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A Systematic Review on Use of a Handheld Indirect Calorimeter to Assess Energy Needs in Adults and Children

Scott O. McDoniel

With the number of individuals becoming overweight or obese, health care professionals are in need of accurate, reliable, and convenient tools to help personalize weight-loss programs. Recently, a new handheld indirect calorimeter (i.e., MedGem/BodyGem; also know as "Gem") was introduced as a convenient way to assess resting metabolic rate (RMR) to determine daily energy needs. Several validation and comparison studies were conducted to determine whether the Gem device is accurate and reliable, and results from these studies are mixed. Fourteen human studies (12 adult, 2 pediatric) were conducted, and 12 met the established criteria for this review. In all Douglas-bag (DB; $n = 4$) validation studies, the Gem device was not significantly different than the DB (mean difference adult ±1%, pediatric ±1%). The intraclass reliability of the Gem ranged from 0.97 to 0.98, and the interclass reliability to the DB ranged from 0.91 to 0.97. Although few ($n = 2$) studies have demonstrated that the Gem device measures RMR significantly lower (–8.2% to 15.1%) than traditional metabolic carts, it performs very comparably (RMR values 0.1–4.0%, interclass reliability 0.76–0.92) to traditional metabolic carts in most ($n = 6$) of the comparison studies. Based on these data, the Gem device is a valid and reliable indirect calorimeter for energy assessment in most adults and children.

Key Words*:* RMR, BodyGem, MedGem, Douglas bag, Deltatrac

The obesity epidemic is continuously rising in the United States. Over the past 4 decades the average weight of a typical U.S. adult has increased by approximately 11.4 kg (i.e., 25 lb) (24). Because of this weight increase, over 65% of the U.S. adult population are now classified as overweight or obese (4). Children are facing a similar obesity issue. Nearly 35% of U.S. children are classified as overweight or obese (25). Unfortunately, the obesity epidemic will only continue to increase. It is projected that by the year 2010 the percentage of obese individuals will increase 5% and normal-weight individuals will decrease 4% (2, 3). Because of the growing obesity problem, effective weight-management solutions are needed.

The author is with the Harold Able School of Psychology, Capella University, Minneapolis, MN 55402.

Currently, most weight-management programs follow industry guidelines for treating obese individuals. The major components of treating overweight or obese individuals involve a low-calorie, low-fat diet; increased physical activity; and behavior modification. An interesting component of the low-calorie, low-fat diet is based on a fixed calorie amount for most individuals (i.e., 1000–1200 kcal for women and 1200–1600 kcal for men) (26). These low-calorie diet programs are often difficult to follow, however, and weight regain is problematic. Approximately 50–70% of individuals who attempt to lose weight will either drop out of a structured weight-loss program or regain the weight (33). Second, as a result of failed weight-loss attempts, obesity experts believe that repeated dietary interventions and weight cycling might lead to eating disorders (i.e., binge eating, anorexia, or bulimia) in some individuals (16). Weight-management programs that are designed for the participant to chose a personal calorie level result in better program adherence and long-term weight maintenance than do traditional low-calorie, low-fat diet programs (30). Based on these factors, weight-management professionals should consider personalizing a nutrition plan to increase the possibility of program adherence and long-term weight maintenance.

Currently, most weight-management professionals who attempt to personalize diet plans use an estimation equation to determine daily energy needs. These estimations often use basic demographic information (age, height, weight, and gender) to determine resting metabolic rate (RMR). RMR accounts up to 75% of total energy expenditure in most individuals (7). Many of the equations, however, are significantly inaccurate in most of the population (10, 12). The most commonly used estimation equation, the weight-adjusted Harris–Benedict equation, has an error rate of 74% when compared with actual measurement of RMR (13). In an earlier study comparing individuals with similar demographics, the inaccuracy of the Harris–Benedict equation could be as high as 450 kcal (11). Because of these significant inaccuracies, the American Dietetics Association has issued clinical guidelines for assessing nutritional needs and recommends using indirect calorimetry over estimation questions to determine RMR (5, 12).

