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Personalizing The Energy Prescription In The Modern ICU

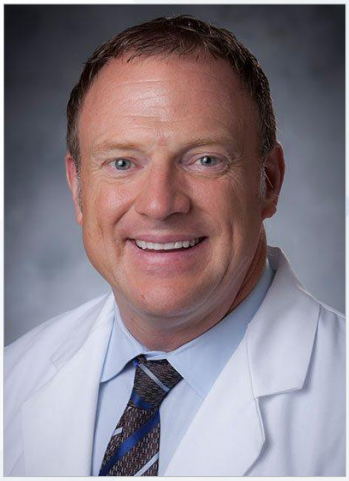
—

The Role of Indirect Calorimetry

Dr. Paul Wischmeyer
August 20th, 2020

1

Faculty



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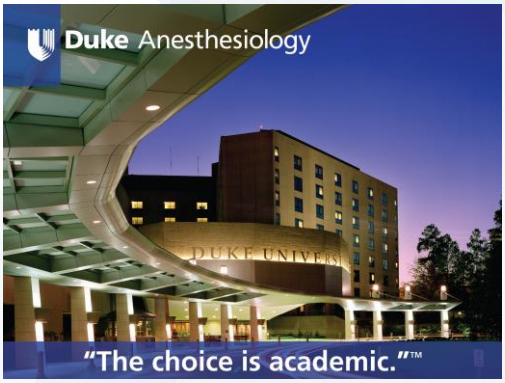
2

Conflicts of Interest



NIH Funding (Past/Pres)

- NIA, NIDDK, NIGMS, NHLBI

CIHR Funding

- RE-ENERGIZE Trial

Mentee Research Grants

- ASPEN, IARS, FAER

Dept of Defense:

- RE-ENERGIZE Trial
- Cardiac Surgery Care

Industry Financial Relationships:

- *Consultant/Grant Support:* Abbott, Baxter, Cosmed, Fresenius, Musclesound, Nestle, Nutricia, Takeda

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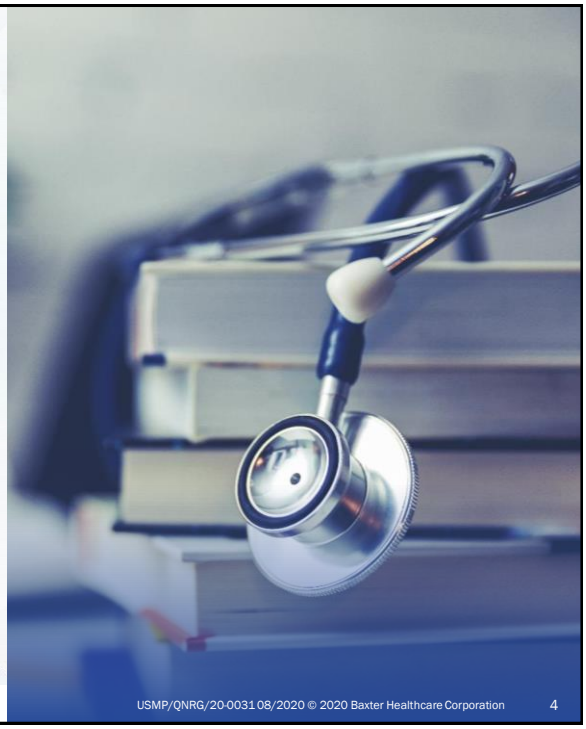
3

Objectives

Describe the international guidelines and clinical evidence regarding the use of indirect calorimetry

Explain the risks of over/underfeeding and the limitation of predictive equations

Discuss current ICU case studies, focusing on the role of Resting Energy Expenditure (REE) measurement in optimizing nutrition therapy



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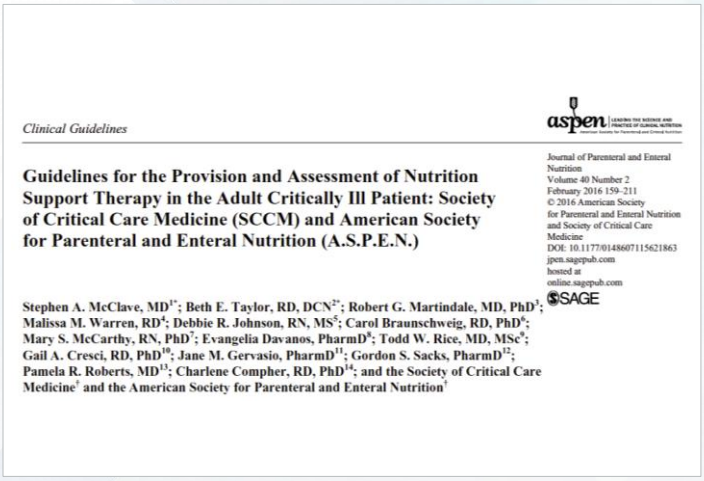
4

SCCM/ASPEN Guidelines (2016)



Clinical Guidelines

aspen

Guidelines for the Provision and Assessment of Nutrition Support Therapy in the Adult Critically Ill Patient: Society of Critical Care Medicine (SCCM) and American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.)

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Question:

What is the best method for determining energy needs in the critically ill adult patient?

A3a. We suggest the indirect calorimetry (IC) be used to determine energy requirements, when available and in the absence of variables that affect the accuracy of measurement

Quality of Evidence: Very Low

McClave SA, et al. JPEN J Parenter Enteral Nutr. 2016;40(2):159-211.

5

ESPEN Guidelines (2018)

Recommendation 15

In critically ill mechanically ventilated patients, REE should be determined by using indirect calorimetry.

Clinical Nutrition 38 (2019) 48–79
Contents lists available at ScienceDirect
Clinical Nutrition
journal homepage: http://www.elsevier.com/locate/clnu

ESPEN Guideline

ESPEN guideline on clinical nutrition in the intensive care unit

Pierre Singer [a, *], Annika Reintam Blaser [b, c], Mette M. Berger [d], Waleed Alhazzani [e], Philip C. Calder [f], Michael P. Casaer [g], Michael Hiesmayr [h], Konstantin Mayer [i], Juan Carlos Montejo [j], Claude Pichard [k], Jean-Charles Preiser [l], Arthur R.H. van Zanten [m], Simon Oczkowski [e], Wojciech Szczeklik [n], Stephan C. Bischoff [o]

Grade of recommendation

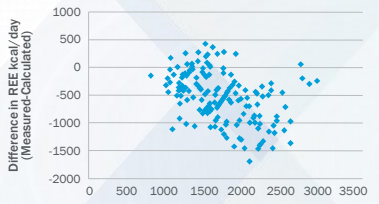
B — Strong consensus (95% Agreement)

Singer P, et al. Clin Nutr. 2019;38(1):48-79.

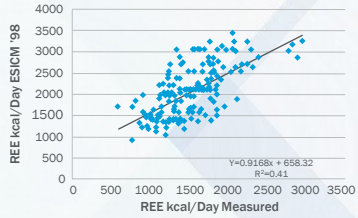
6

Equations that Predict REE Are Inaccurate[1]

Bland-altman Analysis[1]



Correlation Between Predictive Equation for REE by the ESICM '98 Statement and Measured REE by IC[1]



- Large discrepancy between measured REE by IC and predictive equations[1]
- Clinical relevant differences in kcal/24h[1]

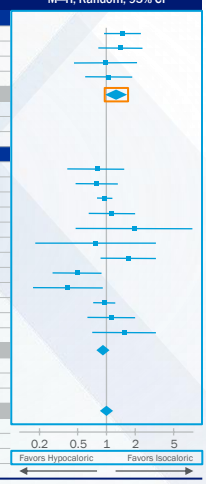
In the EPANIC trial, ESICM '98 statement formula was the basis for determining calorie delivery. Result: Poor outcomes possible associated with under and overfeeding[1,2]

De Waele, et al. demonstrated this formula to have the poorest correlation with IC, suggesting that the results obtained in the EPANIC trial might have been "contaminated" by inadequate feeding of their patients.[1]

REE=Resting Energy Expenditure; ESICM=European Society Intensive Care Medicine; R2=correlation coefficient; EPANIC=The Early Parenteral Nutrition Completing Enteral Nutrition in Adult Critically Ill Patients (EPaNIC). [a]Central solid line: mean bias; Outer solid lines: limits of agreement between methods (±2SD); Fine lines: confidence intervals of mean bias and limits of agreement.
1. De Waele, et al. *Minerva An.* 2015;81(3):272-282; 2. Casaer MP, et al. *N Engl J Med.* 2011;365(6):506-517.

