TITLE PAGE:

1. Title of the Paper: The effect of adequate energy and protein intake on morbidity and mortality in surgical patients nutritionally assessed as high risk and low risk: report from a tertiary care private hospital in the Philippines
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ABSTRACT:

Objectives: To determine the effect of adequate energy and protein intake on morbidity and mortality in surgical patients referred to the clinical nutrition service.

Methodology: Prospective study, non-randomized: Surgery patients referred to the clinical nutrition service were followed up until discharge from March 1, 2007 to August 31, 2008. Inclusion criteria: underwent nutrition risk assessment, adequate intake. Data collected were: malnutrition risk levels, weight taken on admission and on discharge, calorie and protein intake, morbidity, mortality, number of complications, and length of hospital stay. Adequate intake was pegged at 75% of computed requirement. Statistical analysis: Chi-square test and Fisher's exact test for small sample sized data, Wilcoxon rank sum test for non-normal distributed data.

Results: The computed energy requirement in both groups was 1500-1510 kcal/day while the protein requirement was 67.5-68 gm/day. There was no difference in actual intake of energy (low risk: 84.6%; high risk: 82.2%) or protein (low risk: 75.8%; high risk: 75.6%) between groups. There was also no difference in mortality between high risk (22.7%) and low risk group (20.7%), but the presence of complications was higher in the high risk group (63.6%) versus low risk (31%), p = 0.006, Chi Square. Infectious complications were not different between groups (10.3% versus 39.5%, p = 0.052, Chi Square) as well as in weight loss, weight gain, and length of hospital stay.

Conclusion: Adequate intake in energy and protein resulted to no difference in mortality between high and low risk groups indicating lower mortality in the high risk group. There was also no difference in weight change and length of hospital stay, but complications were higher in the high risk groups.

INTRODUCTION:

The goal of nutrition therapy in surgical patients is to lessen or avoid morbidity and mortality in the post-operative period especially for the severely malnourished and/or at high risk of developing malnutrition related complications (1-3). This requires an initial nutrition risk assessment on admission of all surgical patients which practice is sadly not implemented in most institutions in the country (Philippines) (4-6). The nutrition screening and assessment process will be followed by a nutrition care plan which is designed to maintain adequate nutrient intake for the patient. This process is meant to reduce nutrition related complications like wound infection, sepsis, multi-organ dysfunction, and slow wound healing (7-9). Morbidity and mortality would be reduced and length of stay shortened (2,3,7-9). Reports from intensive care units showed that reducing negative nutrient balance through increased nutrient delivery techniques reduced infections and improved mortality (10,11). This present study was therefore designed to find out if achieving the same, that is reaching adequate intake, would also lead to improved morbidity and mortality.

The surgery department and clinical nutrition service of this institution (St. Luke's Medical Center) joined to undertake this study with three main goals: a) to determine the effect of adequate intake on morbidity and mortality in surgical patients whether "low risk" or "high risk", b) to find out if there is an effect on weight change, length of hospital stay, and c) to determine whether this was achieved through enteral, parenteral or combined enteral and parenteral nutrition. This study was also designed to increase awareness among the surgical staff on the value of incorporating clinical nutrition in the management of surgical patients.

METHODOLOGY

Prospective Study: This was a prospective study covering the period from March 1, 2007 to August 31, 2008 where surgical patients ages 19 years old and above were referred to the clinical nutrition service for nutrition management either pre or post-op, for chemotherapy, and radiotherapy. Nutrition risk assessment and nutrition care plan were done for each patient after which the nutrient intake was monitored and documented. The main factor for Inclusion in the study was adequate intake. Excluded were patients who were 18 years old and younger, for medical treatment alone, and those who could not be weighed.

Nutritional assessment and risk leveling: The patients' malnutrition risk level were assessed using a nutrition assessment form (Figure 1) designed by the Philippine Society of Parenteral and Enteral

Nutrition (PHILSPEN), which has been validated in a local study (12).This nutritional assessment and risk leveling tool is a composite of Subjective Global Assessment (SGA) variables (13), BMI, percent weight loss, Total Lymphocyte Count (TLC) and serum albumin. This is scored into three levels: mild, moderate, high risk of malnutrition. Score of 3 and below means the patient is low to moderate risk of developing malnutrition related complications and score of above 3 is considered high risk of developing malnutrition related complications.

