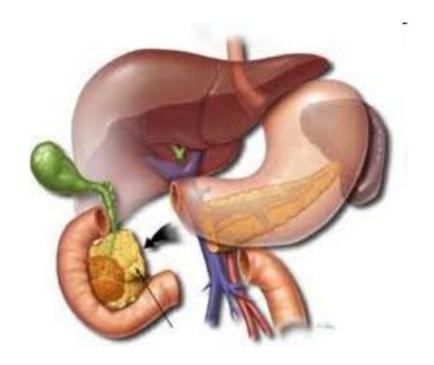
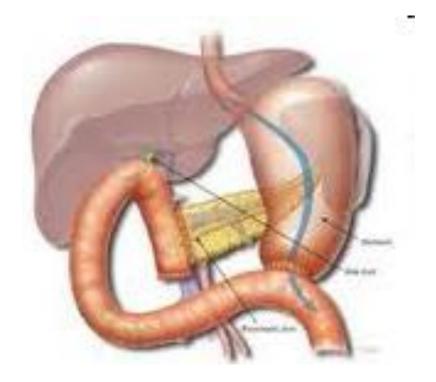
# Quale nutrizione artificiale nella duodenocefalopancreasectomia. Aspetti clinico-economici

#### **Luca Gianotti**

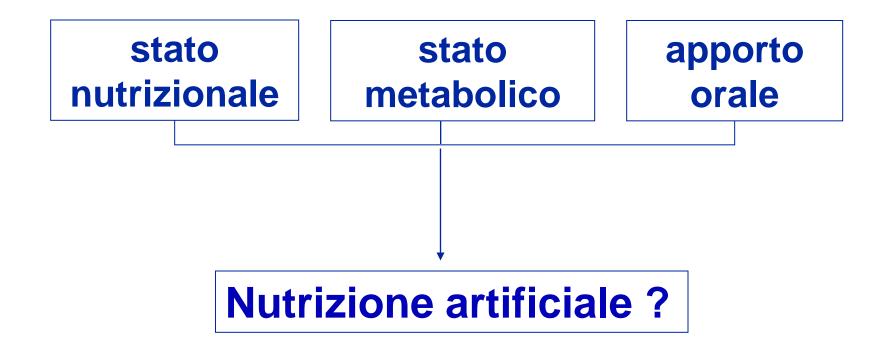
Dip. Scienze Chirurgiche, Università Milano-Bicocca Ospedale San Gerardo, Monza

## Duodenocefalopancreasectomia (DCP)





# VARIABILI CONDIZIONANTI LE INDICAZIONI NELLA N.A.



## Evaluation of the International Study Group of Pancreatic Surgery definition of delayed gastric emptying after pancreatoduodenectomy in a high-volume centre

T. Welsch, M. Borm, L. Degrate, U. Hinz, M. W. Büchler and M. N. Wente

British Journal of Surgery 2010; 97: 1043-1050

Results: DGE occurred in 340 (44.5 per cent) of 764 patients. Median hospital stay was significantly prolonged in patients with DGE: 13, 21 and 40 days for grades A, B and C respectively versus 11 days for patients without DGE. DGE was associated with prolonged intensive care unit (ICU) admission (at least 2 days): 20.6, 28.6 and 61.8 per cent of those with grades A, B and C respectively versus 9.4 per cent of patients without DGE. Factors independently influencing DGE grade A were female sex, preoperative heart failure and major complications (grade III–V). Validation of the DGE definition revealed that DGE grades A and B were associated with interventional treatment in 20.1 and 44.4 per cent of patients.

## Reconsideration of Postoperative Oral Intake Tolerance After Pancreaticoduodenectomy

Prospective Consecutive Analysis of Delayed Gastric Emptying According to the ISGPS Definition and the Amount of Dietary Intake

Emi Akizuki, MD,\* Yasutoshi Kimura, MD, PhD,\* Takayuki Nobuoka, MD,\* Masafumi Imamura, MD, PhD,\* Minoru Nagayama, MD, PhD,\* Tomoko Sonoda, DDS, PhD,† and Koichi Hirata, MD, PhD\*

(Ann Surg 2009;249: 986-994)

Results: The occurrence of DGE as defined by ISGPS was 42%. The postoperative outcomes of DGE patients were significantly poor compared with those of non-DGE patients. TDI values were significantly low in DGE patients, and non-DGE patients with low TDI values showed a significantly extended duration of parenteral nutrition and postoperative hospitalization. Operative bleeding (>1,000 mL) and pancreatic fistulas were likely to be associated with DGE occurrence. Gender (women), BMI (>25 kg/m²), postoperative intraabdominal infection, and DGE were significantly associated with low TDI values.