IC Guided "Isocaloric Feeding" with Trend to Improved Short-term Mortality

Study or Subgroup	Hypocaloric Events	Nutrition Total	Isocaloric Events	Nutrition Total	Weight	Risk Ratio M–H, Random, 95% CI	Year
2.1.1 Studies using indirect calorimetry							
Singer 2011	31	65	21	65	8.4%	1.48 [0.96, 2.28]	2011
Heidegger 2013	28	152	20	153	6.4%	1.41 [0.83, 2.39]	2013
Petros 2016	10	46	12	54	3.7%	0.98 [0.47, 2.05]	2016
Allingstrup 2017	21	99	20	100	6.1%	1.06 [0.61, 1.83]	2017
Subtotal (95% CI)		**362**		**372**	**24.5%**	**1.28 [0.98, 1.67]**	
Total events	90		73				
Heterogeneity: τ^2= 0.00; χ^2= 1.51, df=3 (P=0.68); I^2=0%							
Test for overall effect: Z=1.80 (P=0.07)							
2.1.2 Studies without Indirect Calorimetry							
Desachy 2008	11	50	14	50	4.24%	0.79 [0.40, 1.56]	2008
Arabi 2011	22	120	28	120	6.9%	0.79 [0.48, 1.29]	2011
Casaer 2011	242	2328	251	2312	18.7%	0.96 [0.81, 1.13]	2011
Rice 2011	22	98	20	102	6.2%	1.14 [0.67, 1.96]	2011
Rugles 2013	5	53	3	62	1.2%	1.95 [0.49, 0.78]	2013
Charles 2014	3	41	4	42	1.1%	0.77 [0.18, 3.22]	2014
Peake 2014	18	55	11	57	4.6%	1.70 [0.88, 3.26]	2014
Doig 2015	15	166	30	165	5.5%	0.50 [0.28, 0.89]	2015
Braunschweig 2015	6	38	16	40	3.1%	0.39 [0.17, 0.90]	2015
Arabi 2015	93	447	97	444	14.6%	0.95 [0.74, 1.23]	2015
Rugles 2016	18	60	16	60	5.7%	1.13 [0.64, 1.99]	2016
Wischmeyer 2017	17	73	8	52	3.6%	1.51 [0.71, 3.24]	2017
Subtotal (95% CI)		**3529**		**3506**	**75.5%**	**0.94 [0.78, 1.12]**	
Total events	472		498				
Heterogeneity: τ^2= 0.03; χ^2= 16.36, df=11 (P=0.13); I^2=33%							
Test for overall effect: Z=0.73 (P=0.47))							
Total (95% CI)		**3891**		**3878**	**100.0%**	**1.01 [0/86, 1.18]**	
Total events	562		571				
Heterogeneity: τ^2= 0.03; Chi^2= 22.06, df=15 (P=0.11); I^2=32%							
Test for overall effect: Z=0.09 (P=0.93)							
Test for subgroup differences: χ^2=3.62, df=1 (P=0.06); I^2=72.4%							



Adapted from Singer P, et al. *Clin Nutr.* 2019;38(1):48-79.

Dosing of Calories: ESPEN Guidelines on Clinical Nutrition in the ICU

Recommendation 16

If indirect calorimetry is used, isocaloric nutrition rather than hypocaloric nutrition can be progressively implemented after the early phase of acute illness.

Grade of recommendation:
0 — Strong consensus
(95% Agreement)

Recommendation 17

Hypocaloric nutrition (not exceeding 70% of EE) should be administered in the early phase of acute illness.

Early ~70%

Grade of recommendation:
B — strong consensus
(100% agreement)

Recommendation 18

After day 3, caloric delivery can be increased up to 80-100% of measured EE.

Day 3 +
~80-100%

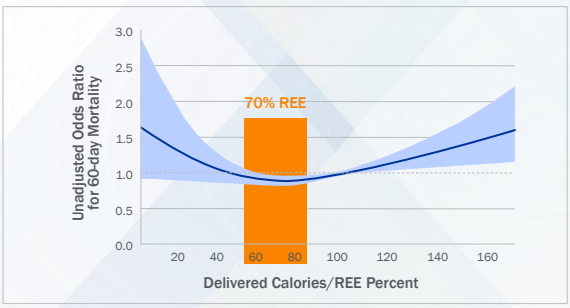
Grade of recommendation:
0 — Strong consensus
(95% Agreement)

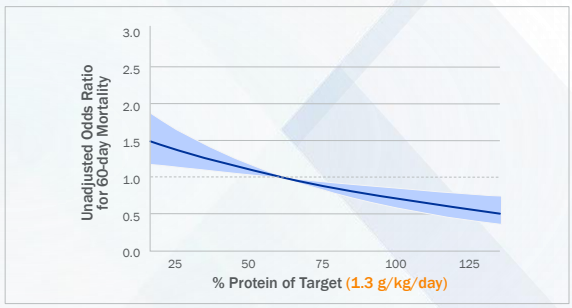
Singer P, et al. *Clin Nutr.* 2018;38(1):48-79.

9

Appropriate Nutrition Dosing Can Help Decrease Mortality

Calories delivered outside range of 70-100% of REE can increase mortality





Meeting both, targeted calories and high protein, are important for decreasing patient 60-day mortality.

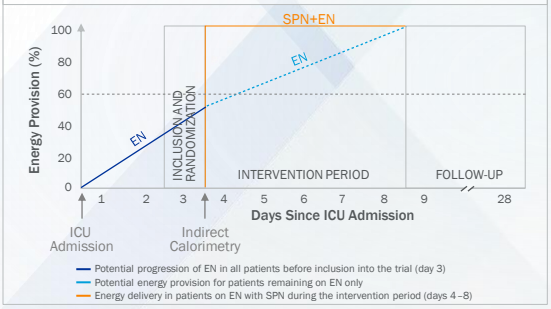
Zusman O, et al. *Crit Care.* 2016;20(1):367.

10

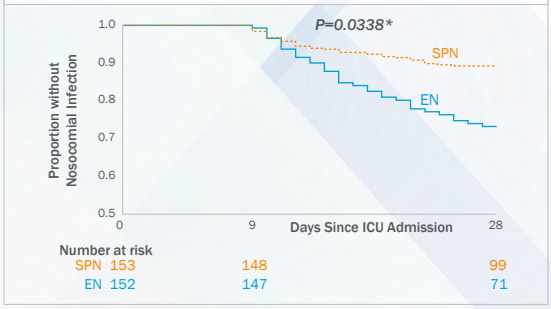
Fewer Nosocomial Infections in Group Fed Closely to Target Measured by IC

Reaching target energy goals (EN+SPN), guided by IC, resulted in significantly decreased hospital-infection rates

Trial Design



Kaplan-Meier Analysis of Nosocomial Infections



EN=enteral nutrition. ICU=intensive-care unit. SPN=supplemental parenteral nutrition.
*Statistically significant with Benjamini-Hochberg correction.
Heidegger CP, et al. *Lancet.* 2013;381(9864):385-393.

