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DOES PERI-OPERATIVE PARENTERAL NUTRITION AFFECT OUTCOME IN PATIENTS UNDERGOING MAJOR ABDOMINAL SURGERIES

NEPAL MEDICAL COLLEGE

SUBMITTED BY

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RESEARCH DESIGN:

Type of study: Retrospective observational study

Place of study: Department of Surgical Gastroenterology, Nepal Medical College and Teaching Hospital, Attarkhel, Gokarneshwor-08, Kathmandu.

Duration of study: 2017, January 1st to 2022, August 31st (5 years 7 months)

Sampling technique: Consecutive sampling technique

Sample Size:

To select the appropriate sample size, we considered the prevalence of malnutrition in surgical patients to be 24% (3) at a confidence interval of 95% (Z = 1.96), and a precision (d) of 7%. Based on these calculations, the sample size obtained was 143.

We obtained the sample size using the following formula:

For large population (infinite population)

$$= 3.84*0.24*0.76/(0.07*0.07) = 142.9 = 143$$

n = Sample size

Z^2= 1.96*1.96=3.84

p = Prevalence value = 24%= 0.24

q = 1-p = 1-0.24 = 0.76

d = desirable error or precision level (5% to 10%) = 7% = 0.07 (pre-set value)

Inclusion criteria:

1. All patients who underwent major gastrointestinal surgery after receiving perioperative TPN.

Exclusion criteria:

1. Patient refused to participate.
2. Perioperative TPN was not given as per the protocol.

Ethical consideration:

All patients enrolled in the study were explained about the enrollment, and verbal and written consent were obtained from the patient. Patients were counseled about the strict confidentiality that would be maintained throughout their participation in this study, and that their name would not be disclosed in the proforma or after the completion of study until voluntarily disclosed by the patient. Ethical approval will be obtained from the Institutional Review Committee (IRC) of Nepal Medical College and Teaching Hospital.

Data collection: All patients that undergo major gastroenterological surgeries are always entered in our data sheet maintained by the department. As all the data regarding the hospital stay, course of illness, management and operation procedures are clearly maintained in these data sheets, we will only select those cases who received perioperative TPN. A sample of this data sheet which is also our proforma is shown in Annex I.

Study Procedure:

1. Consent: After obtaining ethical clearance from the IRC, those patients that fulfill the inclusion criteria will be offered detailed printed information about the proposed study. Since this is a retrospective study, phone calls will be done to the patients and their relatives for consent. Patients agreeing to take part in the study will be requested to sign the consent form. After signing the consent, the patient's data will be recruited in this study. There will be no discrimination of sex, race, religion and geography.

2. Nutritional status assessment: All the patients were evaluated for nutritional status by following the ESPEN guidelines[10] at the time of admission. According to the guidelines, the diagnosis of malnutrition is based on two options:

   (1) BMI < 18.5 kg/m2,

   (2) Combined:

   - Weight loss >10% indefinite of time or >5% over 3 months and
   - Either reduced BMI (<20 kg/m2 in younger than 70 or <22 kg/m2 in patients older than 70 years) or fat free mass index (FFMI) < 15 in women and 17 in men.

   Similarly patients at severe nutritional deficiency risk are defined by presence of one of the following:

   (1) Weight loss >10–15% within 6 months,

   (2) BMI < 18.5 kg/m2, and

   (3) Preoperative serum albumin < 30 g/L (without evidence of liver or kidney dysfunction).

3. Routes and selection of PN: All the patients who were found to have malnutrition or were at severe risk of nutrition deficiency were given preoperative PN. PN was given as infusion via central venous catheter from the day of admission via central venous catheter.[11] The CVC was kept by the anesthesiology team on the day of admission. The PN was available in a standard 3-compartment package developed by BAXTER and comprising lipid, carbohydrate and amino acids with minerals.

4. Duration and dosing of PN: In those patients who required emergency surgery, PN was given in postoperative period until resumption of oral feeding. In non-emergent cases where surgery could be delayed for 5 days, PN was given for 5 days preoperatively based on the fact that our body needs at least 5-7 days to recover its full physiological activity and body protein framework and was continued in the post-operative period until the resumption of enteral feeding. The dosing of PN was based on ESPEN guidelines with total energy of 25-30Kcal/kg/day and 1.2g/kg/day of proteins.

5. Intraoperative and postoperative status: All patients underwent surgery after preoperative assessment on 5th day onwards of admission. All the surgeries were done by the same team of surgeons. The intraoperative events were recorded by taking in consideration the anesthesiology chart. Postoperatively their progress as well as outcome were filled in the datasheet everyday till discharge.

6. Complications: The complications faced by the patient were graded according to the Clavien-Dindo Classification system[12] by keeping records till 30 days of the surgical procedure date.

Data Analysis Technique: Data collected on a hard copy proforma will be entered and analyzed in Microsoft excel and into IBM- Statistical Package for the Social Sciences (SPSS) version 16.0 respectively. Continuous variables will be expressed as the mean value + or - standard deviation (SD) and range, while categorical variables will be expressed as proportions. We will use the chi-square test and the exact test of Fischer for analysis of categorical data and univariate

linear regression analysis to show association. The data, after analysis, will be reported with descriptive statistics, with all data reported as mean $\pm$ SD, and the final result will be compared with various studies listed in the Literature Review section. Various frequency tables, charts, graphs, trends, plots and bar diagrams will be used to present the data.