



TO STUDY THE FEASIBILITY OF LAPAROSCOPIC CHOLECYSTECTOMY AS FASTRACK SURGERY (ERAS PROTOCOL)

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I INTRODUCTION

The ERAS Protocol is the evidence-based care protocol developed by the ERAS Society. There are around 20 care elements that have been shown to influence care time and postoperative complications. MATERIAL AND

II METHODS

Type of Study:

Quasi Experimental study

Duration of Study:

April 2015 to September 2016

Venue:

Department Of Minimal Access and General Surgery , Fortis Escorts Hospital And Research Centre, Faridabad.

III DESIGN OF STUDY

The study would be a Quasi Experimental study on patients underwent Laproscopic cholecystectomy

IV GROUPING OF PATIENTS

All the adult patients presenting to Surgery Department with diagnosis of USG proved Gall stone disease would be included in the study after an informed consent.

Group A (Study group/fastrack): Given coconut water or Glucon-D two hours before surgery and other ERAS guidelines followed

Group B (Control group/day care): No coconut water or Glucon-D

Each group would have 50 patients.



V INCLUSION CRITERIA

Fastrack surgery will offered to all patients with symptomatic, ultrasound proved gallstone disease who:

- (1) Are more than 18 years and less than 70 years, in sound mental health.
- (2) Live within 20 km of the hospital.
- (3) Have access to a telephone at all times and know how to use it
- (4) Are living with a responsible adult and are capable of reaching the hospital on their own without depending on ambulance services
- (5) Are thought to be able to understand instructions
- (6) Agree to the procedure as offered.

VI EXLUSION CRITERIA

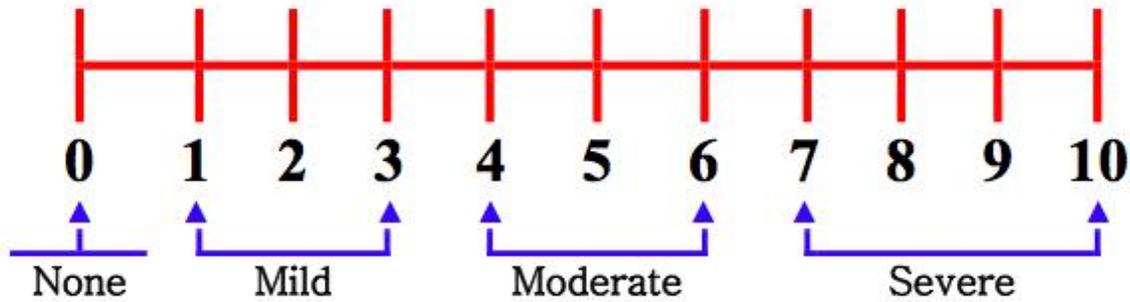
1. Any deviation from the standard procedure (eg. Open)
2. Gall stone disease associated with CBD stones
3. Gall stone disease associated with Pancreatitis
4. Patients presenting to emergency
5. Age >70 year
6. Patient undergoing any other surgical procedure with laparoscopic cholecystectomy.
7. Uncontrolled co-morbidities which would make them unsuitable for a short stay procedure.
8. Pregnant lady

The two groups would be compared for the following study parameters:

- a. Orally tolerability to liquids at 4 hours after surgery
- b. Pain score after surgery at 4 hours after surgery
- c. Ability to ambulate at 4 hours after surgery
- d. Well controlled vital parameters at 4 hours after surgery
- e. Development of immediate post operative complications within 4 hours after surgery
- f. Need for readmission within 2 days(if required)

Discharge Criteria:

1. Tolerating oral liquids(clear liquids-water ,coconut water)
2. Ambulating out of bed without much discomfort with or without the help of attendant
3. Adequate or effective Analgesia(judged by pain scoring...score of< 4 is taken adequate)



For filling the Numeric Pain Rating Scale, the patient is asked any one of the following questions:

1. What number would you give your pain right now?

What number on a 0 to 10 scale would you give your pain when it is the worst that it gets and when it is the best that it gets?

At what number is the pain at an acceptable level for you?

2. When the explanation suggested in #1 above is not sufficient for the patient, we will further explain or conceptualize the Numeric Rating Scale in the following manner:

0 = No Pain

1-3 = Mild Pain [nagging, annoying, interfering little with activity of daily living(ADLs)]

4-6 = Moderate Pain (interferes significantly with ADLs)

7-10 = Severe Pain (disabling; unable to perform ADLs)

4. Vitals within normal range

5. No post operative complications(eg.nausea,vomiting)

VII SAMPLE SIZE

In the absence of previous study on the similar topic, Cohen's effect size is used to calculate sample size of two samples with a continuous outcome variable (pain score) and two samples with a dichotomous outcome variable (other dichotomous study parameters). To detect large scale ES (.8), the minimum required sample size with 80% power of study and two sided alpha of 5% is 25 patients per group. To lower margin of error, sample size taken is 50 per group. Total sample size taken is 100. Formula used

$$n \geq \frac{2(Z_{\alpha} + Z_{\beta})^2}{(ES)^2}$$



A scoring system is developed. Score of 5 means we can discharge the patient and outcome is good, score<5 means poor outcome

VIII RESULT

In group A, 7(14%) out of 50 patients has poor outcome and in group B,27(54%) out of 50 patients has poor outcome

IX CONCLUSION

If ERAS guidelines are followed then laparoscopic cholecystectomy can be performed as a fast-track surgery.