Although indirect calorimetry is recommended over estimation equations, the practical use of a traditional indirect calorimeter system is limited. The cost (i.e., $30,000–50,000) and technical expertise needed to operate most indirect calorimeter systems might be a deterrent for assessing energy needs in a weight-management program. Second, the time needed to assess RMR is approximately 30 min per individual (19). Recently, a new handheld indirect calorimeter device called the MedGem, or "Gem," a 510-K Class II medical device (Figure 1), and its sister device BodyGem (Microlife USA, Dunedin, FL) were introduced as an alternative to traditional indirect calorimetry systems for assessing RMR.

The Gem is designed to be used as a stand-alone device and displays RMR in calories per day and VO_2 in milliliters per day at the conclusion of the measurement. It is autocalibrated before each measurement (a 5-s interval during which the flow sensors are set). The Gem is programmed to begin collecting data when the first breath is detected and continues until either a steady state or 10 min is reached. In this process the data collected during the first 2 min are not used for calculation of steady state. Sensors measure relative humidity, temperature, and barometric pressure for use in internal calculations that derive RMR. Oxygen concentration in the inspired and expired airflow is measured by a proprietary fluorescent-quenching

Figure 1 — Handheld indirect calorimeter (MedGem, Microlife, Inc., Golden, CO).

sensor. The principle operation is based on the deactivation of ruthenium in the presence of oxygen. When the active and reference ruthenium cells are excited by an internal light source, they fluoresce. This reaction is quenched by the presence of oxygen, and the amount of quenching is proportional to the concentration of oxygen. The volume of inspired and expired air is measured using ultrasonic sensing technology. There is a transducer at each end of the flow tube that emits sound pulses. The transmission time from the sending to the receiving transducer is increased or decreased in proportion to the rate and direction of gas flow. The Gem uses standard metabolic formulas to calculate oxygen uptake. RMR is calculated from oxygen consumption and a fixed respiratory quotient (RQ) of 0.85 using a modified de Weir equation (8).

Several studies have been conducted to determine the accuracy and reliability of the Gem device. Results from these studies are conflicting, leaving us with a mixed opinion of the accuracy and reliability of the new handheld indirect calorimeter. The purpose of this article is to provide a systematic review of published human studies used to evaluate the validity and reliability of the Gem device in adults and children. The varying approaches, methodologies, and reference systems employed in these studies are presented along with the major findings.

Methodology

A search was conducted on PubMed using the following keywords: *BodyGem, MedGem, Microlife,* and *HealtheTech*. Results from the search yielded 12 published studies: 8 on the MedGem (1, 6, 9, 14, 22, 27, 30, 31), 3 on the BodyGem (18, 20, 23), and 1 on the HealtheTech (28). Next, a search was conducted for abstract presentations for the MedGem and BodyGem device. In this manner 2 published abstracts (21, 29) were found.

Specific inclusion criteria were established to qualify studies for determination of accuracy and reliability of the Gem device. Specific inclusion criteria included a random or counterbalanced assignment of participants to eliminate measurement bias, similar subject positioning for both Gem and reference-system measurement or adjustment to a measurement for positioning differences, and use of a measurement protocol that is similar to the established "best practice" guidelines for employing indirect calorimetry (5).

Finally, only studies comparing the Douglas-bag (DB) system with the Gem device were included for determination of accuracy and reliability. The DB system is often referred to as the "gold standard" for indirect calorimetry because each variable is measured independently via calibrated and traceable instrumentation. Because many clinicians and researchers use metabolic carts rather than the DB system, studies employing metabolic carts as the "reference system" for validation were included as a general comparison of the Gem's performance with that of traditional metabolic carts.

