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International Consensus Guideline Committee Pancreatitis Task Force

JPEN J Parenter Enteral Nutr published online 28 March 2012

DOI: 10.1177/0148607112440823

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<http://pen.sagepub.com/content/early/2012/03/27/0148607112440823>

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International Consensus Guidelines for Nutrition Therapy in Pancreatitis

Jay M. Mirtallo, MS, RPh¹; Alastair Forbes, MD²; Stephen A. McClave, MD³; Gordon L. Jensen, MD, PhD⁴; Dan L. Waitzberg, MD, PhD⁵; and Andrew R. Davies, MD⁶ for the International Consensus Guideline Committee Pancreatitis Task Force

Journal of Parenteral and Enteral Nutrition
 Volume XX Number X
 Month 2012 1-8
 © 2012 American Society for Parenteral and Enteral Nutrition
 DOI: 10.1177/0148607112440823
<http://jpen.sagepub.com>
 hosted at
<http://online.sagepub.com>


Abstract

Guidelines for nutrition support in pancreatitis have been inconsistently adapted to clinical practice. The International Consensus Guideline Committee (ICGC) established a pancreatitis task force to review published guidelines for pancreatitis in nutrition support. A PubMed search using the terms *pancreatitis*, *acute pancreatitis*, *chronic pancreatitis*, *nutrition support*, *parenteral nutrition*, *enteral nutrition*, and *guidelines* was conducted for the period from January 1999 to May 2011. Eleven guidelines were identified for review. The ICGC used the following process to develop unified guideline statements: summarize the strength of evidence (grading) of the guidelines; establish level of evidence for ICGC statements as high, intermediate, and low; assign published guideline levels of evidence; and define an ICGC grading system. International Pancreatitis Guideline Grades were established as follows: platinum—high level of evidence and consistent agreement among the guidelines; gold—acceptable level of evidence and no conflicting statements in guidelines; and silver—single existing guideline statement with no conflict in other guidelines. Eighteen ICGC statements were derived from the 11 published pancreatitis guidelines. Uniform agreement from widely disparate groups (United States, Europe, Japan, and China) resulted in 4 platinum-level guideline statements for nutrition in pancreatitis: nutrition support therapy (NST) is generally not needed for mild to moderate disease, NST is needed for severe disease, enteral nutrition (EN) is preferred over parenteral nutrition (PN), and use PN when EN is contraindicated or not feasible. This methodology provides a template for future ICGC nutrition guideline development. (*JPEN J Parenter Enteral Nutr.* XXXX;XX:xx-xx)

Keywords

pancreatitis; guideline; nutrition support; enteral nutrition; parenteral nutrition

Clinical guidelines are statements that are systematically developed and contain recommendations for diagnosis and management of patients. Based on rigorous systematic review and evaluation of published literature, guidelines assist the clinician with decisions about appropriate care. Each guideline group develops its own individual methodologies with regard to review of the literature, scoring of the evidence, and procedure for obtaining consensus of committee members. As a result, guidelines from different societal groups concerning the same topic may provide conflicting recommendations. Guidelines that are variable or contradictory between societal reports may cause clinicians to misinterpret, ignore, or apply recommendations according to their own individual bias.

The International Consensus Guideline Committee (ICGC) was formed to adopt current high-quality guidelines from various societal reports and encourage the development of a novel system for combining or converging guidelines that would have international applicability. Membership of the committee was by secondment from the world's most influential clinical nutrition societies following a scene-setting, open meeting in Prague in 2008. These societies proposed one or more of their senior members who had a formal responsibility for guidelines, clinical practice, and/or education. The committee has met twice-yearly since then, with extensive electronic communication and, inevitably, with some evolution of membership over time. The

committee maintains a regular dialogue with each of the primary societies. The authors of this article have expertise in guidelines, nutrition, and/or pancreatitis and have had the most to do with this specific project among the various endeavors with which the committee has concerned itself. They therefore satisfy the normal criteria for authorship of a scientific paper but acknowledge with great appreciation the contributions of the other members of the committee (listed below*), as well as

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Financial disclosure: This article is endorsed by the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) and the Brazilian Society of Parenteral and Enteral Nutrition.

Received for publication January 31, 2012; accepted for publication February 1, 2012.