 TABLE 1. Preoperative characteristics of the 212 patients studied

	Parenteral $(n = 68)$	Standard $(n = 73)$	Immunonutrition $(n = 71)$
Age (y)	60.2 (10.4)	59.8 (12.2)	61.1 (11.9)
Male:female	43:25	47:26	44:27
Body weight (kg)	67.3 (15.3)	65.8 (14.9)	68.7 (16.4)
Patients with weight loss (>10%)	27 (39.7)	31 (42.4)	26 (36.6)
Weight loss (%)	6.4 (3.6)	7.1 (4.0)	6.8 (4.3)
Karnofsky index (%)	74 (12)	76 (15)	72 (13)
Hemoglobin (g/L)	131 (16)	128 (17)	129 (19)
Albumin (g/L)	36.8 (3.9)	37.1 (3.6)	36.7 (3.8)
Bilirubin (g/dL)	2.8 (3.1)	2.2 (3.5)	2.6 (3.3)
Patients with jaundice (%)	42 (61.7)	48 (65.7)	43 (60.5)
Patients with diabetes (%)	15 (22.0)	14 (19.1)	17 (23.9)
Histopathologic finding			
Pancreatic head carcinoma	39	42	41
Periampullary carcinoma	19	20	18
Distal bile duct	11	14	12
Vater ampulla	6	5	3
Duodenum	2	1	3
Endocrine tumor	5	4	6
Chronic pancreatitis	5	7	6

## **TPN** and Pancreatic Resection

Brennan MF, et al. Ann Surg 220: 436; 1994

	TPN (30-35 kcal/kg) (n=60)	Glucose ? (n=57)	P
<b>Major complications</b>	27	13	0.02
<b>Minor complications</b>	32	24	ns
Reoperations	6	3	ns
Median LOS	16	14	ns

Pancreas
Vol. 21, No. 4, pp. 344–351
© 2000 Lippincott Williams & Wilkins, Inc., Philadelphia

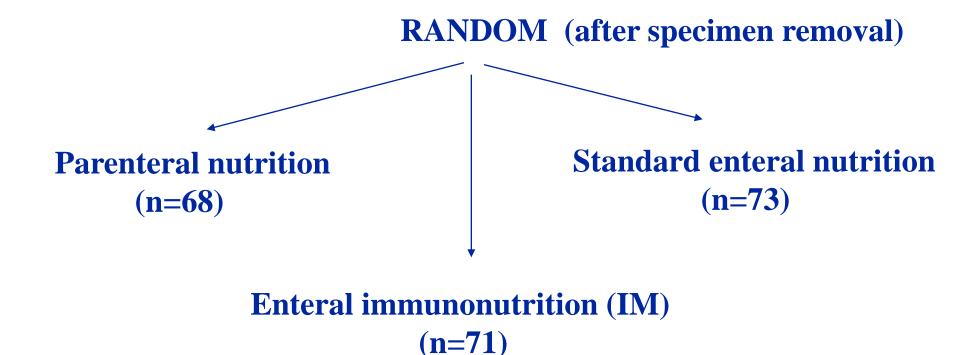
## Artificial Nutrition After Pancreaticoduodenectomy

Luca Gianotti, Marco Braga, Oreste Gentilini, Gianpaolo Balzano, Alessandro Zerbi, and Valerio Di Carlo

Department of Surgery, Scientific Institute San Raffaele Hospital, Milan, Italy

### **Patients and Methods**

- Prospective clinical trial (1994-2000).
- 212 patients undergoing PD.



The 3 regimens were isocaloric and isonitrogenous (25 kcal/kg; 1.2 g protein/kg)

## **Outcome**

	IM	<b>Standard</b>	<b>Parenteral</b>
- Infect complic (%)	6 (8.4)*	11 (15.1)	<b>15 (22.1)</b>
- Non-infect complic (%)	18 (25.3)	21 (28.7)	25 (36.7)
- Major complic (%)	13 (18.3)	13 (17.3)	16 (23.5)
- Mortality	2 (2.8)	1 (1.4)	4 (5.8)
- Sepsis score	5.8 ± 2.4 *	8.1 ± 3.5	10.9 ± 4.1
- Length of stay	15.1 ± 5.4*	$17.0 \pm 6.1$	$18.8 \pm 6.4$

<sup>\*</sup> p < 0.05 vs parenteral and standard

## Cyclic vs. continuous EN after PPPD

Van Berge MI, et al. Ann Surg 226: 677; 1997

	Cyclic (n=27)	Continous (n=30)	P
Nasogastric suction (days)	6.7	9.1	ns
<b>Enteral nutrition (days)</b>	9.3	10.3	ns
Small bowel transit time (min)	130	110	ns
First day of normal diet	12.2	15.7	0.04
Pts with complications	9 (33%)	11 (37%)	ns
Length of stay (days)	17.5	21.4	0.04
Pts with DGE	7 (26%)	7 (23%)	ns

#### **REVIEW**

## Systematic Review of Peri-Operative Nutritional Supplementation in Patients Undergoing Pancreaticoduodenectomy

Kolitha Sanjaya Goonetilleke, Ajith Kumar Siriwardena

Hepatobiliary Unit, Department of Surgery, Manchester Royal Infirmary.