Results

All 14 studies followed similar premeasurement conditions by conducting RMR measurements in the morning after a 4- to 12-h fast, a 2-h abstinence from nicotine and stimulants, a 12- to 24-h abstinence from exercise or strenuous physical activity, and a 15- to 30-min rest period. All studies followed industry guidelines for accurately assessing RMR with indirect calorimetry (5).

Twelve of 14 studies used a counterbalanced or randomized measurement process. Based on the established criteria, studies conducted by Hlynsky et al. (14) and St. Onge et al. (29) were eliminated from the systematic review.

Compher et al. (6) and Alam et al. (1) had subjects in either a supine or semirecumbent position for the reference-system measurement, compared with a seated upright position while holding the Gem device. Previous research indicates a 70-kcal/d increase in RMR measurement while an individual is seated rather than supine or semirecumbent (17). Based on this information, an adjustment of 70 kcal/d to the mean Gem average was applied to both studies. Studies conducted by Melanson et al. (20), Liou et al. (18), and Fields et al. (9) adjusted initial RMR values based on subject positioning. The remaining studies used similar subject position so there was no need to adjust the RMR values.

The Gem was validated against the "gold standard" in 4 different DB studies (3 adult and 1 pediatric). The mean difference between the Gem and DB system from the 3 adult studies is less than 1% (1559 vs. 1568 kcal/d). The mean intraclass reliability coefficient of the Gem device is 0.98. Of the 3 adult studies, 2 provided interclass reliability results (21, 23); mean interclass reliability is 0.94 (range 0.91–0.97). The difference between the Gem device and DB system in the pediatric study is 1.2%, and the device is reliable (interclass = 0.91, intraclass = 0.94). Detailed results from all DB studies are presented in Table 1.

Table 1 Descriptive Statistics of Gem Versus the Douglas-Bag System

Validation study	*N*	Age	BMI	Gem RMR kcal/d	Douglas-bag RMR kcal/d	Delta	Intraclass *R*-value	Interclass *R*-value
Nieman et al. (23)	63	41	26.5	1657	1650	0.4%	0.98	0.91
Storer et al. (32)	54	32	26.5	1494	1518	–1.7%	0.98	NA
Murphy and Kearny (21)	32	NA	NA	1525	1534	–0.6%	0.97	0.97
Nieman et al. (22)	59	11	20.1	1477	1460	1.2%	0.94	0.91

BMI indicates body-mass index, and RMR, resting metabolic rate.

The Gem was compared with 4 different traditional metabolic carts in 8 studies. It device was compared with the DeltaTrac system (Datex-Ohmeda, Madison, WI) in 6 studies, the Sensormedics Vmax 29N system (VIASYS Healthcare, Yorba Linda, CA) in 2 studies, the Sensormedics 2900 system (VIASYS Healthcare) in 1 study, and the Physio-Dyne Max II system (AEI Technologies, Pittsburgh, PA) in 1 study. Six of the 8 studies indicated that the Gem device performs very comparably (RMR range 0.1–4.0%, interclass reliability range 0.76–0.92) to traditional metabolic carts. The studies conducted by Compher et al. (6) and Reeves et al. (27) demonstrated that the Gem measures RMR significantly lower (RMR values range from –8.2 to –15.1%) than traditional metabolic carts do. Detailed results from the included comparison studies are presented in Table 2.

Discussion

Because of the current population obesity problem, accurate and reliable tools are needed for appropriate energy assessment to personalize individual nutritional plans. Previously, indirect calorimetry was unavailable or impracticable for assessing energy needs for personalized weight-management plans. Now, new indirect-calorimetry technology is available to assess energy needs for individuals with weight-management goals. Because of the recent established guidelines for determining energy needs (12), simple and affordable indirect calorimeters are needed by clinicians. The Gem appears to provide a simple and affordable solution compared with a DB system and classic metabolic carts.

The Gem device has been validated against the “gold standard” in 4 studies. Results from these studies suggest that it is accurate and reliable for assessing resting oxygen consumption and resting metabolic rate in adults and children (21, 22, 23, 32).