Nutrition care plan: The Nutrition Care Plan was designed for each patient and implemented once approved by the attending physician. It consists primarily of the computed nutrient requirements, nutrient formulation and mode of delivery, and manner of follow up. The Total Caloric Requirement (TCR) was calculated using actual body weight for underweight and normal patients, ideal body weight or corrected for overweight and obese patients multiplied using the following values: a) 25 kcal/kg body weight used for bedridden or b) 30 kcal/kg body weight or more for ambulatory patients. The Total Protein Requirement (TPR) was calculated using the appropriate weight multiplied by a range of factors, depending on the disease or injury process (0.6 gm to 2 gm/ kg body weight) (14).

Monitoring: Calorie count was performed at least three times a week. These are the monitored outcome variables: adequacy of intake, weight change, complications (wound infection, dehiscence, sepsis, organ dysfunction), morbidity, mortality, and length of stay. Adequacy of feeding was pegged at 75% of computed calorie or protein requirement (15). Amount and method of feeding were progressed depending on the patients' adequacy of intake. Weight on admission was recorded, every 5 days and prior to discharge with Detecto scale (©Detecto, Webb City, MO 64870) for ambulatory patients and bed scale for bedridden patients.

Statistical tools: Differences in values between the chosen variables between groups were analyzed using the independent samples t-test for normally distributed data and Wilcoxon test for non-normal distributed data. Chi square and Fisher exact test were used for categorical variables. Statistical analysis software used was the NCSS2004 /PASS 2002 (16).

RESULTS:

Patient profile (Table 1 and 2): A total of 104 patients were seen by the clinical nutrition service and 94 had complete records. There were 49/104 (47%) males and 55/104 (53%) females, for a male to female ratio of 1:1.1. There were less patients with low to moderate risk (30/94 or 31.9%), and more with high risk scores (64/94 or 68%). There was an equal distribution of adult and geriatric age group in the followed up patients. The majority of patients underwent surgery (59.6%) while the rest were

distributed among readmissions for post-surgical follow up, for chemotherapy, and for radiotherapy treatments.

Patients with Adequate Intake, N=73 (Table 2): The mean computed calorie requirements per day was similar in both patient groups (low risk: 1519 and high risk: 1500 kcal/day), and so was the mean protein requirement per day (low risk: 67.5 and high risk: 68 gm/day). There were similar intakes in both calorie (low risk: 1339.5 and high risk: 1264.5 kcal/day) and protein (low risk: 50.5 and high risk: 52 gm/day) which reached adequacy levels for both calorie (low risk: 84.6% and high risk: 82.2%) and protein (low risk: 75.8% and high risk: 75.6%) requirements.

Outcomes of patients with adequate intake, N=67 (Table 2): There was no difference in the following outcomes in either Low Risk or High Risk categories – mortality, infections, length of stay, weight gain, and weight loss. The significant difference was found in the presence of complications where there was a higher rate in the high risk patients (67.4%) and lower in the low risk patients (29.2%, p=0.0025, Chi Square Test).

Outcomes among the "high risk" patients, N=43: In comparing the effect of having adequate intake or not, there was no difference in mortality, infections, length of stay, weight gain, and weight loss and the only difference was in the presence of complications (adequate intake group (67.4%) versus inadequate intake group (40%) (p=0.0394, Chi Square Test).

Distribution of nutrient intake sources (Table 3): The major sources of nutrient intake were oral, enteral, parenteral, combined enteral and parenteral, and intravenous dextrose. The oral route was more predominant in the low risk group (48% vs. 42%, p = 0.014, Chi Square); enteral nutrition was delivered in similar amounts in both low risk and high risk groups (31%-32%); parenteral nutrition was lower in the low risk group compared to the high risk group (36% vs. 37%, $p < 0.001$, Chi Square and Fisher Exact test); enteral and parenteral nutrition combinations were given which was significantly higher in high risk group (4% vs. 0.8%, p = 0.002, Chi Square.