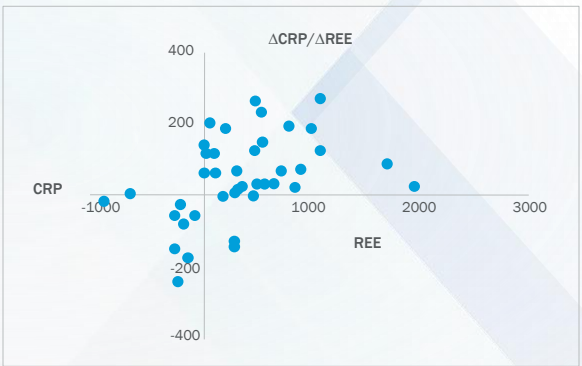
11

Metabolic Monitoring with Indirect Calorimetry

Acute infection in ventilated patients in the intensive care unit

Association between resting energy expenditure and c-reactive protein

- Sepsis is associated to morbidity and mortality
- Apart from CRP and WBC count, additional diagnostic markers are needed to identify signs of infection
- Significant correlation between measured REE and CRP changes, indicating possible signs of an infection with increases in REE



CRP=C-reative protein; REE=resting energy expenditure; WBC:white blood cells.
Dahan D, et al. *Isr Med Assoc J.* 2018;20(10):604-607.

12

The International Multicentric Study Group for IC (ICALIC) Initiative

Clinical Nutrition xxx (2016) 1–12

Contents lists available at ScienceDirect

Clinical Nutrition

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

Review

Indirect calorimetry in nutritional therapy. A position paper by the ICALIC study group

Taku Oshima [a], Mette M. Berger [b], Elisabeth De Waele [c], Anne Berit Guttormsen [d, e, f], Claudia-Paula Heidegger [g], Michael Hiesmayr [h], Pierre Singer [i], Jan Wernerman [j], Claude Pichard [k, *]

- Indirect Calorimetry is needed to optimize nutrition care
- Use is currently limited by practical setbacks
- Initiative was taken to develop new technology
- To be accurate, easy-to-use, and affordable cost

Oshima T, et al. *Clin Nutr.* 2017;36(3):651-662.

The Early Evolution of Indirect Calorimetry

1980s[1]	1990s[2]	Early 2000s[2]
Early IC devices with Douglas Bag methodology	Current mainstream metabolic carts	New handheld IC
	 	
One of the oldest method for sampling expired gas, considered the gold standard for measuring REE	Newer devices that can test on patients on ventilator	Portable, but cannot be used on ventilated patients

- **Large** and unwieldly equipment[1]
- **Calibration** and correct conditions in the room were required **for accurate readings**[1,3]
- Specialized **technicians** were required to analyze a single gas sample at a time[3]
- **Ventilator leaks** resulted in inaccurate measurements[1,3]
- **Personal computer** use is required to record and analyze results[1]

1. Oshima T et al. Clinical Nutrition 2017;36:651–662.
2. Neiman DC et al. International Journal of Sport Nutrition and Exersize Metabolism. 2005;15:186–194.
3. Haugen HA et al. *Nutr Clin Pract.* 2007;22:377.

IC, indirect calorimetry; REE, resting energy expenditure.

Next-generation Indirect Calorimetry

Advances in Indirect Calorimetry technology overcome clinical practice barriers

Q-NRG+ Metabolic Monitor by COSMED is

Fast[1]
- ~10-15 minutes to run test (including warm-up time)
- Minimal calibration time

Accurate[1]
- REE within +/- 3% or 36 kcal/day, whichever is greater
- Range (0-7200 kcal/day)

Intuitive[1]
- Real-time, user-friendly dashboard
- Downloadable data in PDF or spreadsheet file
- Portable and easily transported between rooms
- Flexibility to use in intubated and spontaneously breathing patients

Rx Only: For safe and proper use of this medical device, please refer to User's Manual

1. QNRG+ Users Manual

15

Q-NRG+ As A Way To Address The Problem

Q-NRG+ overcomes current barriers

Barriers seen in current IC technology[1]		Q-NRG+[2]
Workflow / ease of use	Takes 45-60 min to set up and run test	Takes ~ 10-15 min from start to finish
Size	Bulky metabolic carts	Lightweight, portable and easy to transport
Accuracy tested by Mass-spectrometry	n/a[3]	Accurate and reliable, tested vs. Mass spectometry[3]
Flexibility	ICU use limited for ventilated patients only	Use in ventilated and spontaneously breathing pts

"Why guess when we can measure" – Dr. Pierre Singer, ESPEN Guidelines Chair

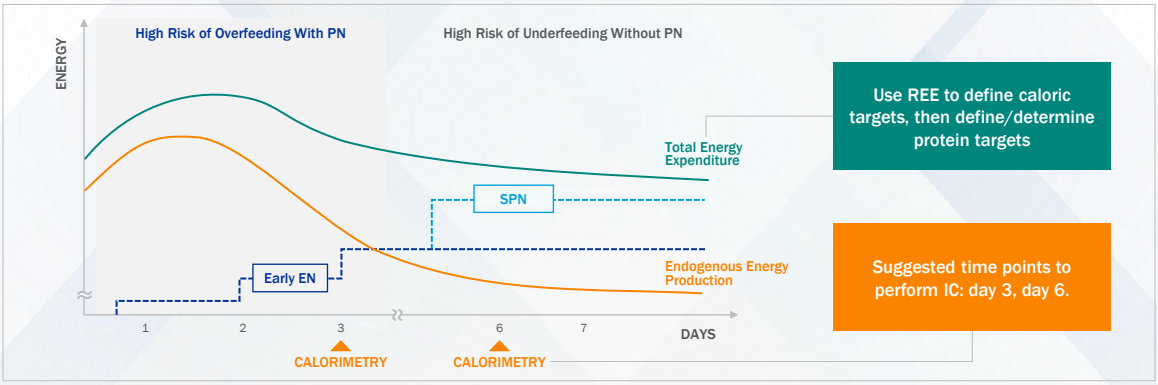
Rx Only: For safe and proper use of this medical device, please refer to User's Manual

1. Oshima T, et al 2017, ICALIC position paper
2. Q-NRG+ User Manual, Cosmed
3. Oshima T et Al., The clinical evaluation of the new indirect calorimeter developed by the ICALIC project, Clinical Nutition

16

Timing of IC according to the ICALIC Position Paper

IC should be performed when the clinical condition of patient changes, so that the Nutrition Rx can be adapted to meet the demands of the patient's altered metabolic state.



Oshima T, et al. *Clin Nutr.* 2017;36(3):651-662.

17

Current Experience

18

IC in SCCM/ASPEN & ESPEN COVID-19 Updates

SCCM/ASPEN Nutrition Therapy in the Patient with COVID-19 disease requiring ICU Care

Updated April 1, 2020

Recommendation 4: Nutrition Dose, Advancing to Goal, and Adjustments

... While energy requirements can ideally be determined by indirect calorimetry, the principle of "clustering" of care is particularly important and we recommend instead using weight-based equations to estimate energy requirements as a practical matter for the COVID-19 patients...

ESPEN expert statements and practical guidance for nutritional management of individuals with SARS-CoV-2 infection

March 24, 2020

2.2. Statement 2

... Energy needs can be assessed using indirect calorimetry if safely available with ensured sterility of the measurement system, or as alternatives by prediction equations or weight-based formulae such as:

(1) 27 kcal per kg body weight and day; total energy expenditure for polymorbid patients aged >65 years (recommendation 4.2 in ref. [7])
(2) 30 kcal per kg body weight and day; total energy expenditure for severely underweight polymorbid patients (recommendation 4.3. in ref. [7])*
(3) 30 kcal per kg body weight and day; guiding value for energy intake in older persons, this value should be individually adjusted with regard to nutritional status, physical activity level, disease status and tolerance (recommendation 1 in ref. [8])

In regards to IC, focus is on limiting physical exposure

SCCM/ASPEN Nutrition Therapy in the Patient with COVID-19 disease requiring ICU Care. April, 2020
ESPEN expert statements and practical guidance for nutritional management of individuals with SARS-CoV-2 infection. March, 2020

19

Longitudinal Evaluation of Energy Expenditure and Metabolic Pathophysiology of COVID-19

(LEEP-COVID)