Table 2 Descriptive Statistics of Gem Versus Traditional Metabolic Carts

Comparison study	Reference system	*N*	Age	BMI	Gem RMR kcal/d	Reference RMR kcal/d	Delta	Intraclass *R*-value	Interclass *R*-value
Rubenbauer et al. (28)	PD	30	42	24	1551	1552	0.1%	NA	0.83
Fields et al. (9)	DT	100	11	19.6	1395	1349	3.3%	0.99	NA
Liou et al. (18)	DT	30	42	24	1179	1135	4.0%	0.96	0.76
Stewart et al. (31)	DT	50	36	25.9	1491	1486	0.3%	NA	0.94
Storer et al. (32)	DT	54	32	26.5	1494	1484	0.7%	0.98	NA
Alam et al. (1)[a]	DT	37	28	20.8	1320	1277	3.7%	NA	0.80
Compher et al. (6)[a]	DT	24	47	21.8	1228	1446	–15.1%	NA	NA
Storer et al. (32)	SMVM	54	32	26.5	1494	1451	3.0%	0.98	NA
Reeves et al. (27)[b]	SMVM	15	65	28.4	1351	1526	–11.5%	NA	NA
Reeves et al. (27)	SMVM	15	60	26.3	1258	1371	–8.2%	NA	NA
Melanson et al. (20)	SM 2900	41	40	26.1	1559	1530	1.9%	0.90	0.92

[a]Post hoc adjustment (70 kcal/d) for subject positioning (17).
[b]Cancer patients.
BMI indicates body-mass index; RMR, resting metabolic rate; PD, Physio-Dyne; DT, Deltatrac; SMVM, Sensormedics Vmax 29N; and SM2900, Sensormedics 2900.

The Gem has been compared with 4 different metabolic-cart systems. Two of those studies suggest that it measures RMR significantly below the RMR values of metabolic carts (6, 27), and the other 6 studies, when adjusting for subject positioning, suggest that it performs similarly to metabolic carts (1, 9, 18, 20, 30, 31, 32).

Melanson et al. (20) indicate that a seated position while holding the Gem device results in an approximate 60-kcal/d increase in RMR when compared with the supine position. Fields et al. (9) also indicate that a seated position while holding the Gem results in approximately 55–60 kcal/d increase in RMR. These results confirm those of an earlier study indicating that sitting upright results in a 70-kcal/d increase in RMR versus a supine position (17). If adjusting for the caloric demands of holding the Gem while in a seated position (i.e., 70 kcal/d), the data from Alam et al. (1) are not significantly different (i.e., adjusted mean Gem RMR: 1320 kcal/d vs. 1277 kcal/d) based on the allowable critical value difference (3–5%) for repeated measures (5).

The results of Compher et al. (6) widened the mean RMR difference between the Gem and reference system from –10.2% to –15.1%. Because of this adjustment, the Gem device did not perform comparably to the reference system. The researchers did indicate that the Gem's readings have adequate reproducibility and acceptability for patients (6).

The large differences between the Gem device and reference system in the Compher et al. (6) and Reeves et al. (27) studies might be the result of 3 possible factors: undetected air leaks by the Gem device, reference-system or Gem-device inaccuracies, or a fixed RQ of 0.85.

In contrast to a reference system using a ventilated hood, the Gem device uses a disposable mouthpiece and a disposable nose clip (Figure 2) similar to the mouthpiece of a snorkel. The Gem provides an error code when it detects an air leak. To remedy the error, the clinician should make sure the subject's mouth is sealed completely around the mouthpiece; the nose clip is across the subject's nose, eliminating any air passing through the nostrils; and the subject is breathing through the mouth. The device might not always detect an air leak, however, if the subject is able to provide enough airflow for the sensors to measure the amount of oxygen during respiration. In these instances, the device will determine RMR from the low airflow, and the measurement will be lower because of the low airflow. Because of the Gem's design, clinicians are unable to determine whether an air leak might have occurred. The manufacturer does provide a software program called Analyzer that enables clinicians to monitor real-time breath-by-breath data. The Analyzer software can be used to monitor potential air leaks by evaluating real-time breath-by-breath data.

