  $<$ 0.50, moderate for ICC between 0.50 and 0.75, good for ICC between 0.75 and 0.90, and excellent for ICC >0.90 [\[15](#page-8-5)]. Patients' characteristics that could have played a role in the difference of measurement between the two devices were assessed using forward multivariate linear regression. Statistical analysis was performed with the Stata/IC 13.1 software for Windows (StataCorp LP, College Station, TX, USA). Statistical significance level was set at  $P < 0.05$ .

## 3. Results

## 3.1. Patients' characteristics

The patients' characteristics are presented in [Table 1:](#page-2-1) 85 patients were included in the study with 45 men (52.9%), and a mean age of 53  $\pm$  18 years. REE was measured in 45 patients using both Quark RMR® and Q-NRG® in canopy mode, and in 40 patients using Quark RMR® in canopy and Q-NRG® in face mask mode. Overall, patients measured with Q-NRG® in canopy mode had a lower body weight ( $P = 0.01$ ), BMI ( $P = 0.02$ ), and REE ( $P = 0.01$ ) than those measured in face mask mode.

## 3.2. Time required to perform REE measurement

The time required to perform REE measurement with Q-NRG® was shorter than with Quark RMR®, both in canopy and face mask mode, with an average measurement time of  $19.7 \pm 2.9$  min for Q-NRG® and  $24.9 \pm 3.1$  min for Quark RMR® [\(Fig. 2\)](#page-3-0). The user-friendly touchscreen of Q-NRG® saved an average of  $11 \pm 28$  s for patient's data entry ( $P < 0.001$ ). However, the gain in time was mainly due to

<span id="page-2-1"></span>



Abbreviations: BMI, body mass index; REE, resting energy expenditure; RQ, respiratory quotient;  $VCO<sub>2</sub>$ , volume of carbon dioxide production;  $VO<sub>2</sub>$ , volume of oxygen consumption. The calorimetric parameters were measured in both groups using Quark RMR® in canopy mode. Data are expressed as mean  $\pm$  standard deviation (P, student t-test between the canopy and the face mask group).

the non-obligatory calibration with Q-NRG® allowing to save 5.3  $\pm$  1.4 min compared to Quark RMR® ( $P < 0.001$ ).

### 3.3. Time to reach a steady state

According to the data range selected by the operator to measure REE, there was no difference in time to reach a steady state with Q-NRG® compared to Quark RMR®, whether in canopy (7.7  $\pm$  2.4 min vs  $8.0 \pm 1.8$  min,  $P = 0.56$ ) or in face mask mode (7.3  $\pm$  2.2 min vs 7.7  $\pm$  1.6 min, P = 0.87). Raw data analysis confirmed that Q-NRG® in canopy mode gave  $VO<sub>2</sub>$ , VCO<sub>2</sub>, RQ, and REE values like Quark RMR® ([Fig. 3](#page-4-0)A-D), with 73% of patients achieving a steady state (CV % <10%) within the 5–15 min interval (REE CV% =  $8.7 \pm 4.6$ % with Q-NRG® vs 8.1  $\pm$  4.6% with Quark RMR®, P = 0.44). In face mask mode, Q-NRG® was less stable than Quark RMR® in canopy mode

<span id="page-3-0"></span>

Fig. 2. Mean time required to perform REE measurement with Q-NRG® in canopy ( $n = 45$ ) or face mask ( $n = 40$ ) mode compared with Quark RMR® in canopy mode.

([Fig. 3](#page-4-0)E-H), with only 40% of patients achieving a steady state within the 5–15 min interval (REE CV% =  $12.0 \pm 4.1$ % with Q-NRG® vs  $6.7 \pm 4.6\%$  with Quark RMR,  $P < 0.001$ ). Data analysis at different time intervals confirmed that the measurement variability of Q-NRG® in canopy mode was similar to Quark RMR®, with a steady state achieved in  $73\% - 82\%$  of the patients within the  $5-10$  min interval, whereas the measurement variability of Q-NRG® in face mask mode was significantly worse than Quark RMR® in canopy mode with only 33% of patients achieving a steady state within the 5-10 min interval [\(Table 2\)](#page-5-0).

#### 3.4. Agreement between the two devices

Correlation between the two devices was stronger when Q-NRG® was used in canopy than in face mask mode, with Pearson coefficients  $\rho$  of 0.96 and 0.86, respectively ([Fig. 4](#page-5-1)). Excellent and good reliability was observed for  $VO<sub>2</sub>$ , VCO<sub>2</sub>, and REE measurement with Q-NRG® in canopy and face mask mode, respectively, while RQ reliability was moderate in both measurement modes [\(Table 3\)](#page-6-0). However, Bland-Altman plots showed wide LoA, especially when Q-NRG® was used in face mask mode. Compared to Quark RMR® in canopy mode, systematic bias  $\pm$  LoA was  $-14 \pm 236$  kcal/day with Q-NRG® in canopy mode and 73  $\pm$  484 kcal/day with Q-NRG® in face mask mode ([Fig. 5\)](#page-6-1).

