ALL INDIA INSTITUTE OF MEDICAL SCIENCES JODHPUR

CERTIFICATE

This is to certify that thesis entitled **"Efficacy of Enhanced Recovery after Surgery (ERAS) Protocol in Maxillofacial Trauma: A Randomized Controlled Trial"** is an original work of **Dr. Astha Jani** carried out under our direct supervision and guidance at Department of Dentistry, All India Institute of Medical Sciences, Jodhpur.

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DECLARATION

I, hereby declare that the work reported in the thesis titled **"Efficacy of Enhanced Recovery after Surgery (ERAS) Protocol in Maxillofacial Trauma: A Randomized Controlled Trial"** embodies the result of original research work carried out by me in the Department of Dentistry, All India Institute of Medical Sciences, Jodhpur. I further state that no part of the thesis has been submitted either in part or in full for any other degree of All India Institute of Medical Sciences or any other institution/ University.

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“EFFICACY OF ENHANCED RECOVERY AFTER SURGERY (ERAS) PROTOCOL IN MAXILLOFACIAL TRAUMA: A RANDOMIZED CONTROLLED TRIAL”

THESIS

Submitted to

All India Institute of Medical Sciences, Jodhpur

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(ORAL AND MAXILLOFACIAL SURGERY)

JULY, 2020 **DR. ASTHA JANI**

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Dedicated
To
My Mentor
Dr. Ankita Chugh

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Dr. Astha Jani

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LIST OF ABBREVIATIONS

ABBREVIATIONS		FULL FORM
ERAS	:	Enhanced Recovery After Surgery
NSAIDS	:	Non-Steroidal Anti-Inflammatory Drugs
ERP'S	:	Enhanced Recovery Protocols
RR	:	Relative Risk
RCT	:	Randomized Control Trial
GDFT	:	Goal Directed Fluid Therapy
AWD	:	Active Warming Devices
PWD	:	Passive Warming Devices
MED	:	Morphine Equivalent Dose
NPO	:	Nil Per Oral
I.V	:	Intravenous
NRS	:	Numerical Rating Scale
PONV	:	Post-operative Nausea and Vomiting
ORIF	:	Open Reduction and Internal Fixation
PACU	:	Post Anesthetic Care Unit
SSI	:	Surgical Site Infection
CRAS	:	Conventional Recovery After Surgery
RALP	:	Robot -Assisted Laparoscopic Radical Prostatectomy
VAS	:	Visual Analog Scale
ICU	:	Intensive Care Unit
IMF	:	Intermaxillary Fixation
ASA	:	American society of Anesthesiologist
OHIS	:	Oral Hygiene Index Simplified
HADS	:	Hospital Anxiety and Depression Scale
INR	:	Indian Rupee
SD	:	Standard Deviation
ANOVA	:	Analysis of Variance
RTA	:	Road Traffic Accident
AMR	:	Antimicrobial Resistance
CDC	:	Centre for Disease Control and Prevention
PVP-I	:	Polyvinylpyrrolidone-Iodine
WHO	:	World Health Organization
NS	:	Normal Saline
RL	:	Ringer's Lactate
DNS	:	Dextrose and Sodium Chloride

SUMMARY

Background: Enhanced Recovery after surgery protocols are newly introduced multimodal pathways which involves modifications in traditionally used surgical guidelines to reduce stress response evoked by surgery and fasten recovery. Implementation of these fast-track programmes have shown to substantially fasten and improve recovery rate and return back to normal life when applied in various fields including colorectal surgeries, vascular surgeries, thoracic, head and neck surgeries etc. significantly reducing the surgical morbidity. However, there is insufficient data in literature for formulation and implementation of ERAS guidelines among maxillofacial trauma. A prospective, randomized control trial was planned aiming to compare the efficacy of ERAS protocols as compared to standard care provided for maxillofacial trauma cases.

Objectives: The primary aim was to formulate and implement ERAS protocols in maxillofacial trauma along with evaluation of immediate post trauma outcomes such as anxiety, pain control, post-operative complications and length of stay. The secondary objectives were to evaluate post-surgery psychological and somatic anxiety, overall satisfaction of patient and comfort, return to work days, cost analysis and overall compliance of patient to ERAS protocol.

Methods: Total 74 patients of maxillofacial fractures requiring open reduction and internal fixation were recruited from All India Institute of Medical Sciences, Jodhpur and were randomly divided into two equal groups. Group I acted as ERAS group and Group II acted as control group receiving standard traditional care. In ERAS group patients were treated based on application of newly formulated ERAS protocol. Patients in both the groups were followed up till predetermined period at 24 hours after surgery, 5 days after surgery and 2 weeks after surgery and parameters were assessed.