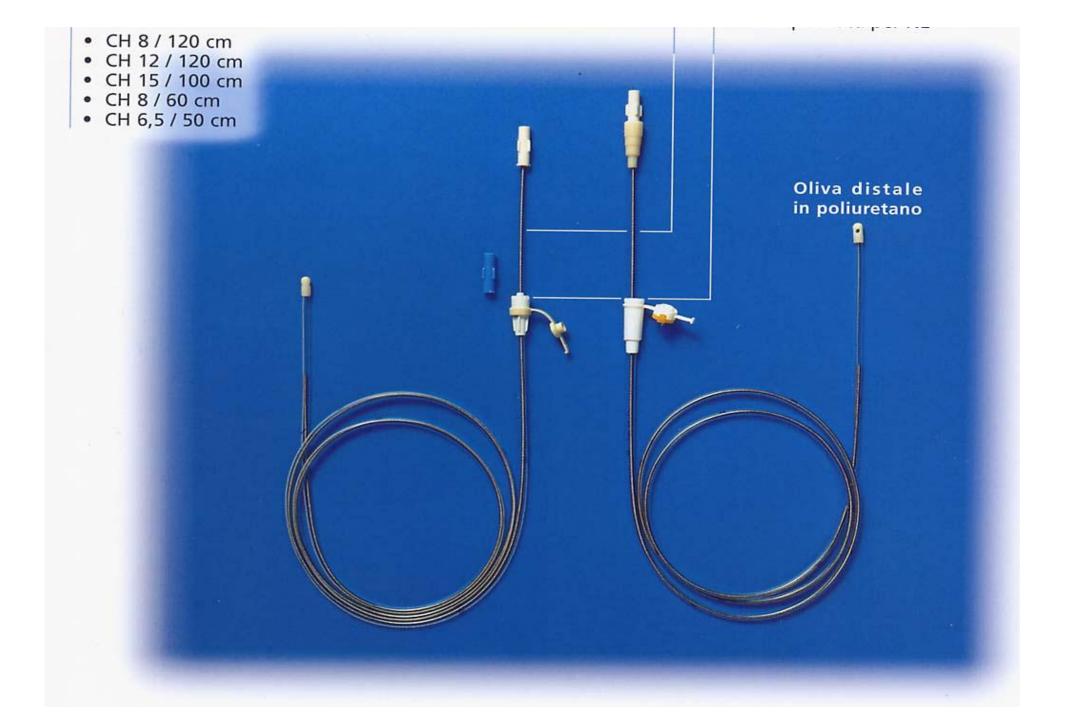
Manchester, United Kingdom

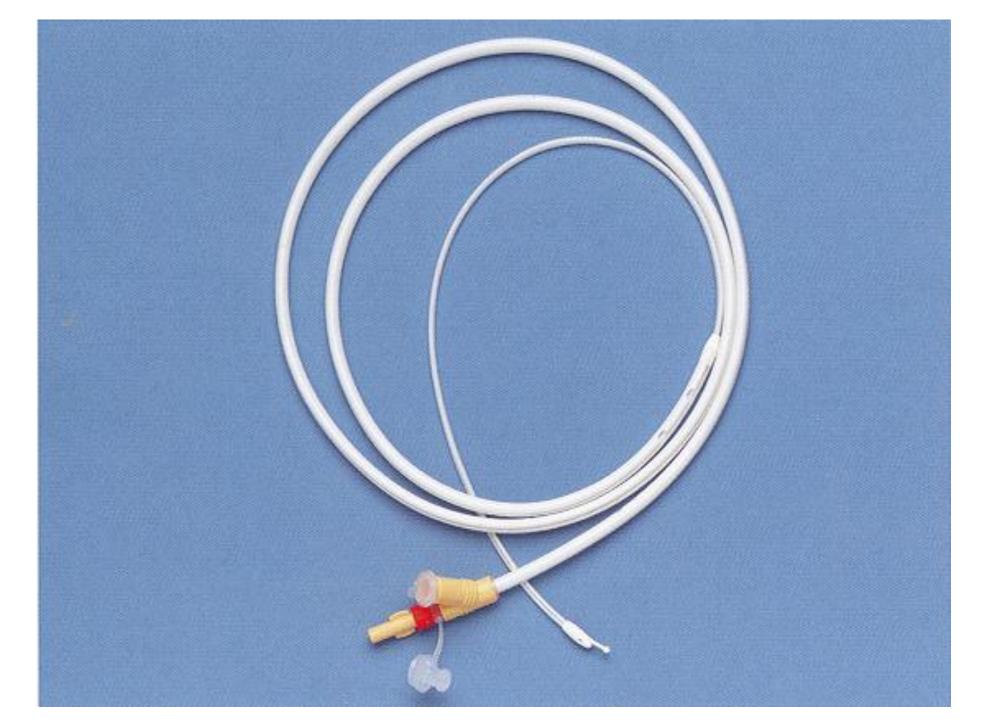
**Table 4.** Duration of peri-operative nutritional support in patients undergoing pancreatic resection for suspected malignancy.