Another possible reason for the RMR discrepancies between the Gem device and reference system is that one or both devices were out of calibration. Compher et al. (6) acknowledged that this was a possibility because of the age of the oxygen sensor in the DT system (i.e., 15+ y) versus the oxygen sensor in the Gem device, which was only a few years old.

Finally, it has been suggested that the Gem's fixed RQ of 0.85 might result in a significant difference when compared with using the actual RQ (27). Few

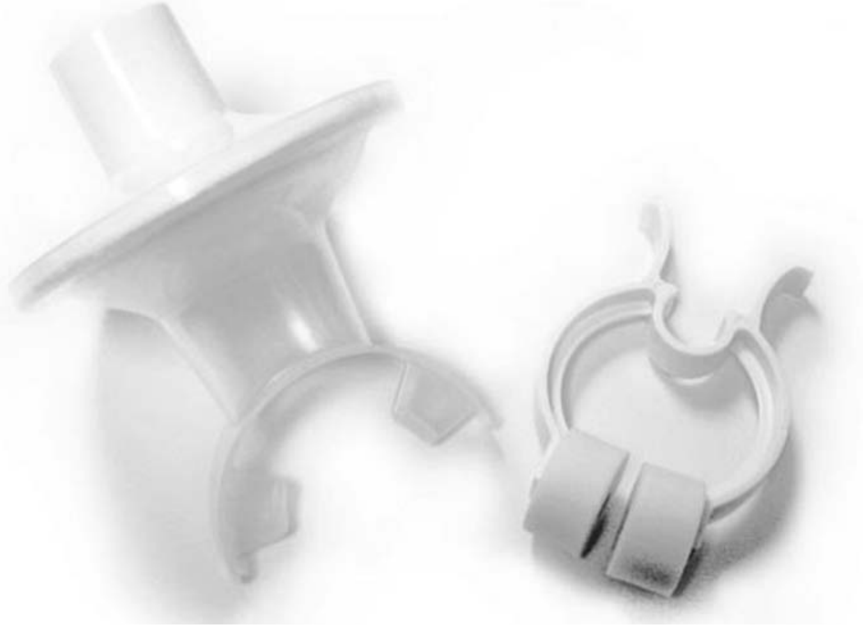

Figure 2 — Disposable mouthpiece and nose clip for the MedGem.

of the published studies provided RQ values. The mean RQs provided were 0.71 ± .09 (27), 0.77 ± .06 (6), and 0.83 ± .01 (28). As noted by Holdy, "within the RQ range of 0.70 to 1.0 assuming a fixed RQ of 0.85, measuring only VO_2 may result up to a ± 4% error rate" (15). According to this assumption, the RQ results of Compher et al. (6) and Reeves et al. (27) should have been an overestimation of RMR using the Gem device compared with a metabolic cart. In both studies, however, the RMR values were significantly higher with the metabolic cart—+9.9% (27) and +15.1% (6)—when RMR values should have been approximately 4% less than the RMR values from the Gem. Based on this information, a fixed RQ of 0.85 might not have resulted in the large measurement differences. Finally, An RQ of 0.85 is generally considered or expected to indicate appropriate energy provision in a patient on a mixed-fuel regimen (15). Therefore, the Gem's fixed RQ of 0.85 might result in a significant but nonmeaningful difference in RMR values.

In conclusion, the Gem device was studied in 14 different human trials, and 12 of these trials employed the methodologies typically used in clinical or research settings. When comparable methodologies are used to validate or compare the Gem device with a referenced indirect calorimeter, the Gem is accurate and reliable for determining RMR. Based on this systematic review, the Gem device might provide clinicians and researchers a viable solution for an accurate assessment of energy needs to develop nutritional plans for most adults and children.

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