Results: The result of 74 included maxillofacial fracture cases showed that the demographic and baseline parameters were comparable in both the groups with appropriate randomization. Statistically significant difference was noted on evaluating parameters such as total number of analgesics used, pre-operative and post-operative

fluids, post-operative anxiety score, post-operative oral hygiene index, timing for start of oral feeds, pre-operative compliance for oral carbohydrates, throat pain, swallowing discomfort, discharge timings, discomfort with arch bar and needle pricks and overall satisfaction, adequate communication from health care staff, return to normal life and cost analysis. Results of all these parameters had better outcome noted with use of ERAS protocols. No significant difference was noted for parameters such as pre and post-operative pain levels, pre-operative anxiety, pre-operative oral hygiene, PONV episodes, post-operative swelling, surgical site infections and need for antibiotic upgrade. No major significant complications were observed during the study.

Conclusion: Results showed successful implementation of ERAS protocols in maxillofacial trauma. Adherence to all key elements of ERAS led to increased compliance and improved clinical outcomes. However, successful implementation requires multiteam approach and sincere coordination with anesthesiologist, nursing staff, patient and caregiver keeping the patient as center of priority. Hence, this study strongly recommends employing of ERAS protocols for improving perioperative surgical care strategies, reducing post-operative complications to facilitate early recovery after surgery.

INTRODUCTION

Maxillofacial trauma occurs as an isolated injury or in association with other concomitant injuries occurring to the head, abdomen, chest, spine, and /or long bones. The etiology of such injuries includes trauma secondary to physical forces, foreign objects, interpersonal violence, sports injuries, gunshot injuries, animal bites, industrial accidents, etc. Incidences of maxillofacial trauma have been exponentially increasing in recent times with road traffic accidents being the leading cause responsible for 1 million death per year and 20-50 million death rates across the world. As per the Indian scenario, 0.2 million deaths in 2017 were reported due to road traffic accidents (1)

Maxillofacial injuries not only render a person physically but also affects work productivity, social obligations and have psychological challenges averaging over a period of 4-8 weeks. Facial fractures lead to aesthetic disfigurements, impaired masticatory function due to occlusion derangement leading to dietary restrictions, poor function of traumatized areas leading to poor masticatory ability, and severe pain at times ultimately leading to poor quality of life. Also, some patients present with psychological anxiety and depression as a consequence. (2)

Recently with ever-increasing patient expectations, patients demand good aesthetic and functional results at the earliest. With evolution, new treatment protocols have been formulated using the multidisciplinary and patient-centered approach. To achieve this objective, specialized designed multimodal Enhanced Recovery care pathways are designed to achieve early recovery after major surgical procedures.

ERAS (Enhanced Recovery after Surgery) protocols were initially in the 1990s, instituted by Professor Henrik Kehlet as enhanced recovery programs (ERPs) or “fast-track” programs. Later they become an important focus of perioperative management after various surgeries such as in colorectal, thoracic, gynaecology, vascular surgery, head and neck, orthopaedics radical cystectomy, and recently in cases of radical cystectomy. Studies by Khokhar and colleagues have additionally outlined the key particulars required for the successful implementation of ERAS protocols (3). ERAS programs particularly function by focusing upon the reduction of

profound overall surgical stress response and concomitantly maintaining pre-operative organ function and thus principally leading to improved outcomes. The basic principles of these programs involve variation in provided standard care from the period of referral from primary care to post-operative and subsequent follow-up periods. Key elements of ERAS include perioperative counselling, nutritional optimization, de-addiction counselling, standardization of analgesics and anesthetics, minimizing the pre-operative fasting period, encouraging early oral intake, and early mobilization and discharge of patient.

Despite the significant body of evidence indicating that ERAS protocols lead to improved outcomes they challenge traditional surgical doctrine, and as a result their implementation was slow. Recently the majority of surgical fields (4) (5) (6) have started adhering to protocols of ERAS which has resulted in significantly improved patient satisfaction rates, early recovery, and return to normal function with less postoperative complications and with reduced length of hospital stay and expense ultimately leading to better post trauma quality of life.

Successful implementation of the ERAS protocol requires a multidisciplinary approach with proper coordination between the surgeon, the anaesthesiologist, the nursing staff, the patient, and the caretaker of the patient. ERAS protocol aims at pre-operative risk factor identification and associated comorbidities, systemic disease evaluation such as diabetes, hypertension, asthma, epilepsy, and bleeding disorders and treatment planned accordingly along with the choice of anesthetic technique.

Optimization of medical conditions as a standard of care focuses on early cessation of alcohol, smoking and tobacco before surgery for better prognosis by psychiatric evaluation and reinforcement to help patients to quit smoking and tobacco use.