Study	Duration of peri-operative nutritional support (days)			
	TPN	EN	I-EN	Control
Brennan MF [10]	12.3 (6-34) <sup>a</sup>	-	-	22.2 (3-69) <sup>a*</sup>
Martignoni ME [9]	-	N/a	-	N/a
Gianotti L [11]	12.7±4.8 <sup>b</sup>	11.5±4.6 <sup>b</sup>	11.8±4.3 <sup>b</sup>	-
Baradi H [12]	-	10.5±16.2 <sup>b**</sup>	-	N/a

**Table 5.** Morbidity in patients undergoing pancreatic resection for suspected malignancy.

Study	Frequency of overall morbidity				P value
	TPN	EN	I-EN	Control	
Brennan MF [10]	27 (45.0%)*	-	-	13 (22.8%)*	0.02 **
Martignoni ME [9]. Overall:	-	13 (43.3%)	-	9 (28.1%)	N/a
Delayed gastric emptying:	-	17 (56.7%)	-	5 (15.6%)	< 0.01
Gianotti L[11] ***	40 (58.8%) <sup>a</sup>	32 (43.8%)	24 (33.8%) <sup>a</sup>	-	$0.005^{a}$
Baradi H [12]	-	64 (65.3%)	-	76 (92.7%)	N/a <sup>b</sup>





#### Gastric Decompression and Enteral Feeding Through a Double-Lumen Gastrojejunostomy Tube Improves Outcomes After Pancreaticoduodenectomy

Lloyd A. Mack, MD,\* Ioannis G. Kaklamanos, MD, PhD,† Alan S. Livingstone, MD,‡ Joe U. Levi, MD,‡ Carolyn Robinson, RN,‡ Danny Sleeman, MD,‡ Dido Franceschi, MD,‡ and Oliver F. Bathe, MD\*

Ann. Surg 2004: 240; 845

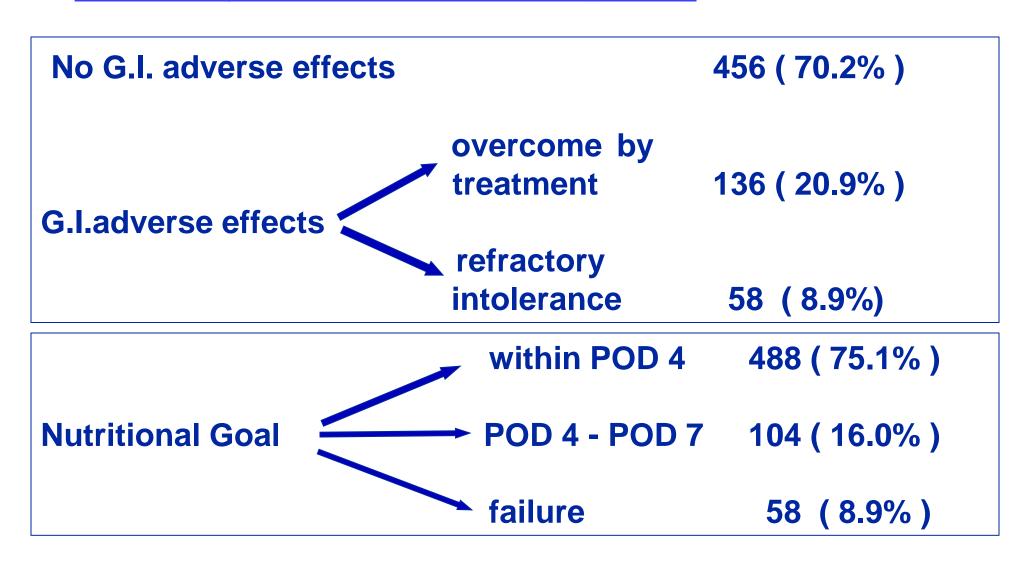
TABLE 3. Postoperative Course

	GJT Group	Control	Significance
Major complications (excluding gastroparesis)	1 (5%)	4 (25%)	0.15
Minor complications	3 (15%)	0 (0%)	0.2
Duration of gastric decompression (days)	5.3 ± 2.2	9.5 ± 6.7	0.02
Gastroparesis	0 (0%)	4 (25%)	0.03
Overall cost (U.S.\$)	52,589 ± 15,964	82,151 ± 56,632	0.036

GJT, gastrojejunostomy tube.

## Early Enteral Nutrition

**Tolerability and nutritional intake (n=650)** 



#### Original article

## Fast-track recovery programme after pancreaticoduodenectomy reduces delayed gastric emptying

G. Balzano, A. Zerbi, M. Braga, S. Rocchetti, A. A. Beneduce and V. Di Carlo

Pancreas Unit, Department of Surgery, San Raffaele Scientific Institute, Via Olgettina 60, 20132 Milan, Italy

British Journal of Surgery 2008; 95: 1387-1393



Table 1 Protocol for early recovery after pancreaticoduodenectomy

Before operation	At the time of informed consent to operation patient informed about fast-track rehabilitation programme
Day 0	Placement of thoracic epidural catheter (T7-T9 level) with continuous infusion of bupivacaine 0·125% with fentanyl 2 μg/ml at a rate of 4-6 ml/h until day 5, plus intravenous paracetamol or NSAIDs, or, if epidural catheter is contraindicated, patient-controlled analgesia with morphine, plus intravenous paracetamol or NSAIDs
Day 1	Removal of nasogastric tube if drainage amount < 300 ml  Mobilization out of bed for >1 h  Intravenous fluid administration (30 ml/kg per day of hydroelectrolytic solution plus 5% glucose) continued until adequate oral fluid intake
Day 2	Enhanced mobilization (> 2 h out of bed)
Day 3	Clear fluid intake (free amount) Enhanced mobilization (> 4 h out of bed, with personal hygiene care in bathroom)
Day 4	Solid food intake
Day 5	Diet increase on daily basis (given as five to six small meals) until reaching a calorie intake of 1000 kcal on day 8 Drain removal (if no pancreatic or biliary fistula, when daily amount < 200 ml) Epidural catheter removal
Discharge criteria	Absence of fever (< 37.5°C for > 48 h), adequate pain control with oral analgesics, ability to take solid foods (at least 1000 kcal/day), passage of stools, adequate mobilization and acceptance of discharge by patient