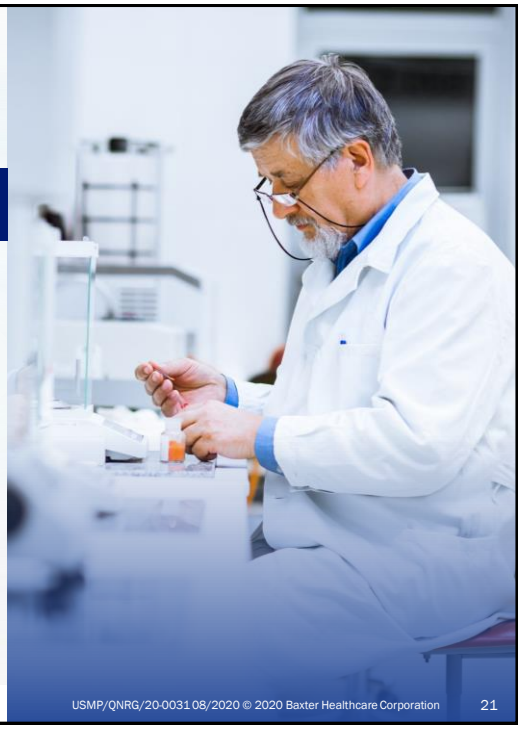
Funded in part by investigator initiated research grants from Baxter Healthcare Corporation

20

Indirect Calorimetry in COVID-19?

LEEP-COVID Study

- LEEP-COVID is an ongoing trial. Results shown are preliminary and should not be considered definitive
- Currently, no longitudinal data exist describing EE & metabolism of COVID-19 infection
- Data urgently needed to assist care & recovery of COVID-19 patients worldwide



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21

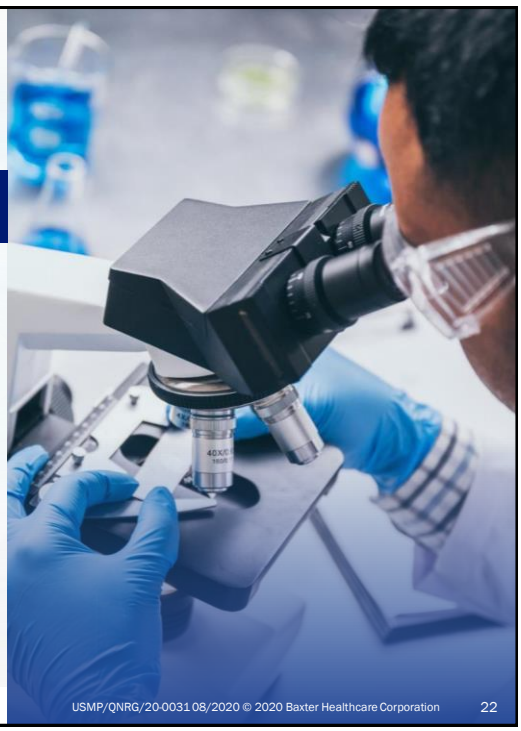
Indirect Calorimetry in COVID-19?

LEEP-COVID Study

Aim: Evaluate **longitudinal EE & metabolic pathophysiology in COVID-19** to understand, guide & optimize nutrition/metabolic care

Will provide objective data to guide physical recovery interventions- i.e. nutrition & physical therapy to ensure functional recovery in COVID-19

* Accepted for publication in Critical Care



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22

LEEP-COVID Study Measures

- Longitudinal Measures from ICU Admit - Hospital Discharge
- Every other day in ICU/3 x week on Floor

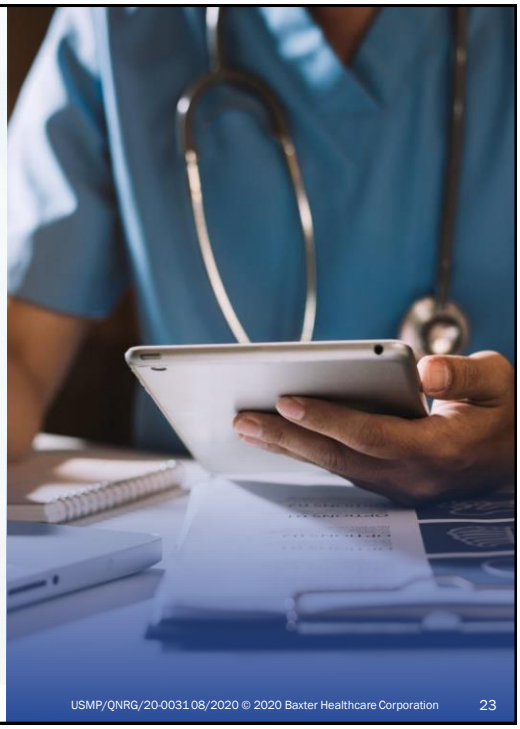
01 **New Q-NRG+ Indirect Calorimetry device**
Provides non-invasive cardiac output (via Fick equation)

02 **New Muscle-Specific Ultrasound**
Measures muscle mass, quality & glycogen content

03 **Advanced Bioimpedance Analysis (BIA) Device**
Measures body composition via bioimpedance analysis

04 **Bedside Cardiac Echocardiography/CV Assessment**

* Accepted for publication in Critical Care



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Case Study

This is a mid-50's LTAC patient COVID (+) (60 kg) early in care (Day 2)

- Spontaneously breathing on vent (not paralyzed)
- 15 kcal/kg is determined by indirect calorimetry
- On Trophic Tube Feeds

* Accepted for publication in Critical Care

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Case Study

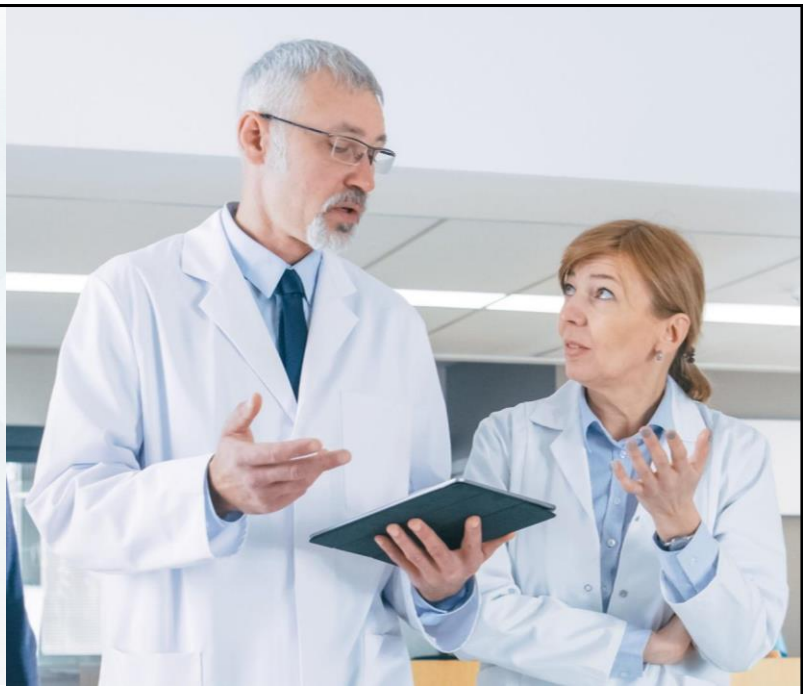
This is our COVID (+) patient early in care (Day 4)

- Being fed 1440 kcal/d- based on 18 kcal/kg
- Proned and Paralyzed when test was done on PEEP of 12

25

What About Chronic and Recovery Phase?

