Fasting vs. Carbohydrate Loading to Prepare for Femur Fracture Surgery

By:

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Presenter’s information

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Outlines

- **Introduction**
  - ✓Background
  - ✓Statement of problem
  - ✓Justification of study
  - ✓Objectives of study
- **Methodology**
- **Result and Discussion**
- **Conclusion and recommendation**
- **Reference**

Introduction:

Background:

- Femur fracture in elder peoples cause long stay at hospital[1]
- Surgical management of patients with different comorbidities facilitates challenges
- Patients are in long fasting to avoid from pulmonary aspiration
- Catabolic state worsens the stress response and contribute to insulin resistance and hyperglycemia lengthening the recovery period[2]
- Leads to distress, confusion, instability, headache, dehydration, electrolyte imbalance, postoperative nausea, and vomiting[3]

Background(Conti….)

- Concept of Enhanced Recovery After Surgery (ERAS)
- 100 g and 50 g of carbohydrates orally the night before and two hours before surgery respectively, called preoperative carbohydrate loading[4]

Advantages of ERAS:

- Decrease of insulin resistivity
- Improvement of metabolic functions
- Less post-operative protein and nitrogen loss improves muscle function and facilitates wound healing
- reduces the intraoperative core body temperature
- Decrease the length of postoperative stay at hospital
- Reduces the financial cost

Statement of problems

- ERAS as novel and scientific approach in Europe
- Mostly practiced in general surgery, obstetrics, and gynecology
- Nutritional support is less prioritorized in orthopaedics for patients' fast postoperative recovery[5]
- Prolonged fasting as traditional anaesthesia still in practice in Nepal

Concern of Issue: To assess the effect of pre-operative carbohydrate loading on the improvement of

I. postoperative pain,
II. functional mobility, and
III. the recovery rate among patients undergoing surgery for femur fracture management.

Methodology

- Study design: Single-center, hospital-based, open-label, parallel-group randomized controlled trial
- Study duration: August 2020 - November 2021
- Study site: Nepal Orthopaedic Hospital, Jorpati, Kathmandu, Nepal (*a charitable 100 bedded specialized orthopaedic and trauma hospital*)

Study population:

- Inclusion criteria: The patients aged 50 years and above having a femur fracture planned for surgery, those patients who were mentally fit, and those patients who provided written informed consent were included in the study.
- Exclusion criteria: Patients with pre-existing diabetes (Type 1 or 2), past carbohydrate intolerance, pathological fracture or any suspected pathology, and surgery failure or non-union cases

sample size

Sample size

- By using a test comparing independent two means in Stata/MP version 14.1 (StataCorp LP, College Station, Texas)
- the primary outcome being the Cumulative Ambulatory Score (Mean ± SE) of the study group versus the control group as 12.76 ± 0.33 and 12.02 ± 0.32 respectively
- taking a level of significance at 5% and power of 80%, the sample size was 60
- With a 10% loss to follow-up and dropout, the total sample size was 66 (33 participants in each group)

Randomization

- Participants assigned to a study and control group in 1:1 ratio
- computer-generated random number using a Microsoft excel sheet were used and coded control as ‘C’ and study as ‘S’
- Preparation of envelopes according to a random number, and the participants 1 to 66 were allocated to either control or study group based on the random number
- After confirmation, the patients were asked to draw the envelop and opened

Intervention

Control group

Prolonged Fasting from midnight to the next morning as in existence

Intervention group

- Carbohydrate loading according to the ERAS protocol *(100 gram glucose and 50 gram glucose orally the night before and two hours before surgery respectively)*
- Glucose-D *(carbohydrate-rich drink of Nepali product (Reg. No.: 3506/045/046, Department of Food Technology and Quality Control, DFTQC No.: 01–33-55–03-218).*
- Composition: *Dextrose Monohydrate (99.4%), Calcium Phosphate (0.6%) and Vitamin D (0.0001%)*

Study variables

Primary outcomes

1. Postoperative pain: Pain assessed on 1st postoperative day with Visual Analogue Score (VAS score)

2. Functional mobility:

A. Cumulative Ambulatory Score (CAS) to find out the regaining basic mobility independence on 1st, 2nd and 3rd postoperative day and added all.