Keeping in mind the catabolic effect on the body systems and nutrition requirement after the maxillofacial trauma, patients are encouraged for an early start of oral feeds thus minimizing fluid overload. The essential element of ERAS considered is patient preparation psychologically by informing the patient and caregiver regarding the procedure, length of stay, risk factors and treatment outcomes. Other factors include correction of nutrition depending on the severity of the trauma, as poor nutritional control leads to poor overall survival. Regarding prolonged fasting,

studies reveal that increased catecholamine release while under stress leads to the signalling of catabolic pathways and hyperglycemia. Prolonged pre-operative fasting is responsible for increased metabolic stress. In such cases carbohydrate loading limits insulin resistance reducing catabolic protein loss and is also associated with decreased pre-operative hunger and postoperative complications. This fundamental theory is implemented in ERAS protocols by reducing pre-operative fasting periods and carbohydrate loading two hours before surgery

In addition to pre-operative carbohydrate loading, early postoperative nutrition can ameliorate the metabolic response leading to less insulin resistance, lower nitrogen losses and reduce loss of muscle strength. One of the early meta-analyses, although relatively small, found that there is no advantage in keeping patients nil by mouth after elective gastrointestinal resection and early feeding may be beneficial by reducing infectious complications and length of hospital stay (8)

Pre-medication regimens and pain control measures are mandatory to avoid postoperative nausea vomiting and undesired effects of anesthesia. Standardization of the anesthetic regimen is done. The main aim during an intra-operative period is the optimization of fluids maintaining euvolemia and avoiding excess fluid overload. This goal-directed fluid therapy reduces the chances of hypovolemia. Multimodal analgesia consisting of acetaminophen, NSAIDS and local infiltration techniques are used to reduce the risk of increased sedation with opioid use.

Throat packs are usually used to prevent aspiration or ingestion of fluid, blood or debris during surgery and to reduce the risk of postoperative respiratory complications such as nausea and vomiting. But the primary disadvantage of throat pack use is the risk of retention post-operatively causing the potential for airway obstruction and post-operative sore throat and difficulty in swallowing. A systematic review on the use of throat packs in ear, nose and dental surgery reveals no clinical benefit with the use of throat packs and finds evidence of increased throat pain when they are used. To eliminate patients' post-operative discomfort and throat pain throat packs are avoided as per ERAS (Enhanced Recovery after Surgery) in Maxillofacial Trauma cases. Hence, ERAS protocols focus on early return to oral diet by regular encouragement and reinforcement of patient and caregiver. Early postoperative catheter removal within 24 hours results in an early return of bladder function and

decreased chances of urinary tract infections. Early mobilization allows for the early return of the patient's normal function and encourages the patient.

Although much of the data arises from colonic surgeries, neurosurgeries (9) head and neck surgeries (10), etc., not much research and formulation of such protocol has been defined for the management of maxillofacial trauma cases. Formalization and compliance to this protocol for Maxillofacial Trauma will be a boon for patients for the reasons mentioned earlier. Thus, we tend to form and evaluate patient-centered ERAS protocols focusing on fundamental shifts in the management of maxillofacial trauma patients facilitating better outcomes and early recovery after surgery.

REVIEW OF LITERATURE

Eskiciogl et al. (2009) (4) performed a meta-analysis of 4 randomized control trials focused on ERAS programs for patients undergoing colorectal surgery. Studies showed significantly shorter primary lengths of stay for patients enrolled in enhanced recovery programs. There was no significant difference in postoperative mortality relative risk (RR) = 0.53; 95% CI = 0.12-2.38; test for heterogeneity, p = 0.40 and I (2) = 0], and patients in enhanced recovery programs were less likely to develop postoperative complications (RR = 0.61, 95% CI = 0.42-0.88; test for heterogeneity, p = 0.95 and I (2) = 0). This study gave some evidence about the efficacy of ERAS programs, but still large, better-quality RCTs were necessary.

Spanjersberg et al. (2011) (10) compared fast-track surgery versus conventional recovery strategies for colorectal surgery. Primarily it focused on investigating whether ERAS protocols lead to less morbidity and secondarily whether the length of stay was reduced or not. 4 RCTs were included and analyzed. The bowel function was noted shorter for ERAS patients. Pain control postoperatively was also found to be reduced in the ERAS group as compared to the conventional group. Both mobilization on postop day 0 (as per Serclova 2009) and day 1 (as per Gatt 2005) was better for ERAS patients. ERAS patients developed significantly fewer complications overall. The risk of readmissions was not increased with ERAS patients, while the primary length of hospital stay was shorter in ERAS-treated patients. Hence, with the use of ERAS programs in peri-operative care for abdominal (ileo-) colorectal surgery better results were noted.