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the many constructive comments received from guidelines committees and key individuals in the primary societies who have reviewed various drafts of this report. The focus of the ICGC was to review a variety of international guidelines and to evaluate the developmental process for their derivation. The committee was also charged with evaluating the degree of consensus for guideline statements across multiple societal reports. Attention was paid as to whether guidelines were developed under rigorous processes, whether high-quality evidence supported each of the recommendations, and whether different societal committees derived similar recommendations on the same topic.

The ICGC selected nutrition therapy in acute pancreatitis as the first set of guidelines for the group to evaluate. Nutrition therapy in acute pancreatitis is a topic where guidelines have been inconsistently adapted to clinical practice. This article describes the methodology used to compare and contrast guidelines published on this subject, as well as the process by which the ICGC could derive consensus recommendations for the nutrition management of this patient population.

Methods

Literature Review

Publications that contained guidelines for nutrition therapy in pancreatitis were identified using the methodologies listed below. PubMed was used as the search engine for the literature review. Search terms included *pancreatitis*, *acute pancreatitis*, *chronic pancreatitis*, *nutrition support*, *parenteral nutrition*, *enteral nutrition*, and *guidelines*. The search was for the period from January 1999 through May 2011 and included both English and non-English publications. Title and content were searched for using the selected terms. References were selected for review if there was a sponsoring organization (society) and a methodology that described a process for guideline development. For general guidelines on the topic of acute or chronic pancreatitis, only those sections dealing with nutrition therapy were included for review by the committee.

Guideline Assessment

Guidelines selected by the ICGC for review had to meet the following criteria:

1. The guideline was developed by practitioners with expertise on the topic. The guideline committee used a transparent process for data collection, review, and analysis.
2. The guideline was clear, pragmatic, and supported by a national or international society.
3. The guideline was founded on evidence specific to pancreatitis.

Specific information, abstracted by the ICGC members from the various guidelines, included the following:

1. Sponsoring organization, strength of the evidence (grading), and guideline development process
2. Guideline recommendations for nutrition therapy in pancreatitis, with references cited from the supportive literature

Once the societal guideline reports were identified, a table was constructed (see the appendix online at <http://jpen.sagepub.com/supplemental>) to list the comments and specific recommendations from each group. Some of the comments included in the table were more of a discussion format, whereas others were specific recommendations. For these latter statements, where appropriate, the individual grade of the recommendation assigned by that societal group was included.

Next, the ICGC focused on the 2 major issues: strength of evidence from the literature and consensus between reports. A table was constructed to demonstrate the grading system for level of evidence used by each societal group (Table 1). Because committee members' strategy, methodology, and bias might vary, successive publications by the same society from different years were regarded as separate and unique societal reports.

Another table was constructed to delineate a simplified 3-tier comparative grading scale for level of evidence of supportive literature for recommendations published across multiple societal reports (Table 2). Despite wide variation in methodology between societal reports, it was easy to divide overall strength of the literature into 3 levels: a high level of evidence included only prospective randomized control trials of any size, an intermediate level of evidence included any studies in which there was a nonrandomized control group (prospective cohort or historical controls), and a low level of evidence included reports that represented observational studies, case series, or expert opinion. Based on this scheme of hierarchy, the individual methodology from each societal group could be organized into 3 grades of evidence (Table 2).

The issue of consensus across multiple societal reports was evaluated by the ICGC by evaluating uniformity and agreement on specific recommendations for nutrition therapy between groups. Table 3 was constructed to show degree of consensus between reports for each specific recommendation. The designation of "yes" in this table indicated positive affirmation of that recommendation, whereas a designation of "no" meant a negative response or disagreement. A blank space reflected the fact that no comment or statement was made on that specific recommendation by that individual report. *Consensus* was defined by uniformity between reports, whereas *lack of consensus* was defined when a recommendation by one or more societal groups was in conflict or disagreement with that from the rest of the reports.