B. Modified Barthel Index-Activities of Daily Living (MBI-ADL) to measure independence at the time of discharge from the hospital.

A score from 0 to 20 for "total dependency" was considered for the study; the higher the score, better the self-care activity

Secondary outcomes

Serum albumin level:

Pre and post-operative serum albumin were collected and the changes were evaluated

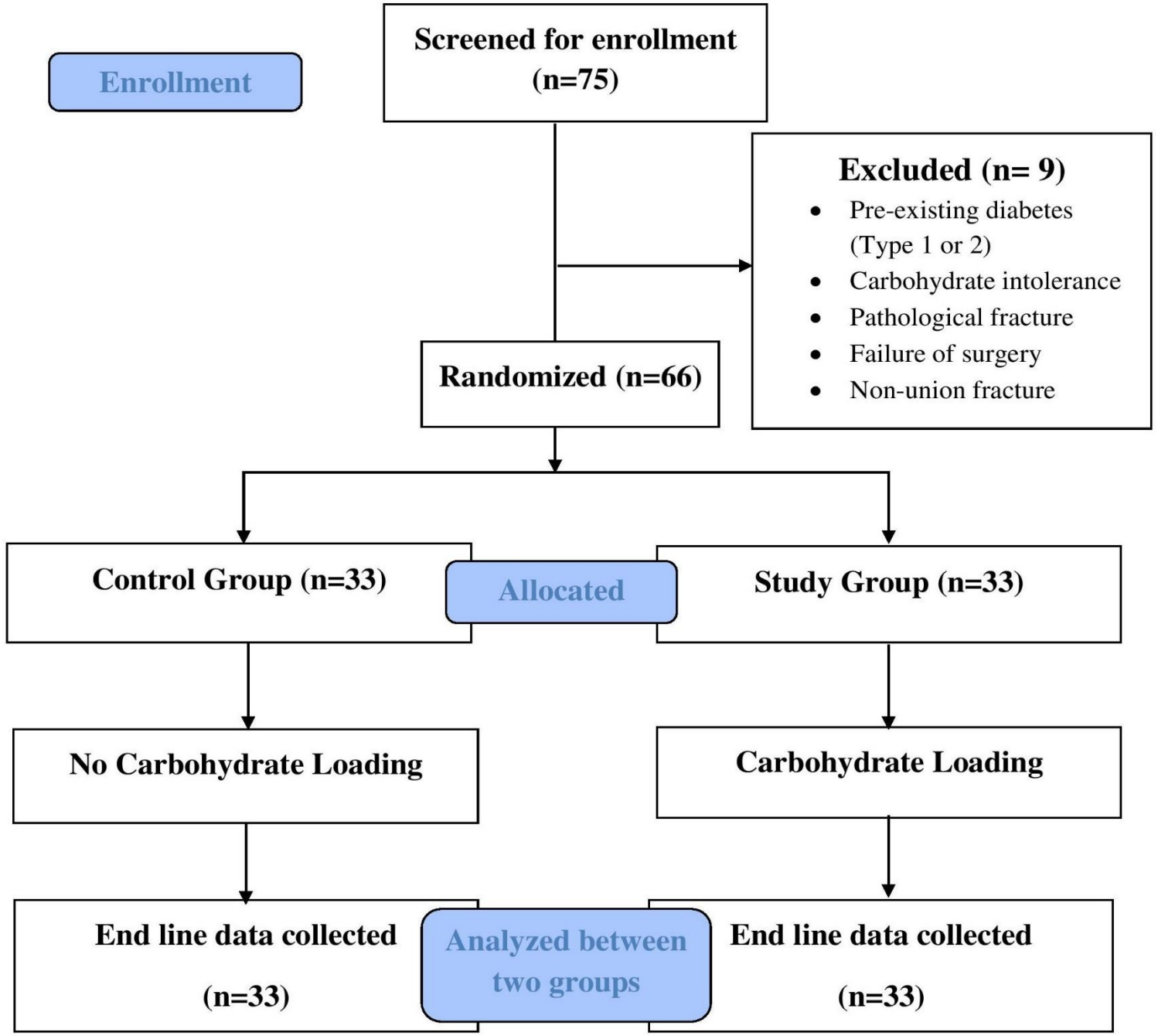
Predictor variables

- **Socio-demographic information with semi-structured questionnaire:** *age, sex, Body Mass Index (BMI), occupation, ethnicity, religion, residence area, and educational level*
- **Nutritional assessments:** Mini Nutritional Assessment Scale (MNA)
- **Clinical parameters**: Site and side of femur fracture, types of fracture, number of fractures
- **Biochemical parameters**: Preoperative hemoglobin level and serum albumin level
- **Intraoperative data**: Types of surgery, types of implants used, duration of surgery, amount of blood loss, blood transfusion and adverse effect