Beyond Day 5-7…



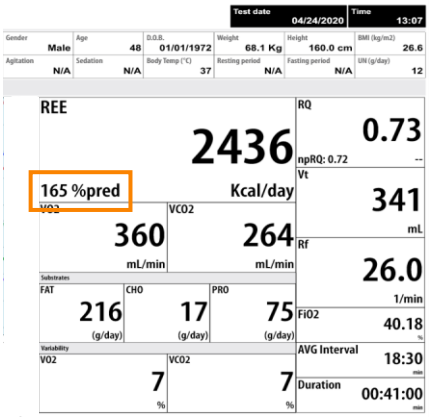
* Accepted for publication in Critical Care

26

Case Study

COVID (+) 49 y/o patient (ICU Day 12)

- Being underfed 1440 kcal/d- based on 20-25 kg/kg
- 35 kg/kg/d by IC
- We changed feeding to 2400 kcal/d as patient weaned on vent on pressure support

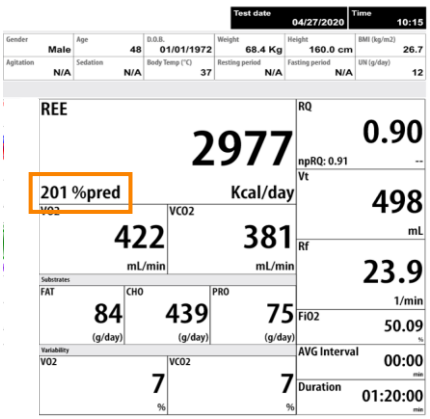


* Accepted for publication in Critical Care

Case Study

COVID (+) 49 y/o patient (ICU Day 15)

- Febrile at time of cart (> 70% of day)
- 44 kcal/kg via IC
- Changed feeding to 2400 kcal/d w/ improved RQ & increased REE as patient weaned on vent on pressure support



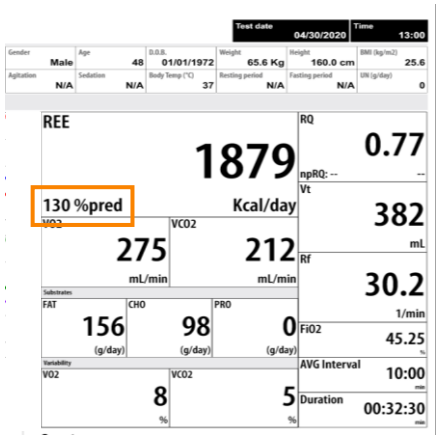
* Accepted for publication in Critical Care

Case Study

COVID (+) 49 y/o patient (ICU Day 18)

(Now Afebrile-previous IC measures patient febrile much of day)

- 28 kcal/kg measured by IC
- We changed feeding to 2100 kcal/d to account for febrile & non-febrile periods as patient weaned on vent on pressure support



* Accepted for publication in Critical Care

Case Study

COVID (+) 49 y/o patient (ICU Day 23)

- Being fed < 50% of goal x 7 days
- RQ showing underfeeding and continued protein breakdown
- 34 kcal/kg measured by IC
- Feeding needs continue to be 156% of predicted and EN+SPN being considered

* Accepted for publication in Critical Care

LEEP-COVID Study

Baseline Characteristics (n=22)	
Age (median, IQR)	58 (31-88)
Male sex - n (%)	13 (59)
Race - n (%)	
• African-American/Black	12 (54)
• Caucasian/White	7 (32)
• Hispanic	3 (14)
BMI (median, IQR)	30.7 (17.4-48.1)
BMI >30 (%)	12 (55)

* Accepted for publication in Critical Care

31

LEEP-COVID Study

Baseline Characteristics (n=22)	
Ventilator days (21-day study period only), (mean, sd)	14.4 (4.7)
Mortality (21-day study period only), (n,%)	3 (14)
Mortality (Hospital mortality), (n,%)	5 (22)

* Accepted for publication in Critical Care

32

Prolonged Hypermetabolism in COVID-19

Indirect Calorimetry / Nutrition Data:	D0-7	D7-14	D14-21	p-value
Measured REE absolute kCal/day (all patients) (median, IQR)	1568 (1175-2215)	1830 (1465-2467)	2789 (1776-3262)	<0.05
Measured REE kCal/kg Actual BW (BMI<30) (median, IQR)	19.2 (16.9-20.7)	26 (24.5-35.5)	29 (23-34.5)	<0.05
Measured REE kCal/kg Actual BW (BMI >30) (median, IQR)	17.5 (12-19.25)	21 (20-23.5)	31.5 (24.8-36)	<0.05
Measured REE kCal/kg Adjusted BW (BMI >30) (median, IQR)	20 (17-22.5)	26.3 (24-29)	32.5 (28.8-35.8)	<0.05
Measured REE kCal/kg Actual BW (all patients) (median, IQR)	19 (13.7-28.5)	26 (22-42)	30.4 (27-35.8)	<0.05
Actual kcal administered - kCal/kg (median, IQR)	9.4 (0.6-14.5)	13.5 (11-24)	26.5 (13.8-29.5)	<0.05
% energy needs actually delivered as determined by measured REE (IBW) (median, IQR)	49.4 (27-58.8)	51.9 (41.5-88.5)	84.1 (83-98.1)	<0.05

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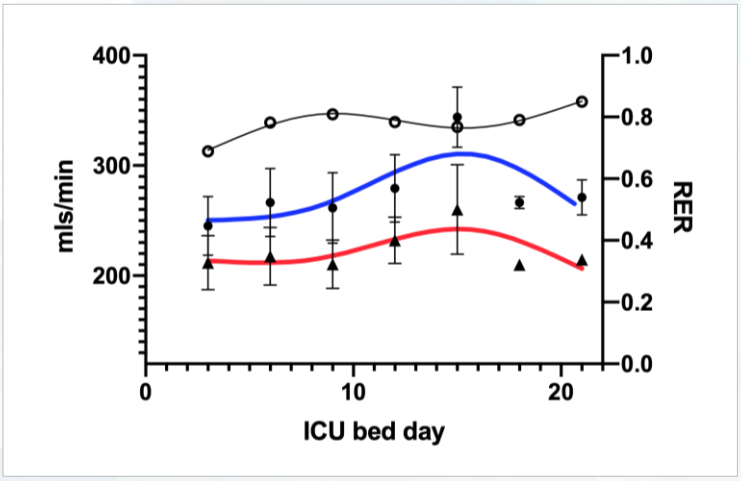
33

Prolonged Hypermetabolism in COVID-19



Respiratory Exchange Ratio (RER ~RQ)

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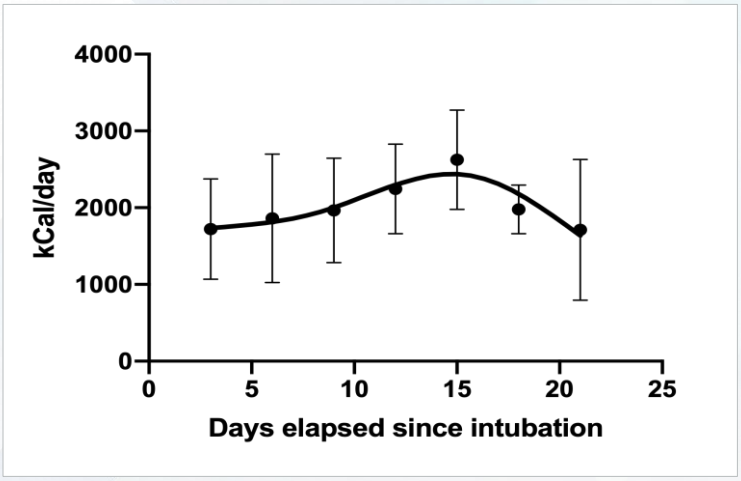
34

Prolonged Hypermetabolism in COVID-19



mREE
(all pts, Actual BW)

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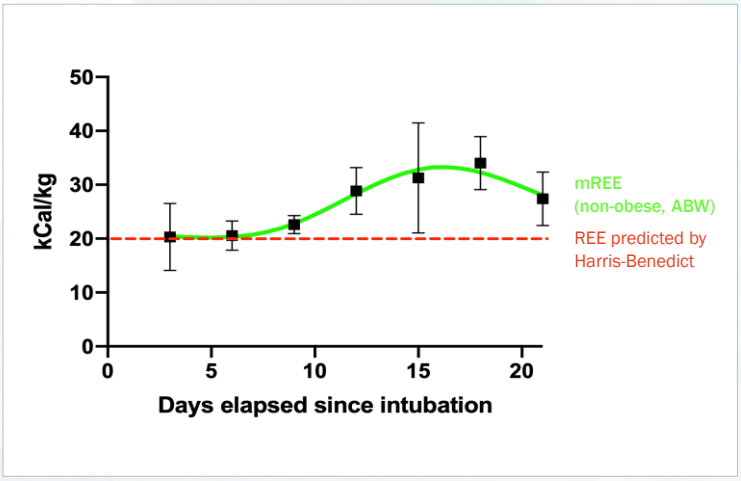
35