Table 1. Grading System for Level of Evidence Used in Each Societal Report¹⁻¹¹

Organization/Citation	Levels of Evidence/Grading
A.S.P.E.N./ <i>JPEN J Parenter Enteral Nutr.</i> 2002;26(1):Suppl (Jan-Feb)	A: There is good research-based evidence to support the guideline (prospective, randomized trials). B: There is fair research-based evidence to support the guideline (well-designed trials without randomization). C: The guideline is based on expert opinion and editorial consensus.
ESPEN/ <i>Clin Nutr.</i> 2002;21(2):173-183	
British Society of Gastroenterology/ <i>Gut.</i> 2005;54(suppl 3):iii1-iii9	Ia: Evidence obtained from meta-analysis of randomized controlled trials Ib: Evidence obtained from at least 1 randomized controlled trial IIa: Evidence obtained from at least 1 well-designed controlled study without randomization IIb: Evidence obtained from at least 1 other type of well-designed quasi-experimental study III: Evidence obtained from well-designed nonexperimental descriptive studies such as comparative studies, correlation studies, and case studies IV: Evidence obtained from expert committee reports or opinions or clinical experiences of respected authorities
	Recommendation Grade
	A: Requires at least 1 randomized controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendations (evidence categories Ia, Ib) B: Requires the availability of clinical studies without randomization on the topic of recommendation (evidence categories IIa, IIb, III) C: Requires evidence from expert committee reports or opinions or clinical experience of respected authorities, in the absence of directly applicable clinical studies of good quality (evidence category IV)
American College of Gastroenterology/ <i>Am J Gastroenterol.</i> 2006;101:2379-2400	I: Strong evidence from at least 1 published systematic review of multiple well-designed randomized controlled trials II: Strong evidence from at least 1 published properly designed randomized controlled trial of appropriate size and in an appropriate clinical setting III: Evidence from published well-designed trials without randomization, single group pre-post, cohort, time series, or matched case-controlled studies IV: Evidence from well-designed nonexperimental studies from more than 1 center or research group or opinion of respected authorities, based on clinical evidence, descriptive studies, or reports of expert consensus committees
Japan (JSEAM)/ <i>Hepatobiliary Pancreat Surg.</i> 2006;13:42-47	A: Good evidence to support a recommendation for use B: Moderate evidence to support a recommendation for use C: Poor evidence to support a recommendation D: Moderate evidence to support a recommendation against use E: Good evidence to support a recommendation against use
ESPEN—enteral nutrition: pancreas/ <i>Clin Nutr.</i> 2006;25:275-284	A 1a: Meta-analysis of randomized controlled trials A 1b: At least 1 randomized controlled trial B 11a: At least 1 well-designed controlled trial without randomization B 11b: At least 1 other type of well-designed, quasi-experimental study B III: Well-designed nonexperimental descriptive studies such as comparative studies, correlation studies, and case control studies C IV: Expert opinions and/or clinical experience of respected authorities
AGA/ <i>Gastroenterology.</i> 2007;132:2022-2044	Not stated
A.S.P.E.N. and SCCM/ <i>JPEN J Parenter Enteral Nutr.</i> 2009;33(3):277-316	Grade of recommendation A: Supported by at least 2 level I investigations B: Supported by 1 level I investigation C: Supported by level II investigations only

(continued)

Table 1. (continued)

Organization/Citation	Levels of Evidence/Grading
	D: Supported by at least 2 level III investigations E: Supported by level IV or level V evidence Level of evidence I: Large, randomized trials with clear-cut results; low risk of false-positive (α) error or false-negative (β) error II: Small, randomized trials with uncertain results; moderate to high risk of false-positive (α) and/or false-negative (β) error III: Nonrandomized, contemporaneous controls IV: Nonrandomized, historical controls V: Case series, uncontrolled studies, and expert opinion
Chinese Societies/ <i>Chin J Dig Dis.</i> 2005;6(1):47-51	Based on the grading and categorization of acute pancreatitis (AP) established at the International Symposium of Acute Pancreatitis (Atlanta, GA, 1992) and the guidelines for management of AP at the World Conference on Gastroenterology (Bangkok, Thailand, 2002), combined with the situation in China, the following terminology and definition of AP have been formulated for the guidance of Chinese clinicians and researchers.
Bangkok World Congress of Gastroenterology 2002/ <i>J Gastroenterol Hepatol.</i> 2002;17(suppl):S15-S39	Level 1: Evidence obtained from systematic reviews of all relevant randomized controlled trials Level 2: Evidence derived from at least 1 properly designed randomized controlled trial Level 3: Evidence from a well-designed control trial without randomization or from well-designed cohort or case control analytical studies, preferably from more than 1 center or research group or from multiple time series with or without intervention Level 4: Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees. This level signifies the need for further research.

