



# EFFICACY AND FEASIBILITY OF ENHANCED RECOVERY AFTER SURGERY (ERAS) PROTOCOL ON FUNCTIONAL RECOVERY IN WOMEN UNDERGOING ELECTIVE CAESAREAN DELIVERY: A RANDOMIZED CLINICAL TRIAL

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## Introduction

- ERAS: Enhanced Recovery After Surgery
  - Goal: Maintaining normal physiology in perioperative period
  - Benefits:
    - Reduces length of hospital stay
    - Decreases postoperative pain & need for analgesia
    - Rapid return of bowel and bladder function
    - Decreases complications & readmission rates
    - Increases patient satisfaction
- ACOG, Obstet Gynecol. 2018
- Initial studies were done on patients undergoing colorectal surgery
  - Caesarean section is most commonly performed surgery; approximately 15% of pregnant women worldwide deliver by caesarean section
  - Caesarean section rates in India: 32.6 %
  - Most of published studies evaluating ERAS in caesarean are retrospective in nature
- Spanjersberg et.al., Cochrane Database Syst Rev. 2011
- Bhatia et.al., JAMA Netw Open. 2020.

Randomized Controlled Trial was planned on ERAS protocols for caesarean delivery at a tertiary care referral hospital in the Indian setup

## Aim & Objectives

- Primary Objective**
- To compare efficacy of ERAS protocol implementation vs. routine perioperative care for pain control in women undergoing elective cesarean delivery
- Secondary Objectives**
- To compare
    - Postoperative functional recovery
    - Patient's readiness for discharge from Maternity unit
    - Patient satisfaction in the two groups

## Methodology

- Study design : Prospective randomized controlled trial
- Ethically approved
- CTRI Number : 2020/10/028652
- Study Duration : Oct 2020 to March 2022
- Study Population : Women undergoing elective caesarean section
  - Sample size : Total 140 (n =70 in each group).
  - Pre-calculated with 90% power at 5% level of significance
  - Based on previous study by Pan et.al., Ther Clin Risk Manag, 2020.
- Intervention:
  - Group-1 (n=70): ERAS Protocol
  - Group-2 (n=70): Routine postoperative care

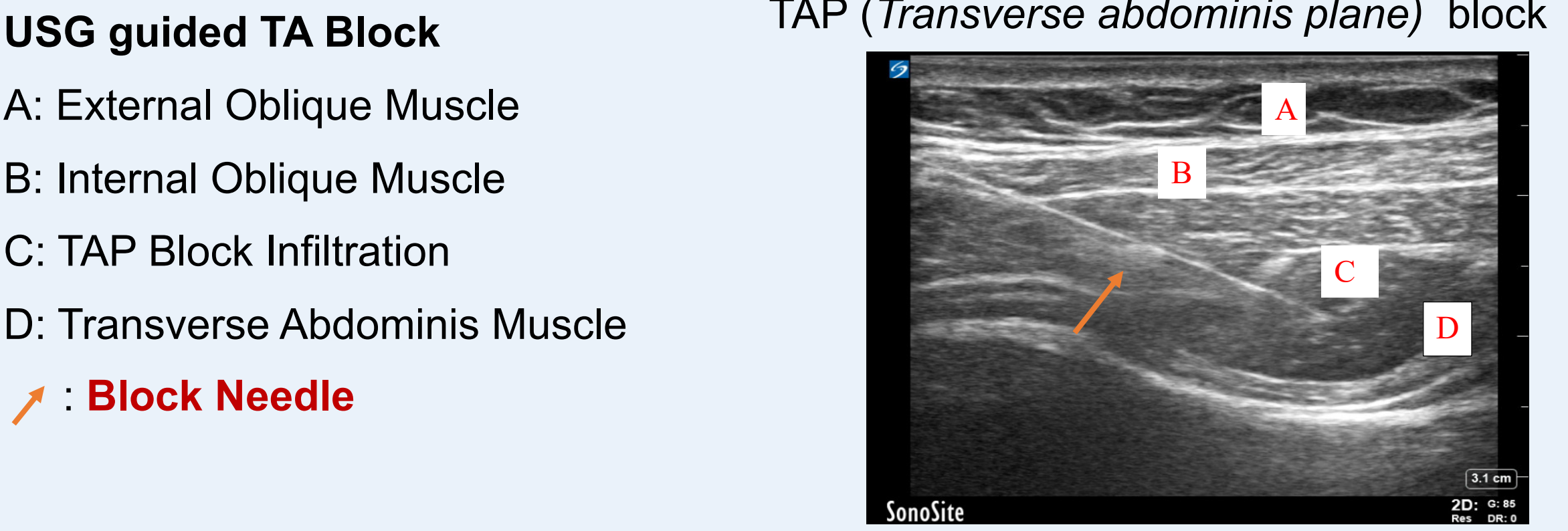
### Eligibility criteria:

- Inclusion Criteria**
- Patients aged 18 - 45 years, scheduled for elective caesarean
- Exclusion Criteria**
- BMI >35kg/m<sup>2</sup>
  - Significant obstetric & medical complications
  - Previous ≥ 2 LSCS or other abdominal surgeries
  - On Tt for abdominal tuberculosis
  - Contraindications for neuraxial anaesthesia
  - Not willing to give consent

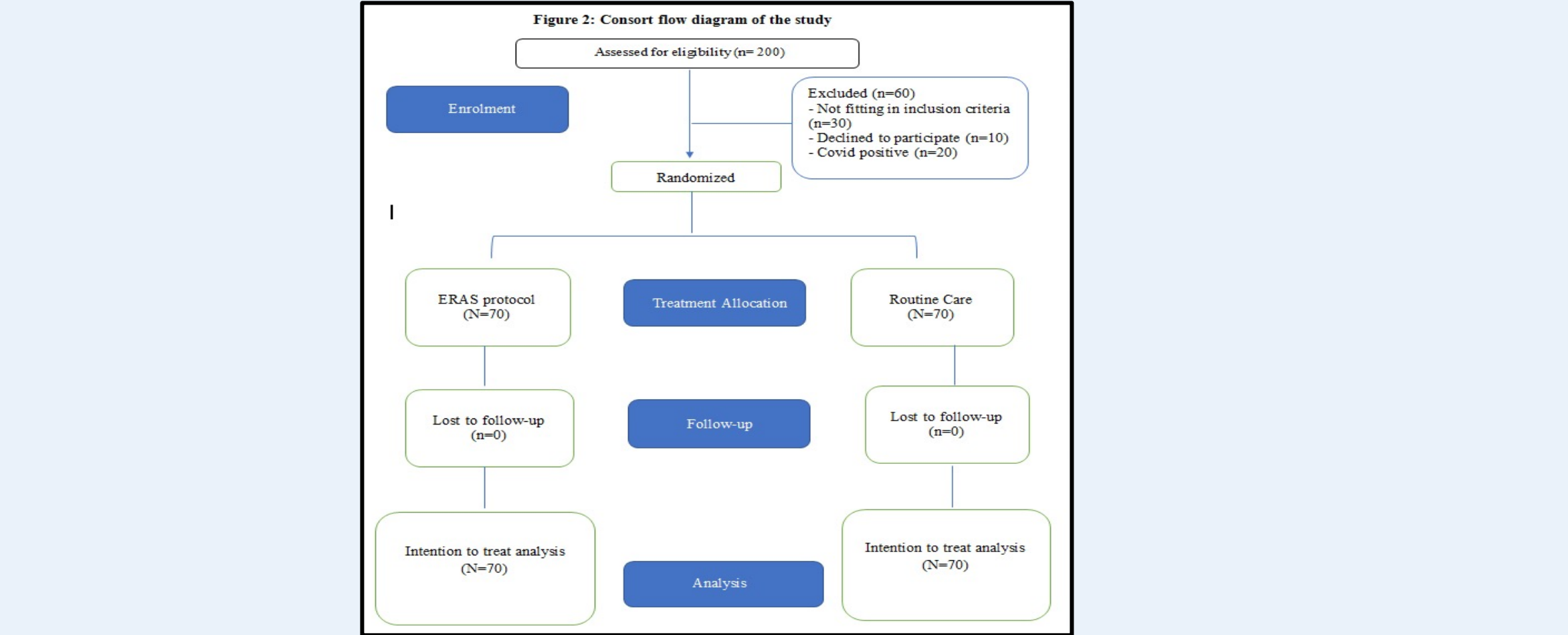
### Components of ERAS Protocol included in our study