DISCUSSION:

The nutrition risk assessment tool used in the study (Figure 1) yielded a great number of patients who are at high risk of developing malnutrition or nutrition related complications (64/94 or 68%). A previous study using the same tool showed a significant number of deaths (18.4%, $p < 0.05$, ANOVA) and complications (36.4%) in the high risk population (12). The expected complication rate was high as predicted by this nutrition risk assessment tool.

The nutrition management by the clinical nutrition service achieved adequate intake in both

nutrition risk groups (low risk: 84.6% and high risk: 82.2% for calorie requirements /low risk: 75.8% and high risk: 75.6% for protein requirements), thus showing that with close follow up goals are achieved in most patients. There was no difference in mortality between the high risk and low risk groups indicating that adequate intake resulted to lesser mortality in the high risk groups. (Figure 2) This result was also observed in studies on calorie intake of intensive care patients. (17,18) The factors responsible for this change in outcome are the lack of difference noted in the infection rates between the two groups, weight gain, and weight loss. This was further supported in a report where enteral nutrition reduced infectious complications. (19) The only significant difference was in the complication rate (31%, low risk vs. 63.6%, high risk) which is a reflection of the relationship between nutritional high risk status and complication rate (10.11).

It is thus shown in this study that nutrition management makes a difference in the outcome of mortality and morbidity for the high risk group of surgical patients through its effect of improved nutrient intake and thus maintenance of body composition status resulting to better wound healing and lesser infectious complications. It is also shown that with the knowledge of a high risk status, optimum nutrition care could be delivered to avoid these expected complications. The achievement of intake goals was done through a distribution of delivery methods utilizing all possible routes. The oral route was highest in the low risk group indicating a fully functional gastrointestinal tract, however, this was not possible in the high risk patients, hence more enteral and parenteral nutrition (either singly or combined) was delivered to them (Table 3). The implementation of feeding protocols has rationalized and simplified the process. (20)

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TABLES:

Table 1: Patient Profile (N=104)			
Characteristics*	Low to mod risk (score ≤ 3)	High risk (score > 3)	Total
Adult (19-60 yr)	18 (50%)	36 (53%)	54 (52%)
Geriatric (>60 yr)	18 (50%)	32 (47%)	50 (48%)
Male	18	31	49
Female	18	37	55
Conditions			
Surgical	19 (53%)	44 (65%)	63 (60.6%)
Readmitted for follow up	11 (30%)	20 (29%)	31 (29.9%)
For chemotherapy	2 (6%)	2 (3%)	4 (3.8%)
For radiotherapy	1 (3%)	1 (1.5%)	2 (1.9%)
Chemo-Radiation Therapy	3 (8%)	1 (1.5%)	4 (3.8%)
Total	36 (34.6%)	68 (65.4%)	104
*Not significant, Chi-Square			

Table 2: Nutrition Data and Outcome *		
Variables †	Low to mod risk (score ≤ 3)	High risk (score > 3)
Nutritional Requirements (N=94)		
TCR (kcal/day), (95% LCL and UCL)	1519 (1432-1692)	1500 (1400-1600)
TPR (gm/day), (95% LCL and UCL)	67.5 (60-73)	68 (60-70)
Nutritional Intake		
Calorie intake (kcal/day) (95% LCL and UCL)	1339.5 (1198-1457)	1264.5 (1125-1367)
Percent Calorie Intake (Mean/StDev)	84.6% (15.8)	82.2% (19.6)
Protein intake (gm/day)(95% LCL and UCL)	50.5 (46-60)	52 (45-60)
Percent Protein Intake (Mean/StDev)	75.8% (22.1)	75.6% (21.9)
Total Number of Patients	30	64
Patients with Adequate Intake (≥75%)	24/30 or 80%	44/64 or 68.7%
Outcome Data of Patients with Adequate Intake (N=73)		
Mortality	6/29 (20.7%)	10/44 (22.7%)
Complications	9/29 (31%)	28/44 (63.6%)**
Infectious complications	3/29 (10.3%)	13/44 (39.5%) †
Weight gain	19/29 (65.5%)	26/44 (59%)
Weight loss	2/29 (6.9%)	6/44 (13.7%)
Weight – No change	7/29 (24.1%)	12/44 (27.4%)
Hospital Stay (days), median (95% LCL and UCL)	14 (8-24)	22 (13-31)