AGA, American Gastroenterological Association; A.S.P.E.N., American Society for Parenteral and Enteral Nutrition; Chinese Societies, Chinese Society of Gastroenterology, Chinese Medical Association–Pancreatitis Disease Group; ESPEN, European Society for Clinical Nutrition and Metabolism; JSEAM, Japanese Society of Emergency Abdominal Medicine; SCCM, Society for Critical Care Medicine.

Table 2. Comparative 3-Tier Grading Scale for Level of Evidence of Recommendations Published Across Societal Reports

International Guidelines Recommendations—Comparative Scale		Guideline Source: Organization/Year					
Level of Evidence	Type of Studies	World Congress of Gastroenterology/ 2002	A.S.P.E.N./ 2002	British Society of Gastroenterology/ 2005	American College of Gastroenterology/ 2006	ESPEN/ 2006 and 2009	SCCM- A.S.P.E.N./ 2009
High	Any prospective randomized controlled trials	1, 2	A	A (Ia,b)	I, II	A (Ia,b)	A–C (I–III)
Intermediate	Controlled nonrandomized	3	B	B (IIa,b, III)	III	B (IIa,b, III)	D (IV)
Low	Descriptive case series Expert opinion	4	C	C (IV)	IV	C (IV)	E (V)

A.S.P.E.N., American Society for Parenteral and Enteral Nutrition; ESPEN, European Society for Clinical Nutrition and Metabolism; SCCM, Society for Critical Care Medicine.

Combining the issues of level of evidence from the literature (Table 2) with that of consensus of opinion (Table 3) facilitated the convergence of societal reports and the derivation of a final set of International Consensus Guideline Recommendations. Three separate grades of recommendations (Table 4) were developed by this schema as follows:

- Platinum (A): guideline statement meeting the criteria for high grade of evidence with uniform consensus across multiple societal reports
- Gold (B): guideline statement that meets criteria for low/intermediate grade of evidence or where there is lack of consensus across societal reports (at least 1 societal report is in disagreement)

Table 3. Consensus Across International Societal Reports and Guideline Statements

	A.S.P.E.N. 2002 ¹	ESPEN 2002 ²	Bangkok World Congress of Gastroenterology 2002 ¹⁰	Chinese Societies 2005 ⁹	British Society of Gastroenterology 2005 ³	American College of Gastroenterology 2006 ⁴	Japan 2006 ⁵	ESPEN 2006 ⁶	AGA 2007 ⁷	A.S.P.E.N. 2009 ⁸	ESPEN 2009 ¹¹
1. Pancreatitis patients at nutrition risk should be screened	Yes	Yes	—	—	—	Yes	—	—	—	Yes	—
2. For mild to moderate disease, analgesics, IV fluids, NPO, advance diet	—	Yes	—	—	Yes	Yes	—	—	—	—	—
Need for NS											
3. Not needed for mild to moderate disease	Yes	Yes	—	Yes	—	Yes	—	Yes	Yes	Yes	Yes
4. Needed only if anticipated NPO >5–7 d	Yes	—	—	—	—	Yes	—	—	Yes	—	Yes
5. Needed in mild to moderate disease when NPO 5–7 d	—	—	—	—	—	—	—	Yes	—	Yes	—
6. Needed only for severe pancreatitis	—	Yes	Yes	Yes	—	—	—	Yes	Yes	Yes	—
7. Needed for complications or for surgery	—	Yes	—	—	—	—	—	Yes	—	Yes	—
Use of EN											
8. EN preferred over PN or start with EN	Yes	Yes	Yes	—	Yes	Yes	Yes	Yes	Yes	Yes	Yes
9. EN may be used in face of complications (fistula, ascites, pseudocyst)	—	Yes	—	—	—	—	—	Yes	—	—	—
10. Use continuous-infusion EN	—	Yes	—	—	—	—	—	Yes	—	Yes	—
11. Nasogastric tube may be used	—	—	Yes	—	Yes	Yes	Yes	Yes	Yes	Yes	—
12. Use small peptide (MCT oil formula to improve tolerance)	—	Yes	Yes	—	—	—	—	Yes	Yes	Yes	—
Use of PN											
13. Use if NS indicated but not tolerant to EN (goal not reached)	Yes	Yes	—	—	—	Yes	Yes	Yes	Yes	Yes	Yes
14. PN lipids are safe (keep triglycerides <400 mg/dL)	Yes	Yes	—	Yes	—	—	—	—	—	—	Yes
15. Glucose is the preferred carbohydrate source (control blood glucose close to the normal range)	—	—	—	—	—	—	—	—	—	—	Yes
16. Consider use of glutamine (0.30 g/kg Ala-Gln dipeptide)	—	—	—	—	—	—	—	—	—	—	Yes
17. No specific complications of PN unique to pancreatitis; avoid overfeeding	—	—	—	—	—	—	—	—	—	—	Yes
18. Meet requirements with EN or PN: 25–35 kcal/kg/d, 1.2–1.5 g protein/kg/d	—	Yes	—	—	—	—	—	—	—	—	Yes