Data management and analysis

- data entry was done using EpiData version 3.0
- Analysis based on intention to treat (ITT) approach using Stata/MP version 14.1 (StataCorp LP, College Station, Texas)
- Descriptive statistics such as frequency, percentage, and mean (standard deviation)
- Chi-square and Student’s two-sample t-tests were used
- All p-values less than 0.05 were considered statistically significant

Flow Chart


Enrollment
Screened for enrollment (n=75)
Excluded (n= 9)
Pre-existing diabetes (Type 1 or 2)
Carbohydrate intolerance
Pathological fracture
Failure of surgery
Non-union fracture
Randomized (n=66)
Control Group (n=33)
Allocated
Study Group (n=33)
No Carbohydrate Loading
Carbohydrate Loading
End line data collected (n=33)
Analyzed between two groups
End line data collected (n=33)

Ethical consideration

- Funded by the Provincial Research Grant of Nepal Health Research Council (NHRC), Nepal *(Grant number: 110/2021)*
- Ethical approval from NHRC *(Reg. Number: 3104, approved on 11/05/2021)*
- Clinical trial registry from Clinical Trial.gov. *(Identifier: NCT04838366. Registered on 09/04 2021)*
- Formal permission from *Nepal Orthopaedic Hospital*, Kathmandu, Nepal
- Formation of *Data Safety and Monitoring Board (DSMB)*
- Written informed consent obtained from *all participants study*
- Safety pre-caution of COVID-19 followed

Results

Variables	Control group (n=33)	Study group (n=33)
	n (%)	n (%)
Sex		
Female	16 (45.7)	19 (54.3)
Male	17 (54.8)	14 (45.2)
Age categories (years)		
50-70	15 (41.7)	21 (58.3)
71-96	18 (60.0)	12 (40.0)
Age in years (mean ± SD)	69.3 ± 13.9	66.4 ± 11.8
Education		
Literate	7 (35.0)	13 (65.0)
Illiterate	26 (56.5)	20 (43.5)
Ethnicity		
Advantaged ethnic group	18 (58.1)	13 (41.9)
Disadvantaged ethnic group	15 (42.8)	20 (57.1)
Religion		
Hindu	27 (57.5)	20 (42.5)
Non Hindu	6 (31.6)	13 (68.4)
Occupation		
Employed	4 (57.1)	3 (42.9)
Unemployed	29 (49.1)	30 (50.9)
Ecological region		
Hill	12 (54.5)	10 (45.5)
Mountain	12 (40.0)	18 (60.0)
Terai	9 (64.3)	5 (35.7)
Place of residence		
Rural	17 (42.5)	23 (57.5)
Urban	16 (61.5)	10 (38.4)

Table 1. Socio-demographic characteristics of participants

Table 2. Clinical parameters of participants

Variables	Control group	Study group
	n (%)	n (%)
Fracture site		
Distal femur	4 (50.0)	4 (50.0)
Proximal femur	20 (47.6)	22 (52.4)
Shaft of femur	9 (56.3)	7 (43.7)
Fracture side		
Left	15 (42.8)	20 (57.2)
Right	18 (58.1)	13 (41.9)
Number of fractures		
Two or more	4 (57.1)	3 (42.9)
Single	29 (49.2)	30 (50.8)
Type of surgery done		
Open reduction	30 (51.7)	28 (48.3)
Closed reduction	3 (37.5)	5 (62.5)
Type of implants used		
Nailing	9 (50.0)	9 (50.0)
Others	1 (100)	0
Plating	23 (48.9)	24 (51.1)
Surgery duration		
Less than one hour	4 (80.0)	1 (20.0)
More than one hour	29 (47.5)	32 (52.5)
Blood loss		
Less than 500 ml	26 (45.6)	31 (54.4)
More than 500 ml	7 (77.8)	2 (22.2)
Blood transfusion		
No	26 (46.4)	30 (53.6)
Yes	7 (70.0)	3 (30.0)
Adverse effect		
No	33 (51.6)	31 (48.4)
Yes	0	2 (100)
Nutritional status		
Malnutrition	7 (53.8)	6 (46.2)
Risk of malnutrition	22 (46.8)	25 (53.2)
Normal	4 (66.7)	2 (33.3)