- ERAS-protocol in our study included:**
- 4 preoperative, 8 intraoperative, and 9 postoperative components; including
- Preoperative**
- Counselling
  - Avoidance of prolonged perioperative fasting (Light meal up to 6 hours before procedure; clear liquids up to 2 hours before procedure)
  - Carbohydrate loading drink (2 hours before surgery)
- Perioperative**
- First-generation cephalosporin or amoxicillin-clavulanic acid within 60 minutes before skin incisions
  - Regional anaesthetic & nonopioid analgesic approaches with ultrasound guided **TAP block** after skin closure
  - Goal-directed fluid therapy, Maintenance of normothermia
  - Single dose Intravenous paracetamol at shifting to recovery
- Postoperative**
- Round the clock **Multimodal analgesia** (Paracetamol + ketorolac ) for 24 hours with rescue (Fentanyl) if NRS > 3
  - Early mobilization
  - Fluid restrictions followed by early feeding
  - Early catheter removal
  - Appropriate thromboprophylaxis

- Primary Outcome Measures**
- Pain as assessed by **Numerical rating scale (NRS)**: At rest & on movement
  - At 6, 12, 24 & 48 hours after caesarean & at discharge
  - Need for rescue analgesics (Fentanyl) when:
    - Patients complained of pain or when NRS-score was >3.
- Secondary Outcome Measures**
- Adherence to ERAS protocol, postoperative functional recovery and complications were also noted.