# 3.5. Factors affecting REE measurement difference between the two indirect calorimeters

The difference in REE measurement observed between Quark RMR® and Q-NRG® was not correlated with the patient's weight and BMI regardless of the measurement mode. Only patient's sex  $(P = 0.005)$  and, to a lesser extent, age  $(P = 0.04)$ , and height  $(P = 0.05)$  were correlated with difference in REE measurement between Quark RMR® and Q-NRG® in face mask mode, using univariate regression analysis ([Table 4\)](#page-7-7). Only sex remained significant in multivariate regression analysis ( $P = 0.04$ ). Q-NRG® in face mask mode overestimated REE by 150  $\pm$  51 kcal/day in men compared to Quark RMR® in canopy mode, while there was no significant difference in women.

# 4. Discussion

This study showed that Q-NRG® in canopy mode saved about 5 min compared to Quark RMR®, while maintaining the same REE measurement precision. In contrast, REE measurement in face mask mode was found to be less stable and led to significant REE overestimation in men.

The time saved with Q-NRG® was mainly due to the nonobligatory calibration prior to each use. In this study, we did not consider the 30-min warm-up required for Quark RMR® [\(Fig. 1\)](#page-2-0), because the devices were turned on long before measurement. As Q-NRG® does not require warm-up time in canopy mode, its use should save at least 35 min when unscheduled measurement must be carried out rapidly. Moreover, due to its compact design and a single-use canopy veil, Q-NRG® can save another 10 min for its disinfection after measurement. Other compact indirect calorimeters are available on the market, but they have either not been evaluated precisely enough yet [\[16](#page-8-6)[,17](#page-8-7)], or were found to be less reliable than Q-NRG®, with large LoA compared to Quark RMR® [[18](#page-8-8)] or Deltatrac® Metabolic Monitor (Datex, Finland) [[19\]](#page-8-9).

In a previous study, we demonstrated both in vitro and in healthy subjects a very good intra- and inter-unit precision of Q-NRG® in canopy mode with CV%  $\leq$ 1%, as well as a very good accuracy with bias of 0.9% when compared to a reference mass spectrometer [[10\]](#page-8-2). The present study showed that REE measurement with Q-NRG® in canopy mode was as stable and precise as Quark RMR®. It is generally accepted that a steady state is reached when CV% is  $\leq$  10% for at least 5 min [\[20\]](#page-8-10). Our results showed that a steady state was reached within the first 10 min of measurement in about three quarters of the patients with the two devices. Similar to us, Irving CJ et al. showed that 72% of the subjects reached a steady state within the first 15 min of measurement with Quark RMR® in canopy mode [[21\]](#page-8-11). Another study carried out with Vmax Encore 29n (CareFusion Corp, USA) in canopy mode concluded that 10 min of measurement is sufficient in healthy young adults provided the first 5 min are discarded [\[22\]](#page-8-12). Our results confirm the possibility to measure REE whitin the first 10 min with both Q-NRG® and Quark RMR® in canopy mode, provided that a steady state has been reached and that the first 5 min of measurement are discarded. Face mask could be an alternative for use in those individuals who suffer

<span id="page-4-0"></span>

Fig. 3. Coefficient of variations (CV%) of VO<sub>2</sub> (A and E), VCO<sub>2</sub> (B and F), RQ (C and G), and REE (D and H) measurements with Q-NRG® in canopy (A-D) or face mask (E-H) mode compared with Quark RMR® in canopy mode. CV% was calculated as SD/mean x 100 of patient measurements normalized to the mean value of measurements between 5 and 15 min.

## <span id="page-5-0"></span>Table 2





REE, resting energy expenditure (kcal/day) measured during the time interval (mean  $\pm$  SD).

CV%, coefficient of variation of REE measurement during the time interval (mean  $\pm$  SD).

SS, percentage of patients reaching a steady state with CV% < 10% during the time interval.

Diff., difference of REE measurement between Q-NRG® and Quark RMR® in the time interval (P, paired t-test).

<span id="page-5-1"></span> $^*$ , P < 0.05;  $^{**}$ , P < 0.01;  $^{***}$ , P < 0.001: different from REE measurement in the interval of 0–5 min (repeated measures ANOVA + post-hoc Bonferroni tests).