Variables	Control group	Study group
	Mean ± SD	Mean ± SD
Pre-operative hemoglobin level (gm/dL)	11.2 ± 1.1	11.0 ± 1.2
Post-operative hemoglobin level (gm/dL)	9.9 ± 1.2	9.9 ± 0.9
Pre-operative albumin level (gm/dL)	***3.3 ± 0.4***	***3.4 ± 0.3***
Post-operative albumin level (gm/dL)	***3.1 ± 0.4***	***3.4 ± 0.5***
Pre-nutritional status	20.6 ± 2.9	20.3 ± 2.5

Table 3.Biochemical parameters and pre-nutritional status between the control group and study group

Variables	Control group		Study group		P value[2]
	Mean ± SD	95% CI	Mean ± SD	95% CI	
VAS pain score	6.1 ± 2.1	5.3-6.8	4.8 ± 1.8	4.7-5.4	0.010
CAS score	6.8 ±2.8	5.8-7.8	8.1 ± 2.8	7.1-9.1	0.033
Length of hospital stay	8.8 ± 4.5	7.2-10.4	6.7 ± 2.4	5.8-7.6	0.024
Modified Barthel Index (MBI)	11.8 ± 3.1	10.6-12.9	13.1 ± 2.3	12.2-13.9	0.027

[2]*Student's two-sample t-test*

Table 4. Primary outcomes between the control group and study group

Discussion

Adverse effects

- Pre-operative carbohydrate loading has no adverse effects[6,7]
- Two participants experienced hypoglycemia during surgery
- The alterations in blood glucose might be multifactorial and other modifiers may be concerned with its homeostasis[8]

Pain reduction

- Pre-operative carbohydrate loading significantly reduced post-operative pain[9,10]
- Preoperative carbohydrate loading reduces C-Reactive Protein (CRP)[11] and neutrophil lymphocyte ratio (NLR)[12]
- inflammation is the underlying origin of all pain[13]
- Also, dietary intake enhance nervous, immune, and endocrine system which has an impact on pain experience[14]

Functional mobility

- Cumulative ambulatory scores on the 1st, 2nd, and 3rd postoperative days were higher in study group
- Improvement of carbohydrate uptake, utilization, storage, and protein metabolism with a 50% reduction in loss of lean body mass[15]
- Also helps to store glycogen in the muscle and prevent the loss of lower limb mass[16]
- Modified Barthel Index-Activities of Daily Living (MBI-ADL) index score, degree of independence was higher at the time of discharge[17]

Secondary outcomes

- Preoperative carbohydrate decreased serum albumin in the body
- Preoperative fasting induces perioperative insulin resistivity which inhibits the synthesis of serum albumin[18]
- Low serum albumin leads to a poor prognosis delaying in the clinical outcome
- It decreased in hospital stay from 0.4 to 0.2 days

Limitations of study

- No evaluation of insulin resistivity and other hematological parameters
- No assessment of the patient's medical co-morbidities based on the American Society of Anesthesiologists (ASA)
- Limited sample size
- Interruption of data collection with the first wave of COVID-19 pandemic in Nepal

Conclusion and Recommendation

Conclusion

Accelerated recovery rate;

- postoperative pain reduction
- ambulatory function enhancement and
- Shortening hospital stay

Recommendation:

- Larger trials with a higher sample size needs for stronger evidence
- Beverages as preoperative drinks containing carbohydrates, fat, protein, and other micronutrients to acquire additional better postoperative outcomes can be further studied

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- Nepal Orthopaedic Hospital, Kathmandu, Nepal

- Participants who voluntarily participated in study

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Thank you
for
your kind attention