Table 3 Postoperative course in patients having traditional care and those in the fast-track programme

	Traditional (n = 252)	Fast track (n = 252)	Р
Mortality	7 (2.8)	9 (3.6)	0.798§
Morbidity	148 (58-7)	119 (47-2)	0.014§
Relaparotomy (deaths excluded)	20 (7.9)	17 (6-7)	0.733§
Percutaneous drainage (deaths and relaparotomy excluded)	6 (2-4)	9 (3-6)	0.598§
Intra-abdominal complications	106 (42-1)	93 (36-9)	0.236§
Pancreatic fistula	65 (25-8)	60 (23.8)	0-315§
Type A†	31 (12-3)	29 (11.5)	0-892§
Type B†	19 (7.5)	20 (7.9)	0.999§
Type C†	15 (6⋅0)	11 (4-4)	0.578§
DGE	62 (24-6)	35 (13.9)	0-004§
Primary	35 (13-9)	14 (5-6)	0-003§
Secondary	27 (10-7)	21 (8-3)	0.447§
Time to passage of flatus (days)*	3 (1–7)	3 (1-6)	0.172‡
Time to passage of stool (days)*	6 (1-10)	5 (1-9)	< 0.001‡
Postoperative stay (days)*			
All patients	15 (7-102)	13 (7-110)	< 0.001¶
Patients with no complications	13 (7–17)	11 (7–15)	< 0.001¶
Readmission	16 (6-3)	18 (7-1)	0-865§

#### **EDITORIAL**

## Current Status of Fast-Track Recovery Pathways in Pancreatic Surgery

#### Efthymios Ypsilantis, Raaj K Praseedom

Department of Hepatobiliary and Transplant Surgery, Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust. Cambridge, United Kingdom

Table 2. Description of studies and summary of outcomes.

	Kennedy et al., 2007 [11]	Berberat <i>et al.</i> , 2007 [12]	Balzano et al., 2008 [13]
Type of study	Case-series with historic control ("before-after")	Retrospective case-series	Case-series with historic control ("before-after")
Patients in pathway	91	283	252
Patients in control	44	n/a	252
Length of stay (days; study group vs. control)	7 vs. 13 (P<0.0001) Median values	10 (4-115) Mean value (range)	13 (7-110) vs. 15 (7-102) (P<0.001) Median values (range)
Morbidity rate (study group vs. control)	37% vs. 44%	24.7%	47.2% vs. 58.7% (P<0.01)
30-day re-admission rate (study group vs. control	) 7.7% vs. 7.0%	3.5%	7.1% vs. 6.3%
30-day mortality rate (study group vs. control)	1.1% vs. 2.3%	2.0%	3.6% vs. 2.8%

## Conclusions

- Early enteral feeding should be considered the first option to nourish patients after pancreaticoduodenectomy.
- The use of TPN should be restricted to the few subjects with severe malnutrition and intolerance to enteral feeding.
- The administration of immunonutrition improves host defense mechanisms, modulates protein synthesis and significantly decreases infectious morbidity and hospitalization.
- Fast-track program after PD is safe and feasible. This strategy may allow earlier resumption of oral feeding and therefore represent an alternative to AN.

#### **DECISION MAKING IN EVIDENCE-BASED MEDICINE**

- 1) Benefits of treatment X
- 2) Risks of treatment X
- 3) Economic (cost-benefit / effectiveness) analysis of treatment X

Are the potential clinical benefits of treatment X be worth the health care resources consumed ? (not unlimited).

#### **DOMINANCE FOR DECISION**

(resolution of the clinical scenario)

Effectiveness of treatment compared with control

Cost of treatment compared with control

	More	Same	Less
More	7	4	2
Same	3	9	5
Less	1	6	8



1=Accept treatment

2=Reject treatment

Weak dominance for decision:

3=Accept treatment

**4=Reject treatment** 

**5=Reject treatment** 

**6=Accept treatment** 

Non dominance: No obvious decision.

7=Is added effect worth added cost to adopt treatment?
8=Is reduced effect acceptable given reduced cost to accept treatment?
9=Neutral on cost and effect. Other reasons to accept treatment?

#### Cost-Benefit Analysis (CBA)

'A CBA is an economic evaluation in which all costs and consequences of a program are expressed in the same units, usually money. CBA is used to determine allocative efficiency; i.e., comparison of costs and benefits across programs serving different patient groups. Even if some items of resource or benefit cannot be measured in the common unit of account; i.e., money, they should not be excluded from the analysis' (15). Herman (1) identifies the challenge of CBA in that its analysis requires putting a monetary value on all health outcomes and ultimately on life. There is inherent difficulty with this type of analysis and as a result very few true CBAs have yet been performed (15).