Prolonged Hypermetabolism in COVID-19



Non-Obese, BMI<30

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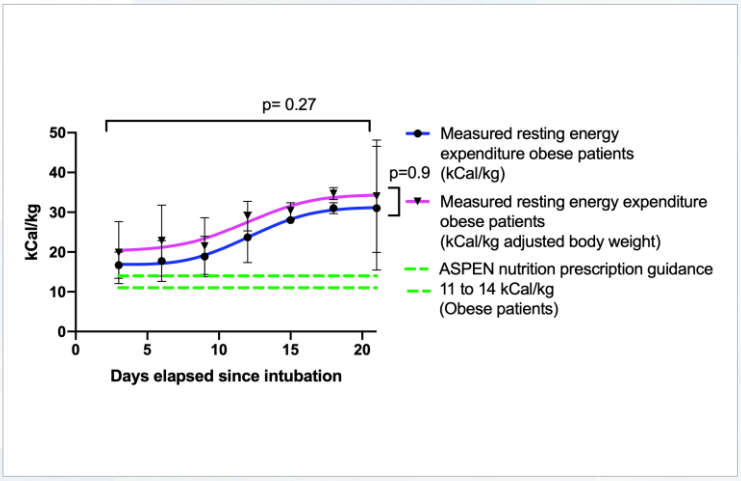
36

Prolonged Hypermetabolism in COVID-19



Obese, BMI>30

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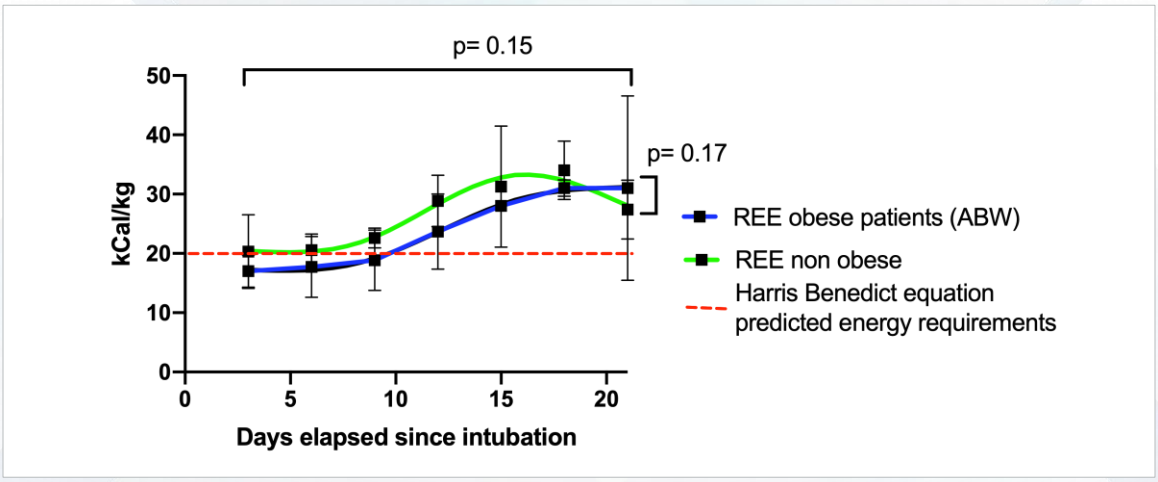
37

Prolonged Hypermetabolism in COVID-19



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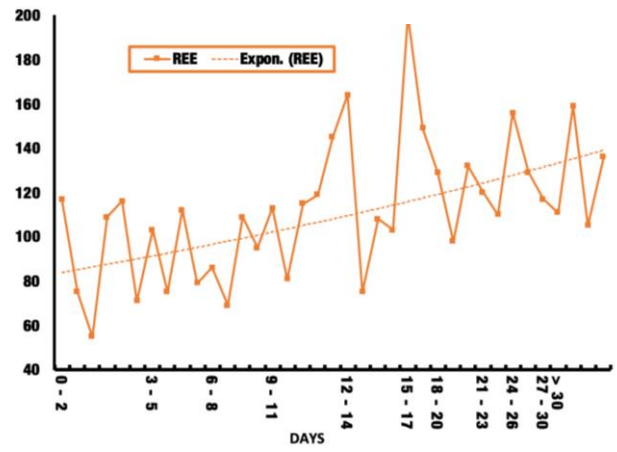
38

Caloric Need Vs Predicted in COVID-19



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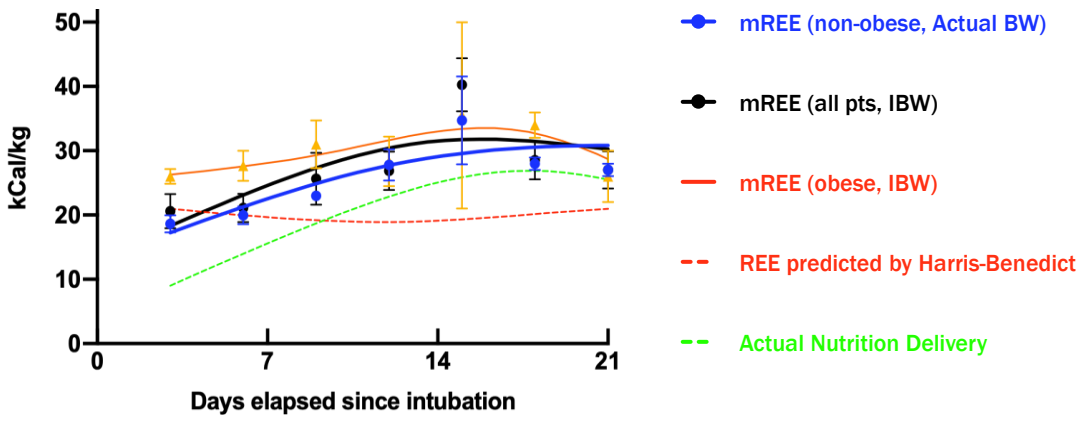
39

Prolonged Hypermetabolism in COVID-19



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40

LEEP-COVID Study

Clinical Data	D0-7	D7-14	D14-21	p-value
Use of prone positioning (%) (mean,sd)	12.3 (8.6)	7 (2.4)	12.2 (4.3)	0.17
Use of paralysis with neuromuscular blocker (%) (mean, sd)	14.8 (8)	9.7 (1.7)	12.3 (3.4)	0.2
SOFA score (mean, sd)	9 (3.6)	9 (3.2)	9.5 (3.6)	0.5

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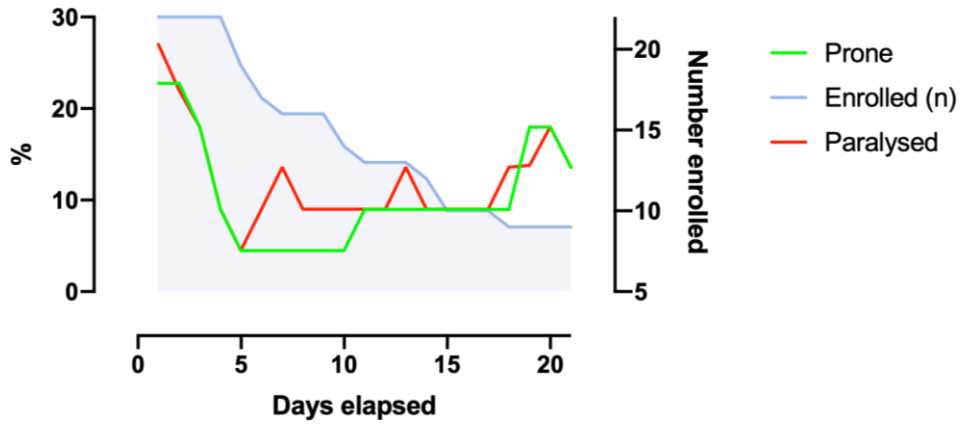
41