AGA, American Gastroenterological Association; A.S.P.E.N., American Society for Parenteral and Enteral Nutrition; Chinese Societies, Chinese Society of Gastroenterology, Chinese Medical Association–Pancreatitis Disease Group; EN, enteral nutrition; ESPEN, European Society for Clinical Nutrition and Metabolism; IV, intravenous; MCT, medium-chain triglyceride; NPO, nil per os; NS, nutrition support; PN, parenteral nutrition.

Table 4. Final Grade of Recommendation for International Consensus Guidelines

International Guidelines Recommendations—Grade Categorization			
Grade of Recommendation	Number of Societies	Strength of Evidence	Consensus Agreement
A (platinum)	Multiple societies	High level of evidence	Consensus
B (gold)	Multiple societies	Intermediate to low level of evidence	Lack of consensus
C (silver)	Single society	High level of evidence	NA

NA, not applicable.

- Silver (C): guideline statement meeting the criteria for high grade of evidence, published only in a single societal report (consensus not applicable in this case)

Results

Of the 11 societal reports identified, 8 reported a well-defined guideline development process using acceptable methodologies from reputable sources.^{1,3-6,8,10,11} Three of the reports were developed by nationally recognized groups/organizations but did not have a well-defined process of guideline development or used methodology that resulted in practice recommendations in a review format rather than guideline statements.^{2,7,9} These latter reports were excluded from this analysis.

Using this unique methodology involving evaluation of both level of evidence and consensus of opinion, the ICGC was able to derive the following:

International Consensus Guidelines for Nutrition Therapy in Pancreatitis

Indication for Nutrition Therapy

1. Pancreatitis patients are at nutrition risk and should be screened. (Grade B: Gold)
2. For mild to moderate disease, analgesics, intravenous (IV) fluids, and nil per os (NPO) with a gradual advancement to diet (usually within 3–4 days) are recommended. (Grade C: Silver)

The need for nutrition therapy (NT) by the enteral or parenteral route should be based on the extent of disease and nutrition status of the patient.

3. NT is not generally needed for mild to moderate disease unless complications ensue. (Grade A: Platinum)
4. NT should be considered in any patient regardless of disease severity if the anticipated duration of being NPO is >5–7 days. (Grade B: Gold)

5. NT is needed in mild to moderate disease when the patient has been NPO for 5–7 days. (Grade B: Gold)
6. Early NT is indicated for severe pancreatitis. (Grade A: Platinum)
7. NT is useful in the management of patients who develop complications of surgery. (Grade B: Gold)

Use of Enteral Nutrition

8. Enteral nutrition (EN) is generally preferred over parenteral nutrition (PN), or at least EN should, if feasible, be initiated first. (Grade A: Platinum)
9. EN may be used in the presence of pancreatic complications such as fistulas, ascites, and pseudocysts. (Grade C: Silver)
10. Continuous EN infusion is preferred over cyclic or bolus administration. (Grade B: Gold)
11. Nasogastric tubes may be used for administration of EN. Postpyloric placement is not necessarily required. (Grade B: Gold)
12. For EN, consider a small peptide-based medium-chain triglyceride (MCT) oil formula to improve tolerance. (Grade B: Gold)

Use of Parenteral Nutrition

13. Use PN if NT is indicated, when EN is contraindicated or not well tolerated. (Grade A: Platinum)
14. IV fat emulsions are generally safe and well tolerated as long as baseline triglycerides are below 400 mg/dL (4.4 mmol/L) and there is no previous history of hyperlipidemia. (Grade B: Gold)
15. Glucose is the preferred carbohydrate source with metabolic control of glucose as close to normal as possible. (Grade C: Silver)
16. Consider use of glutamine (0.30 g/kg Ala-Gln dipeptide). (Grade C: Silver)
17. No specific complications of PN are unique to patients with pancreatitis. In general, avoid overfeeding. (Grade C: Silver)