#### Cost-Effectiveness Analysis (CEA)

'A CEA is an economic evaluation in which the costs and consequences of alternative interventions are expressed as costs per unit of health outcome. CEA is used to determine technical efficiency; i.e., comparison of costs and consequences of competing interventions for a given patient group within a given budget' (15). The result will be a comparison of cost per unit of improvement between examined treatments (15). Comparison of multiple outcomes is not possible with this type of analysis (1); however, the analysis does help answer urgent questions, such as how much it would cost to reduce hip fractures in osteoporotic women (1).



NUTRITION

Nutrition 21 (2005) 1078-1086

www.elsevier.com/locate/nut

Applied nutritional investigation

Hospital resources consumed for surgical morbidity: effects of preoperative arginine and  $\omega$ -3 fatty acid supplementation on costs

Marco Braga, M.D.<sup>a</sup>, Luca Gianotti, M.D., Sc.D.<sup>b,\*</sup>, Andrea Vignali, M.D.<sup>a</sup>, Alexandra Schmid, Ph.D.<sup>c</sup>, Luca Nespoli, M.D.<sup>b</sup>, and Valerio Di Carlo, M.D.<sup>a</sup>

Department of Surgery, Vita-Salute San Raffaele University, Milan, Italy
 Department of Surgical Sciences and Intensive Care, Milano-Bicocca University, Monza, Italy
 HealthEcon AG, Basel, Switzerland

Table 3. Outcome Variables

		•	Perioperative (n = 101)
Death	1	1	2
Patients with infectious			
complications	31	14ª	$16^{b}$
Patients with noninfectious			
complications	36	30	28
Patients with any			
complication	49	36	34
Length of hospital stay			
(days)	$14.0 \pm 7.7$	$11.6 \pm 4.7^{c}$	$12.2 \pm 4.1^d$

NOTE. Values are means  $\pm$  SD or number of patients.

$$^{d}P = 0.03$$
 vs. conventional.

 $<sup>^{</sup>a}P = 0.006$  vs. conventional.

 $<sup>^{</sup>b}P = 0.02$  vs. conventional.

 $<sup>^{</sup>c}P = 0.008$  vs. conventional.

## **Materials and Methods**

#### **ANALYSIS:**

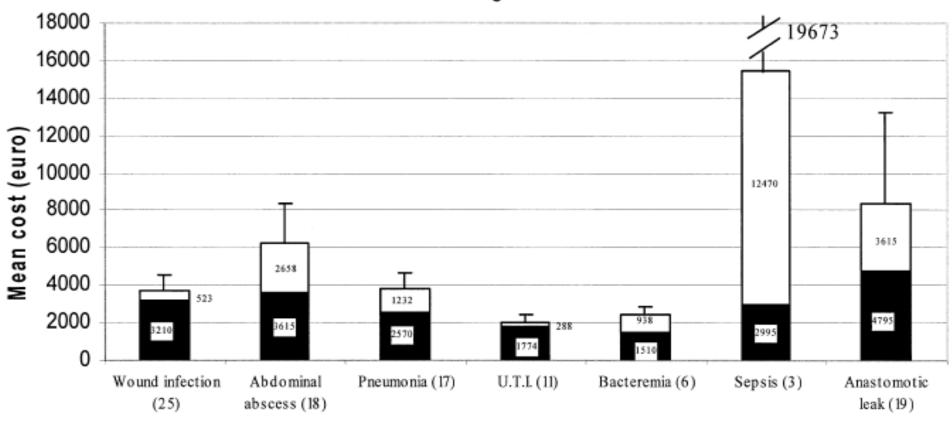
- **§ Costs of treating complications**
- **§ Costs of clinical nutrition.**
- **§ Effectiveness\* of nutrition on outcome.**
- § Based on the above data, cost-comparison and costeffectiveness analysis were carried-out.
- \*Definition: Effectiveness is defined as the percent of complication-free patients. Thus, this parameter reflects the ability of a treatment X to prevent the occurrence of complications.
- Cost-effectiveness is more favorable as more the complication rate in the control group is high and the relative difference between treated and control group is great.

#### **Complication-related parameters:**

- Diagnostic and therapeutic measures during inpatient stay (e.g. lab analysis, microbiological samples, X-ray, ultrasound, CT scan, relaparotomy, abscess drainage, etc..)
- Number of days in the ICU.
- Daily dose and duration in days of any pharmaceutical treatment.
- Prolonged LOS (to estimate the costs of board, lodging, and routine medical and nursing care)
- > Ambulatory treatment after discharge.

- ➤ Diagnostic, therapeutic measures and devices to treat complications: derived from medical records of each patients who developed complications. Costs valued on the National List of Sanitary Costs by the Italian Ministry of Health and medical Diagnosis-Related-Group reimbursement rate.
- ICU stay: valued at a flat rate per day which covers average daily ICU-costs.
- Prolonged LOS: valued by comparing the average LOS of patients without complications undergoing the same type of surgery. At a daily rate which covers the cost of board, lodging, routine medical and nursing care.