Use of Prone Positioning and Paralysis in LEEP-COVID



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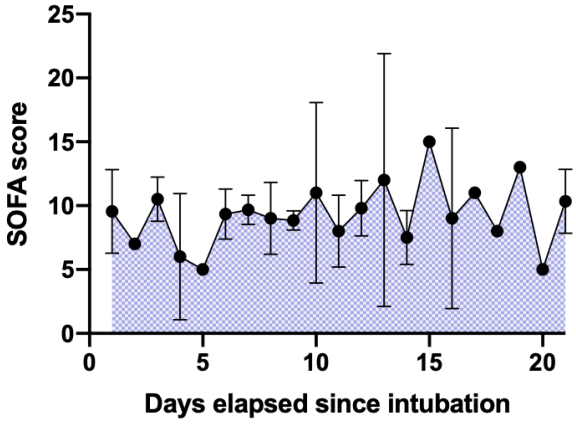
42

Severity of Organ Failure (SOFA) Score in LEEP-COVID



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43

Indirect Calorimetry Data in COVID-19

NCT:04350073

Initial LEEP-COVID Data

In first 3-7 days

COVID-19 patients are NormoMETABOLIC (80-100% of predicted/17-20 kcal/kg/d)

After day 7

COVID-19 patients are HYPERMETABOLIC - 120-200% of equation predicted even paralyzed... (25->35+ kcal/kg/d)

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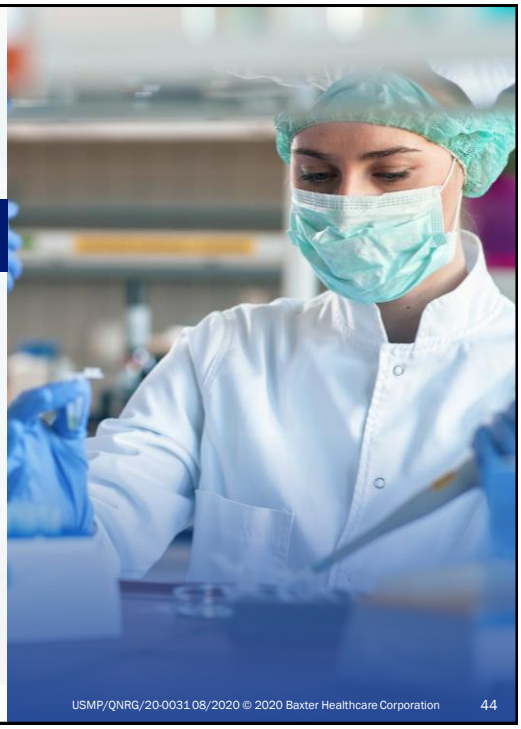

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44

Indirect Calorimetry Data in COVID-19

NCT:04350073

Initial LEEP-COVID Data

First ICU Week

~20 kcal/kg (Actual BW for BMI < 30 and Adjusted BW for Obese BMI 30-50) are close to mREE

Acute Phase (First 1-5 days?)

Per ESPEN Guidelines would feed 70% of ~20 kcal to prevent overfeeding in non-malnourished pts

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45

Indirect Calorimetry Data in COVID-19

NCT:04350073

Initial LEEP-COVID Data

After day 7

Considerable variability from day to day exists

Key Factors To Consider in Setting Goals

- **Age:** (Over 70= ↓ kcal/kg/d)
- **Obesity:** (30-32 kcal/kg/d IBW: post-1st ICU wk)
- **Fever:** Significant ↑ kcals (500-1000 kcal/d)

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46

Indirect Calorimetry Data in COVID-19

NCT:04350073

Initial LEEP-COVID Data

- **Hypermetabolism** does not appear related to severity of organ failure
- **Hypermetabolism** may only have minor relationship (if any) to paralysis and sedation (such as for proning)

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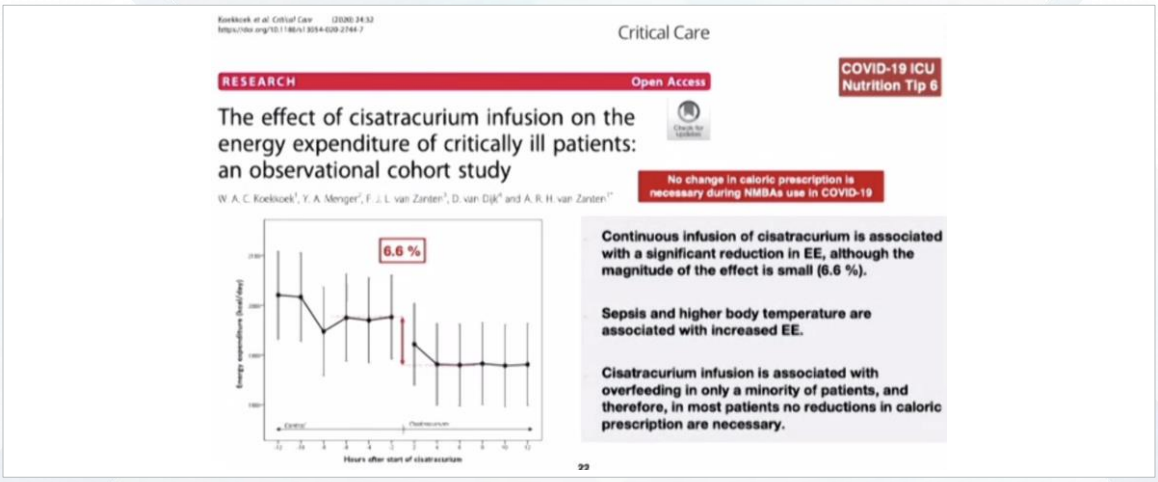
47

The effect of cisatracurium infusion on the energy expenditure of critically ill patients[1]



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COVID-19 ICU Nutrition Tip 6

The effect of cisatracurium infusion on the energy expenditure of critically ill patients: an observational cohort study

No change in caloric prescription is necessary during NMBAs use in COVID-19

6.6 %

Continuous infusion of cisatracurium is associated with a significant reduction in EE, although the magnitude of the effect is small (6.6 %).

Sepsis and higher body temperature are associated with increased EE.

Cisatracurium infusion is associated with overfeeding in only a minority of patients, and therefore, in most patients no reductions in caloric prescription are necessary.