† Unless indicated all values are expressed as median (95% upper and lower class limits)
TCR = Total Calorie Requirement; TPR = Total Protein Requirement; StDev=Standard Deviation; LCL = Lower Class Limits; UCL = Upper Class Limits
*Not significant for (1) Mann Whitney U Test or (2) Chi Square Test
** P=0.006, Chi Square Test; † P=0.052, Chi Square Test

Table 3: Nutrient Delivery Type		
Nutrient Delivery Type	Low to mod risk (score ≤ 3)	High risk (score > 3)
Oral	176/354 (49.7%) *	386/916 (42.1%)
Enteral Nutrition (EN)	109/354 (30.8%)	297/916 (32.4%) *
Parenteral Nutrition (PN)	128/354 (36.2%)	475/916 (37.4%) *
EN and PN combined	3/354 (0.8%)	38/916 (4%) *
* p <0.05 (1) Chi Square Test and/or (2) Fisher Exact Test		

Figure 1: Nutritional assessment and risk leveling form

CLINICAL NUTRITION SERVICES

NUTRITIONAL ASSESSMENT AND RISK LEVEL FORM

Date Admitted	Room / Bed No.	File No.	PIN
Patient's Name (Last, First, Middle Name)			Age / Sex
Height (m)	Weight (kg)	BMI	
Attending Physician	Diagnosis		

Criteria	Normal / Mild	Moderate	Severe
Weight Loss	☐ none	☐ < 10% of usual weight	☐ > 10% of usual weight
Food Intake (last 1-2 months)	☐ no change	☐ suboptimal	☐ starvation
Gastro symptoms (>2 weeks)	☐ none	☐ nausea, vomiting	☐ anorexia, diarrhea severe
Functional Capacity	☐ no change	☐ dysfunction < 3 weeks suboptimal work bedridden < 2 weeks	☐ bedridden > 2 weeks
Disease and relation to nutritional requirements	☐ no or low stress	☐ moderate stress	☐ severe stress
Physical Examination	☐ 0 subcutaneous fat and/or muscle loss	☐ +1 to 2 subcutaneous fat and/or muscle loss	☐ +3 subcutaneous fat and/or muscle loss
Edema / Ascites	☐ none	☐ none	☐ +1 or +2
SGA Grade	A 0 ☐	B 1 ☐	C 3 ☐
BMI	18.5 – 24.9 0 ☐	25 – 29.9 1 ☐	< 18.5 or > 30 2 ☐
Albumin g/dL	> 3.4 0 ☐	2.5 – 3.4 1 ☐	< 2.5 2 ☐
TLC	> 1500 0 ☐	900 but < 1500 1 ☐	< 900 2 ☐

TOTAL SCORE	NUTRITION RISK LEVEL	NUTRITIONAL STATUS
☐	0 ☐ Level 1 LOW RISK 1-2 ☐ Level 2 MODERATE RISK > 3 ☐ Level 3 HIGH RISK	☐ Normal ☐ Moderate malnutrition ☐ Severe malnutrition

☐ **Risk Level 1 or 2**
Would you like to refer your patient to the Clinical Nutrition Dietitian for follow-up?
☐ Yes ☐ No

☐ **Risk Level 3**
Required to be followed up by the Clinical Nutrition Physician

Name and Signature of Attending Physician _____ Date _____

Assessed by:

Signature over Printed Name _____ Date _____

FIGURE 2: Effect of adequate energy and protein intake on mortality and complications in low and high risk surgical patients