Fig. 4. Scatterplot correlation showing the difference in REE measurement (kcal/day) between Quark RMR® and Q-NRG® in canopy (A) or face mask (B) mode. The dashed regression line represents the trend between the mean REE measurements of the two indirect calorimeters.

## <span id="page-6-0"></span>Table 3





<span id="page-6-1"></span>Absolute and relative (%) bias, Q-NRG® - Quark RMR®; ICC [95% CI], intra-class correlation using two-way mixed effects with absolute agreement and confidence interval of 95%; LoA, mean bias  $\pm$  1.96\*standard deviation; P, paired t-test; REE, resting energy expenditure; RQ, respiratory quotient; VCO<sub>2</sub>, volume of carbon dioxide production; VO<sub>2</sub>, volume of oxygen consumption. Data are expressed as mean  $\pm$  standard deviation.



Fig. 5. Bland-Altman plots showing the difference in REE measurement (kcal/day) between Quark-RMR® and the Q-NRG® in canopy (A) or face mask (B) mode. The dotted lines represent the mean bias. The dashed regression line represents the trend between the differences of methods and the mean of both methods.

#### <span id="page-7-7"></span>Table 4

Univariate linear regression analysis evaluating the association between patients' characteristics and the difference in REE measurement between Q-NRG® in canopy or face mask mode and Quark RMR® in canopy mode.



Abbreviations: BMI, body mass index.

from claustrophobia under the canopy hood [\[23\]](#page-8-13). However, our results showed that its use was not optimal especially in men whose REE tended to be overestimated by 8.2%. Consistent with these findings, Forse observed an increase in  $O<sub>2</sub>$  consumption by 7.1% and in  $CO<sub>2</sub>$  production by 4.1% with the use of face mask compared to canopy hood, resulting in a 7.2% increase in REE [\[24\]](#page-8-14). Higher REE measurement with the face mask could be explained by increased ventilation in subjects who experience discomfort when wearing the face mask. This discomfort is probably due to the resistance resulting from turbulence caused by airflow through a small orifice [\[25\]](#page-8-15). It is notable however that in our study the difference in REE measurement between the canopy hood and the face mask was observed only in the men. Thus, this difference could also be explained by other factors such as the jaw shape and beard causing dead space or leak [[26](#page-8-16)]. Unfortunately, we did not collect data regarding patients' facial hair and shape. It has already been suggested that canopy hood is preferable to face mask in the presence of beard, abnormal facial structure, nasoenteric tubing, and stomatitis to ensure complete seal and normal patient's breathing patterns [\[27](#page-8-17)]. The larger tidal volume of the men compared to the women may also have emphasized changes in inhaled and exhaled minute volumes, and hence differences in REE measurement between the canopy hood and the face mask. Askanazi et al. indeed observed a 32% increase in tidal volume with face mask compared to canopy hood, which was explained by an increase in inspiratory flow [[28](#page-8-18)]. Overall, REE measurement was significantly less stable when utilizing the face mask compared to the canopy hood, given that only a half of the patients reached a steady state after 15 min of measurement. Therefore, the use of Q-NRG® in face mask mode for REE measurement may not provide reliable results in the clinical setting. In addition, the use of face mask is problematic, especially under pandemic conditions, due to the lack of filtration system, unlike the canopy hood which can be utilized in patients wearing an FFP2 mask [[29](#page-8-19)].

In this study, it was not possible to compare the results of Q-NRG® in canopy mode with those in face mask mode, because they were conducted by different investigators on different patients. The group with the canopy hood was recruited before the COVID-19 pandemic and the group with face mask during the pandemic for logistic reasons. Second, this study was initially planned to be multicentric and compared across other indirect calorimeters, but this was limited by the difficulty of recruiting and carrying out measurements in patients during the pandemic.

In conclusion, our results show that the use of Q-NRG® in canopy mode saved time compared to Quark RMR® while maintaining the same precision of REE measurements. However, its use in face mask mode could lead to REE overestimation especially in men and, therefore, should not be recommended in the clinical

setting. Optimisation of tight face mask would probably be relevant for a broader clinical use of calorimetry.

#### Funding statement

This work was funded by ESPEN, ESICM and the Foundation Nutrition 2000 Plus.

#### Author contribution

CP and YD designed the study; MD, KHJ, MMB, and YD recruited the participants and collected the data; YD analyzed the data, performed statistical analysis and wrote the original draft; All the authors participated in the critical revision of the manuscript. All authors gave final approval of the version to be submitted.

#### Conflict of interest

The authors declare no competing interests.

#### Acknowledgment

The authors would like to thank Géraldine Bagnoux (RD, CHUV) for assistance with measurements.

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