Both Enteral and Parenteral Nutrition

18. Meet macronutrient requirements with NT. (Grade B: Gold)
 - a. Calories: 25–35 kcal/kg/d
 - b. Protein: 1.2–1.5 g/kg/d

Discussion

The unique contribution of this project and article is a process by which a variety of recommendations on a specific topic from international societies around the world can be used to construct a single set of “global guidelines” based on level of evidence from the literature and consensus of opinion between groups. A similar approach was used for living kidney donors using the AGREE (Appraisal of Guidelines for Research and Evaluation) methodology to assess methodological quality of the guidelines.¹² The ICGC approach to pancreatitis guidelines was from the perspective of identifying guideline consistency from reliable methodology for the purposes of identifying consensus among the guidelines rather than critiquing the guidelines themselves. The ICGC committee findings from this process are consistent with that found for kidney donors: there is variation in guideline methodology among the groups but similarities that result in unnecessary duplicative efforts. Therefore, there is a need for international collaboration and coordination of future guidelines to ensure consistency and comprehensiveness.

Eighteen ICGC statements were derived from 11 published guidelines that addressed nutrition therapy in pancreatitis. The guideline methodologies used by each sponsoring society were unique to that organization, but most were consistent with acceptable principles of guideline development at the time of publication. The challenge was negotiating the wide range of methodology found in these publications, especially because guideline methodology was evolving over this time period. The level of evidence (grading) determined by each societal group was also a challenge for the ICGC, but this issue was easily resolved within the framework of a more global ranking of evidence as high, intermediate, and low.

Minor problems arising from comparison of the societal reports were easily resolved by the ICGC members. For example, the grade A platinum guideline statements tended to be present in several societal reports, but the grades in the published manuscripts ranged from intermediate to high. These differences may have been due to variances in the perspective of the sponsoring organization. Grade B gold statements also varied in grade from low to high among the published societal reports, but many may have been affected by the fact that nutrition therapy was only part of a broader overall guideline topic such as general management of acute pancreatitis. These latter guidelines by nature did not provide as much detail about

nutrition therapy as the guidelines that focused specifically on nutrition in pancreatitis. Most grade C silver guidelines were PN-specific recommendations.¹¹ These provided much more specific statements for PN than those reports that covered a broader more comprehensive subject of management of acute pancreatitis. Even with these limitations, there was surprisingly uniform agreement from widely disparate groups (United States, Europe, Japan, and China). Some of this uniformity may reflect the similarity of the literature reviewed and used by these groups.

Anecdotes from clinical experience were evident throughout the societal reports reviewed by the committee. The ICGC noted that the caloric requirements used in the guideline references for PN and EN ranged from 25–35 kcal/kg/d or 1.5–1.8 times the basal energy expenditure.^{13–20} When evaluating prospective trials comparing PN with EN in patients with pancreatitis, it was noted that PN was generally better able to achieve caloric goals than EN. The higher calorie prescriptions were associated with a greater frequency of hyperglycemia. As expected, the incidence of hyperglycemia was also higher for patients receiving PN compared with EN. Energy expenditure was measured in patients with pancreatitis using indirect calorimetry, even though the number of evaluated patients was small. Dickerson et al²¹ found energy expenditure to be about 25 kcal/kg/d, with this value being similar regardless of whether the patient had acute, chronic, or acute/chronic pancreatitis with sepsis. These observations suggest a need to reconsider the volume or dose of feeding being provided to patients with pancreatitis, to investigate whether outcomes would be improved from delivery of fewer calories (while optimizing glucose control).

The ICGC statements for pancreatitis send a clear message to clinicians, providing action statements to help patient management. With the degree of consensus and consistency seen across the varied societal reports, one would question why there is such variation in the practice of nutrition therapy for patients with pancreatitis. At the very least, practitioners should focus on patients with severe disease, favoring EN over PN and only using PN when EN is contraindicated or not feasible.

Conclusion

Current guidelines for nutrition therapy in pancreatitis were assessed for common guideline statements that could be universally applicable. Irrespective of the guideline methodology used by separate groups, a process that combines level of evidence from the literature with consensus of opinion across multiple societal reports provides a unique single set of “global guidelines” to help direct clinicians in the nutrition therapy of the patient with acute pancreatitis. This article provides a template for the future by which to derive International Consensus Guidelines on a wide variety of topics.

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