#### ■ Prolonged LOS □ Resources Used



#### ■ Prolonged LOS □ Resources Used

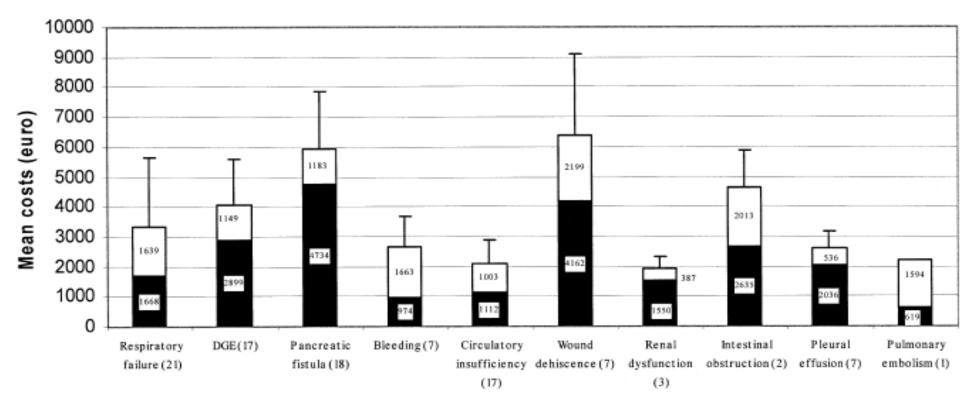


Fig. 2. Mean cost of non-infectious complications split in resources used and additional LOS. Data are reported as mean ± standard deviation. DGE, delayed gastric emptying; LOS, length of hospital stay.

Table 3
Mean costs of patients without complications\*

Mean costs/patient	Conventional $(n = 102)$	Preoperative $(n = 102)$	Between- arm difference
Gastro-esophageal resection	3909 (33)	3639 (37)	+270
Pancreatic resection	5816 (3)	5334 (10)	+482
Colorectal resection	2552 (15)	2425 (17)	+127
Mean costs	3622 (51)	3581 (64)	+41

<sup>\*</sup> Numbers of patients without complications are presented within parentheses.

Table 4 Mean costs of patients with complications

	Conventional	Preoperative	Between-arm difference
Mean costs of complication/patient*	6178 (1951-3 977)	4639 (1631-10 082)‡	+1539 (320-3895)
Resources used	2921 (477-6710)	1858 (411-3683) <sup>‡</sup>	+1063 (66-2847)
Additional LOS	3257 (1085-6197)	2781 (930-5671)	+476 (155-526)
Mean costs of routine care <sup>†</sup>	4316 (51)	4181 (38)	+135
Mean costs of patients with complications <sup>†</sup>	10 494 (51)	8793 (38)	+1701

LOS, length of hospital stay

<sup>\*</sup> Values are reported as mean (95% confidential intervals).

 $<sup>^\</sup>dagger\,\text{Numbers}$  of patients with complications appear within parentheses.

 $<sup>^{\</sup>ddagger}P = 0.05$  versus conventional.

Table 5 Mean cost of infectious and non-infectious complications

Type of complication*	Resources used <sup>†</sup>	Additional LOS <sup>†</sup>	Total
Infectious			
Conventional (41)	2710 (930-6197)	2809 (474-6881)	5518 (1943-13 196)
Preoperative (19)	991 (254-2314)‡	2900 (1751-4028)	3891 (2087-6343)‡
Between-arm difference	+1719 (676-3883)	-91 (-1277 to 2853)	+1627 (144-6853)
Non-infectious			
Conventional (34)	1078 (188-2932)	2329 (930-5144)	3407 (1612-7261)
Preoperative (32)	1331 (448-3156)	2520 (930-5438)	3851 (1500-7445)
Between-arm difference	-253 (-260  to  -222)	-191 (0 to -294)	-444 (-760 to -221)

LOS, length of hospital stay \* Numbers of complications appear within parentheses.  $^{\dagger}$  Values are reported as mean (95% confidential intervals).  $^{\ddagger}P < 0.001$  versus conventional.

Table 6 Total costs and DRG reimbursement rates

	Conventional*	Preoperative*	Between-arm difference
Patients without complications	184 725 (51)	229 208 (64)	-44 483
Patients with complications	535 236 (51)	334 148 (38)	+201 088
Nutrition	3407 (102)	14 729 (102)	-11322
Total costs	723 368 (102)	578 085 (102)	+145 283
Mean total costs	7092	5668	+1424
DRG reimbursement	781 392 (102)	740 301 (102)	+41 091
Mean DRG reimbursement	7660	7257	+403
Mean gain in DRG	569	1590	-1021

DRG, diagnosis-related group

<sup>\*</sup> Numbers of patients studied appear within parentheses.

Table 7
Cost comparison and cost-effectiveness analyses

	Conventional	Preoperative	Between-arm difference
Complication cost/ randomized patient	3089	1728	+1361
Nutritional cost/patient	33	144	-111
Total cost/randomized patient	3122	1872*	+1250
Effectiveness <sup>†</sup>	50.0	62.8	-12.8

<sup>\*</sup> P = 0.04 versus conventional.