## Results

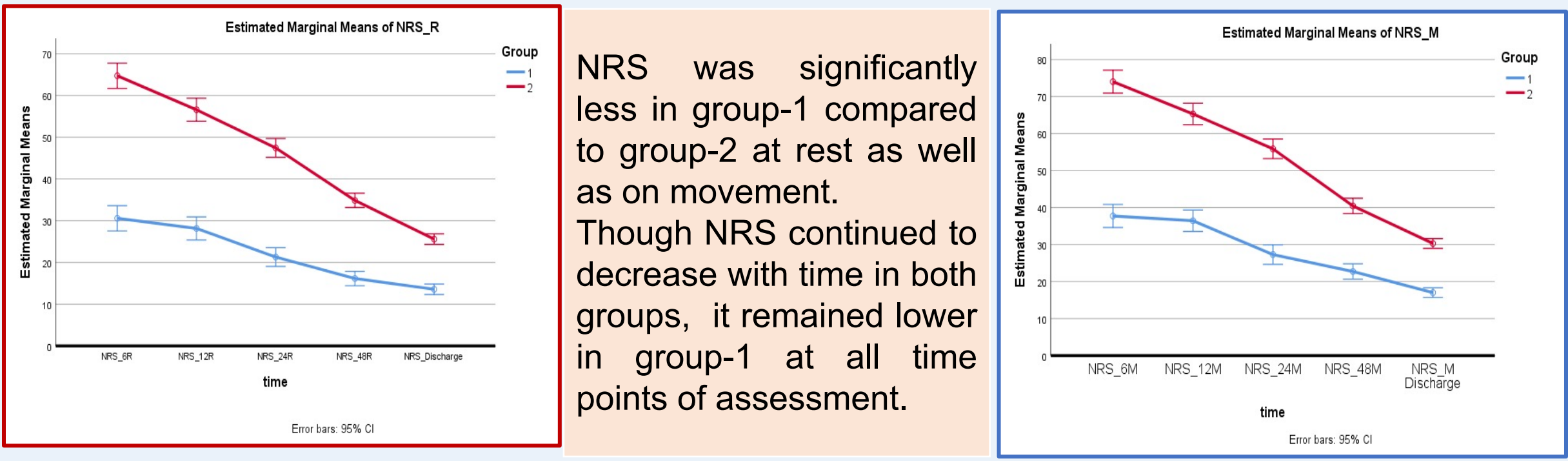


| Baseline Characteristics |                                            |                                               |         |
|--------------------------|--------------------------------------------|-----------------------------------------------|---------|
| Parameters               | Eras group ( N = 70 )<br>M ± SD<br>N ( % ) | Control group ( N = 70 )<br>M ± SD<br>N ( % ) | P value |
| Age                      | 28.74 ± 4.85                               | 29.73 ± 4.56                                  | 0.65    |
| Socioeconomic status     | 3.45 ± 3.2                                 | 3.84 ± 3.6                                    | 0.12    |
| BMI                      | 22.99 ± 2.9                                | 23.27 ± 2.4                                   | 0.06    |
| POG at Cesarean          | 37.66 ± 1.9                                | 37.04 ± 2.1                                   | 0.071   |
| Gravida (Primi)          | 22(31.4)                                   | 34(48.6)                                      | 0.22    |
| NICU admission           | 3(4.3)                                     | 6(8.6)                                        | 0.493   |
| Previous Caesarean       | 30(55.5)                                   | 24 (44.44)                                    | 0.38    |

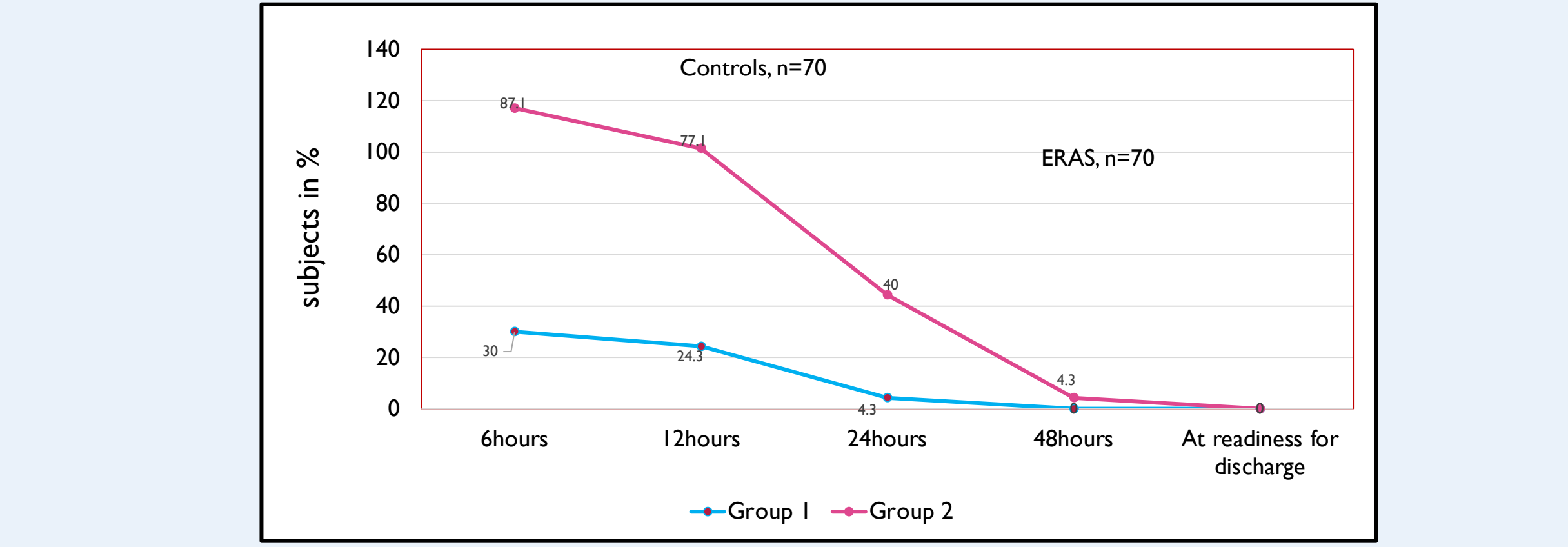
All parameters were comparable in the two groups