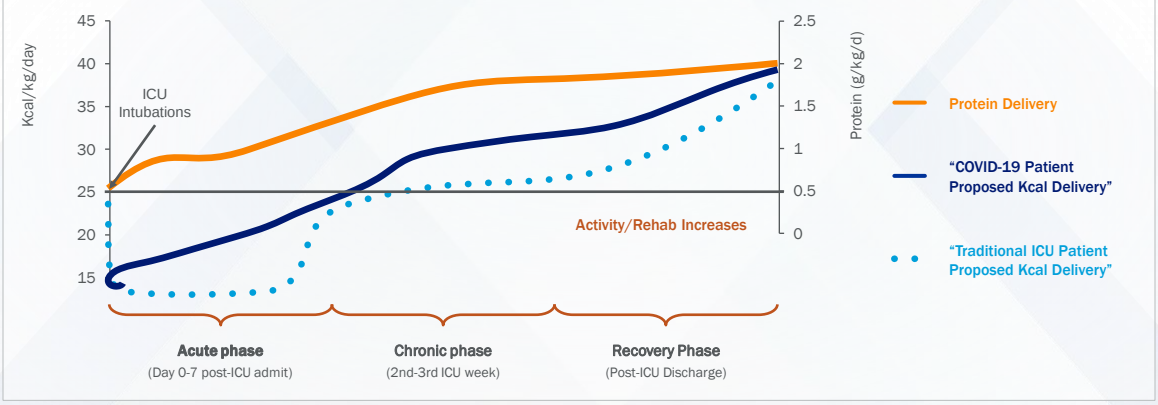
Courtesy: Arthur Van Zanten

1. Koekkoek et al. Critical Care (2020) 24:32

48

Nutrition Delivery Targets in COVID-19 from LEEP-COVID Data

Adapted from Wischmeyer PE. Crit Care Clin 34:107-125. 2018



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49

Personalized Nutrition Rx Using Indirect Calorimetry

01 Perform IC when a nutrition care plan is indicated

02 Use Measured Resting Energy Expenditure to define your caloric target, then define/determine protein target

03 Choose artificial nutrition type (e.g. EN, PN, SPN)

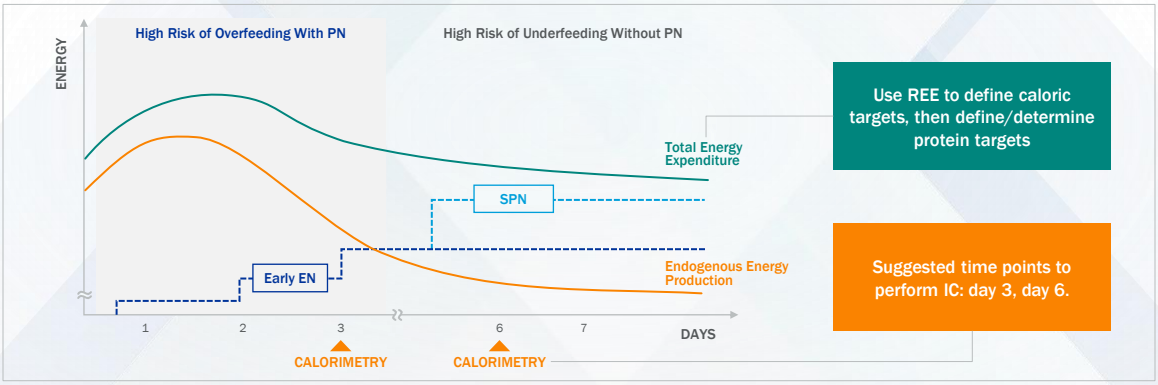
04 Provide optimal nutrition to patients according to target

05 When metabolic needs change, repeat IC and adjust treatment plan/nutrition Rx

50

Indirect Calorimetry in Nutrition Therapy, Position Paper by ICALIC Study Group

IC should be performed when the clinical condition of patient changes, so that the Nutrition Rx can be adapted to meet the demands of the patient's altered metabolic state.

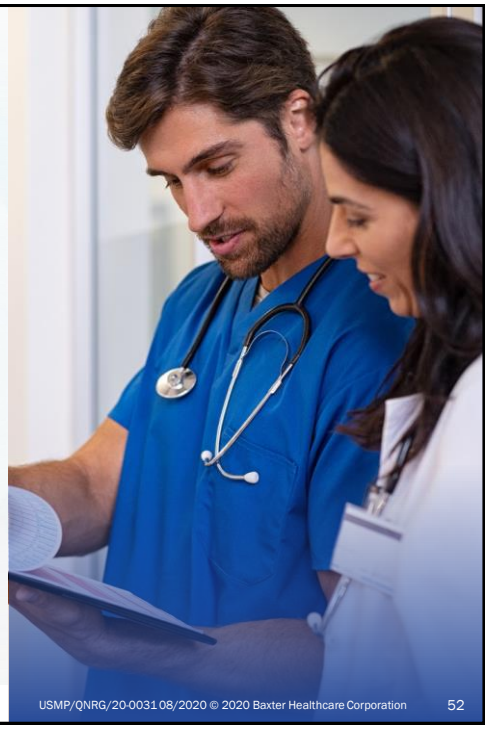


Oshima T, et al. *Clin Nutr.* 2017;36(3):651-662.

51

Clinical recommendations and integration of Indirect Calorimetry

- Indirect Calorimetry (IC) provides **individualized energy targets** for patients as recommended by international **guidelines**[1,2]
- **Optimal nutrition** that meets nutrition targets can significantly **decrease patient mortality**[3]
- **IC** should be **integrated** into the **patient's nutrition assessment/plan**[4]



1. McClave SA, et al. JPEN J Parenter Enteral Nutr. 2016;40(2):159-211.
2. Singer P, et al. Clin Nutr. 2019;38(1):48-79.
3. Zusman O, et al. *Crit Care.* 2016;20(1):367.
4. Oshima T, et al. *Clin Nutr.* 2017;36(3):651-662.

52

Longitudinal Energy Expenditure and Metabolic Pathophysiology of COVID-19 (LEEP-COVID)

ClinicalTrials.gov Identifier: NCT04350073

https://clinicaltrials.gov/ct2/show/NCT04350073?term=Paul+Wischmeyer&cond=Covid19&draw=2&rank=2

Prospective, observational cohort study of 120 patients

Study Questions:

We propose to evaluate longitudinal metabolic and cardiac pathophysiology in patients with COVID-19 to understand, guide and optimize our metabolic clinical care during acute hospitalization.

Further, this data will be essential in providing objective data to guide physical recovery interventions including nutrition delivery and physical therapy to ensure functional recovery of COVID-19 patients.

We hypothesize:

- COVID-19 will lead to significant, EE/metabolic changes, systemic mitochondrial dysfunction, significant muscle wasting and loss of function throughout the course of illness and during recovery.
- Metabolic needs will initially decrease in acute illness and subsequently increase as patients transition from the acute phase of COVID illness to recovery phases. This data will guide nutrition and metabolic/clinical care in all phases of COVID-19 care where, for example, over-and under-feeding may pose risk to patient outcome.
- Loss of muscle mass and physical function occurring in COVID-19 will significantly affect nutritional/rehabilitative/recovery of function/qol needs and requires addressing to personalize care to optimize clinical and functional recovery efforts in older COVID-19 patients.

53

Q-NRG+ Metabolic Monitor Indications and Instructions for Use

The Q-NRG+ portable Metabolic Monitors are indicated for the measurement of Resting Energy Expenditure (REE) for spontaneously breathing and ventilated patients, within the following populations:

- Spontaneously breathing subjects >15 kg (33 lb) when using a canopy
- Spontaneously breathing subjects age >6 yrs and > 10 kg (22 lb) when using a face mask
- Ventilated subjects age > 10 yrs and > 10 kg (22 lb)

The Q-NRG+ Portable Metabolic Monitors are **intended to be used in professional healthcare facilities only.**

CE 0476

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One Baxter Parkway
Deerfield, IL 60015
www.baxter.com

Precautions/Contraindications: Carefully re-check ventilator functionality after connection of the ports. Make sure that the patients cuff pressure is high enough to avoid air leakage. Manipulation of the ventilator circuit may cause leaks that may lower alveolar ventilation.

Indications for Use: The Q-NRG+ portable Metabolic Monitors are indicated for the measurement of REE for spontaneously breathing and ventilated patients, with some limitations in accordance with labeling, within the following population: spontaneously breathing subjects > 15 Kg (33 lb), when tested with the canopy dilution technique, ventilated subjects > age 10 and 10 Kg (22 lb), and spontaneously breathing subjects > age 6 and 10 Kg (22 lb), when tested with face mask. The Q-NRG+ Portable Metabolic Monitors are intended to be used in professional healthcare facilities only. This device is not suitable for operating in presence of flammable anesthetic gases or gases other than 02, C02, N2 and water vapor. The device is to be used by physicians or by trained personnel under the responsibility of a physician. The device is not intended as a continuous monitoring device for surveillance of vital physiological processes.

Warnings: This devices measures clinical parameters used to aid diagnosis and it is intended only as an adjunct device in patient assessment. In case of disturbing conditions, the shutdown is allowed because the safety of the device towards patients and operators is not affected, since the final evaluation is performed on the outcome data measured during a complete test. No modification of this device is allowed.

Rx Only. For safe and proper use of this device please refer to the User's Manual.

54