<sup>&</sup>lt;sup>†</sup> Percentage of complication-free patients.

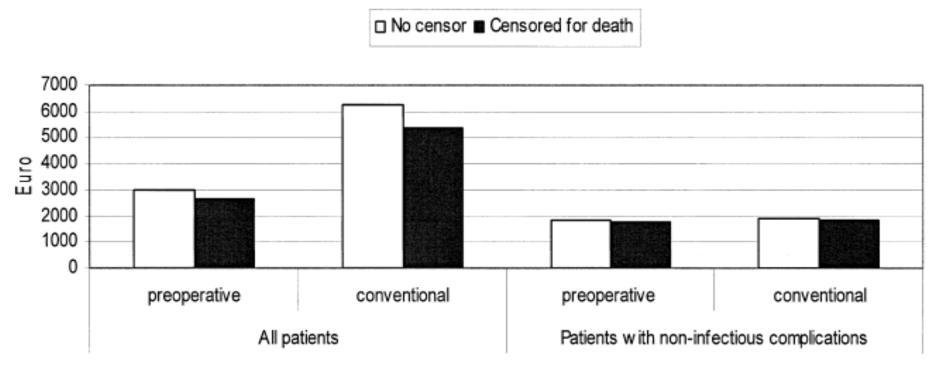


Fig. 3. Cost effectiveness with and without censoring for death.

#### **DOMINANCE FOR DECISION**

Effectiveness of treatment compared with control

Cost of treatment compared with control

	More	Same	Less
More	7	4	2
Same	3	9	5
Less	1	6	8

Strong dominance for decision:

1=Accept treatment

2=Reject treatment

Weak dominance for decision:

3=Accept treatment

**4=Reject treatment** 

**5=Reject treatment** 

**6=Accept treatment** 

Non dominance: No obvious decision.

7=Is added effect worth added cost to adopt treatment?
8=Is reduced effect acceptable given reduced cost to accept treatment?
9=Neutral on cost and effect. Other reasons to accept treatment?

## **Conclusions**

The results of the present economic analysis support that preoperative administration of the specialized diet could be the dominant nutritional strategy in well-nourished patients who are candidates for major GI surgery for cancer. Preoperative treatment resulted in a positive cost-effectiveness ratio with a net saving of €3260 per treated patient compared with conventional treatment. Moreover, the mean cost of treating a complication was significantly lower in the preoperative group, and this trend was also observed when the complication costs were split by the type of surgery performed.

Looking in detail, this overall net saving in cost effectiveness is largely due to the differences observed for infectious complications, whereas no effect was observed for non-infectious complications or anastomotic leaks. This reflects the decrease in postoperative infection rate in the treatment group as consistently reported by others [6,7,10,11], whereas no significant decrease was found in non-infectious complications. The lower costs of complica-

## **Limitations**

Some general limitations of economic analyses should be noted on the transferability of the present clinical and economic data, which may also influence their reproducibility. Comparable cost saving by the routine preoperative use of the specialized diet might be achieved in hospitals where the same types of operations are performed on a similar scale and complication rate. The economic parameters that we used for the present analysis may differ from country to country based on the type of health care system and reimbursement rates. The present analysis is based only on calculation of hospital resources spent. The assessment of community-associated costs, including sick leave, rehabilitation, and full recovery of physical and social performance would probably magnify our findings even more.

TABLE 3. Number and mean costs (euros) per complication

Intent-to-treat analysis

1,

	Treatment group (n = 102)		Control group (n = 104)	
	N°	Costs	N°	Costs
Anastomotic	•			
leak	5	6,055 (2,911)	10	15,770 (12,883)
Pneumonia	4	1,428 (1,713)	10	4,555 (6,428)
Wound				
infection	4	1,755 (1,936)	6	2,886 (1,218)
UTI	2	1,682 (1,101)	3	, 1,759 (1,030)
Sepsis	1	5,286	2	1,576 (275)
Abscess	1	6,498	2	3,756 (1,821)
Peritonitis	1	20,196	1	7,386
Mean cost per				
complication	18*	4,352 (4,828)**	34	7,173 (9,487)
Total costs		78,336		243,882

UTI: Urinary tract infection. In parenthesis: standard deviation. \*P = 0.009 vs. control.

#### Core Analysis

	Treatment group (n = 90)		Control group (n = 96)	
	N°	Costs	N°	Costs
Anastomotic leak	5	6,055 (2,911)	10	15,770 (12,883)
Pneumonia	4	1,428 (1,713)	9	4,468 (6,811)
Wound infection	3	833 (722)	6	2,886 (1,218)
UTI	2	1,682 (1,101)	3	1,759 (1,030)
Sepsis	0		2	1,576 (275)
Abscess	0		2	3,756 (1,821)
Mean cost per				
complication	14^	2,989 (2,958)^	^ 32	7,224 (9,783)
Total costs		41,846		231,168

 $<sup>^{\</sup>hat{}}P = 0.006 \text{ vs. control.}$ 

<sup>\*\*</sup>P = 0.12 vs. control.