### Primary Outcome Measure

| Numerical Rating Scale (NRS) at rest and movement |                             |                             |         |                             |                             |         |
|---------------------------------------------------|-----------------------------|-----------------------------|---------|-----------------------------|-----------------------------|---------|
| Primary outcome                                   | NRS at rest                 |                             |         | NRS at movement             |                             |         |
|                                                   | Group 1 (N=70)<br>(Mean±SD) | Group 2 (N=70)<br>(Mean±SD) | P value | Group 1 (N=70)<br>(Mean±SD) | Group 2 (N=70)<br>(Mean±SD) | P value |
| Time post-caesarean                               |                             |                             |         |                             |                             |         |
| 6 hours                                           | 30.57±1.52                  | 64.71±1.52                  | <0.001  | 37.71±1.57                  | 74.00±1.57                  | <0.001  |
| 12 hours                                          | 28.14±1.39                  | 56.57±1.39                  | <0.001  | 36.42±1.46                  | 65.28±1.46                  | <0.001  |
| 24 hours                                          | 21.28±1.13                  | 47.42±1.13                  | <0.001  | 27.28±1.33                  | 55.85±1.33                  | <0.001  |
| 48 hours                                          | 16.14±0.86                  | 34.85±0.86                  | <0.001  | 22.71±1.05                  | 40.42±1.05                  | <0.001  |
| At readiness for discharge                        | 13.57±0.63                  | 25.57±0.63                  | <0.001  | 17.00±0.66                  | 30.28±0.66                  | <0.001  |



### Percentage of women needing rescue analgesia



- Significantly lesser need for rescue analgesia in Group-1 till 24 hours
- No difference after 24 hours (p=0.245)
- There was no requirement for rescue analgesics after 48 hours till discharge in either group

- Overall functional recovery were achieved significantly earlier in group-1 with comparable postoperative complications.
- Time for readiness for discharge; as defined by pain relief with oral analgesics, tolerance to diet, no complications and ambulation; was 53.69±7.6 vs. 81.91±33.85 hours; (p<.001) in group-1 and 2 respectively.

## Discussion

- ERAS encompasses comprehensive care plan involving a surgeon, anaesthetist, sisters and other staff required in perioperative patient care
- It may not be possible to follow all the components of ERAS protocol and may be modified according to patient baseline characteristics and availability of facilities
- ERAC is associated with reduction in length of stay, times to first mobilization and urinary catheter removal and opioid consumption. ERAC does not significantly affect maternal hospital readmission rates following discharge

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- Sultan P et al, 2021
- Kleimen et al, 2022
- Tamang T et al. BMC Pregnancy and Childbirth, 2021

- In our study, 30% subjects in ERAS group received rescue analgesia while compared to the control group in which 87.1% received rescue drugs. Similar results found in study
- Herbert et al, 2022

- Strengths of present study**
- Prospective randomized study design
  - Adequately powered sample size
  - Multidisciplinary contribution of anaesthesia, obstetric, nursing, and paediatric teams

- Limitations**
- Single centre serving predominantly referral patients
  - Excluded emergency caesareans and high-risk pregnancies
  - No auditing to verify quality improvement
- Future research**
- Role of ERAS may be evaluated using obstetric quality-of-recovery score (ObsQoR-11) to assess quality of life.

Ciechanowicz S. et al, 2019

## Conclusion

- ERAS-protocol reduces postoperative pain scores by approximately 50% with earlier functional recovery and similar complication rates, when compared to routine postoperative care.
- Implementation of ERAS protocol can significantly decrease the postoperative length of hospital stay without increasing the complications and readmission rates
- Also need for rescue analgesics is almost one-third with ERAS implementation.