Blom et al. (2013) (11) investigated initial experiences of an Enhanced Recovery Protocol in oesophageal Surgery and the feasibility and possible benefits of a perioperative ERAS program in patients undergoing esophagectomy for malignant disease. ERAS program emphasized pre-operative nutrition, early extubation, early removal of nasogastric tube, and early mobilization. The primary outcome parameters measured were hospital stay and the incidence of postoperative complications. The patient included in the ERAS group were 103 and compared to 78 patients in the conventional group. Median length of hospital stay was found significantly shorter in ERAS. There were no significant differences in complications or in-hospital mortality rates between the two groups. Results have reported an early return to the normal diet,

reduced duration of hospital stay and the incidence of infectious and gastrointestinal complications and median daily time of mobilization among ERAS patients with lower readmission rates.

Hughes et al. (2014) (12) did a systematic review and meta-analysis aimed at the evaluation of impact of ERAS program on outcomes following hepatic surgery. Results from 9 included studies yielded positive results with decreased overall complication rates by 25% in ERAS as compared to 31% in patients with conventional care. Also, a comparison of length of stay included that the median stay length was 5 (range-2.5-7) days in ERAS patients as compared to 7.5 days (range – 3-11) in non-ERAS patients. This study concluded that the adoption of ERAS protocols leads to decreased morbidity and improved outcomes postoperatively.

Ford et al. (2014) (13) in their prospective cohort study implemented and inspected the effectiveness of an enhanced recovery program after esophagus-gastrectomy It included 80 patients which were studied in the pre-ERAS group, 75 patients were enrolled in the ERAS program and 41 in the non-ERAS group over 21 months. A significant reduction in postoperative length of stay was recorded with the introduction of the ERAS programs. No significant increase or decrease in postoperative complications was recorded in the ERAS group compared to the pre-ERAS era or non-ERAS patients. No significant differences in 30-day re-admission rates were noted between the group.

Ni et al. (2015) (6) evaluated the efficacy of ERAS program over traditional care by performing a metanalysis of 5 RCT's containing 723 patients undergoing hepatectomy.354 patients were included in the ERAS group while 369 received traditional treatment. ERAS program has decreased overall complications (RR=0.66; 95%CI: 0.94-0.88; P=0.005), grade I complications, hospital length of stay and decreased time to first flatulence. This review hence proved, the speedy recovery of patients with reduced incidence of postoperative complications in ERAS group.

Dumlu et al. (2015) (14) in a prospective and controlled clinical study determined the efficacy of local bupivacaine for postoperative pain management in thyroidectomized patients. 30 patients in each group were included undergoing thyroidectomy Group 1 (control group) treated with standard thyroidectomy surgery without additional intervention. In group 2 (paratracheal infiltration with bupivacaine): following

thyroidectomy, 0.25% bupivacaine was applied to the surgical area and in group 3 (subcutaneous infiltration with bupivacaine): following thyroidectomy, 0.25% bupivacaine was injected into the cutaneous, subcutaneous region and fascia of the surgical area. Postoperative pain was evaluated by a visual analog scale (VAS) at 1st, 4th, and 12th hours after thyroidectomy. VAS score of patients in the paratracheal infiltration with bupivacaine was significantly lower than control group patients at 1, 4, and 12 hours following the thyroidectomy operation suggesting intra-operative local bupivacaine effective in post-operative pain control.

Shridharani et al. (2015) (15) analyzed the requirement of postoperative antibiotic mandible fractures. 32 patients with compound mandibular fractures receiving either oral or parenteral prophylaxis with variable types of antibiotics were included and the postoperative complication rate was noted which was found to be 6% compared to 53% in 30 patients who received no antibiotics. In patients with compound mandibular fractures- 40 cases treated without antibiotics had a 20% complication rate compared to patients with less than 48 hours of antibiotics (5%) and those with greater than 48 hours of antibiotics (10%). Short-term (less than 48 hours) use of antibiotics significantly decreased the infection rate; however, longer-term (more than 48 hours) did not decrease the rate of infection. Evidence supported the use of short-course postoperative antibiotics for < 24 hours in patients undergoing open or closed reduction of mandible fractures

Coyle et al. (2016) (9) formulated the ERAS program for head and neck surgery (free flap reconstruction for head and neck cancer) patients and patient compliance was studied over 12 months. Key elements of ERAS included a daily patient diary, nutritional optimization, avoiding tracheostomy, when possible, goal-directed fluid therapy intra-operatively and a specific head and neck postoperative pain management protocol. Overall compliance was high. Only 75% took pre-operative carbohydrate drinks, 10% had individualized goal-directed fluid therapy, and 7% were mobilized in the first 24 hours after surgery. The mean length of hospital stay was reduced to 14.55 days.

Stuckiet et al. (2017) conducted a pilot ERAS study in the case of complete oral rehabilitation utilizing 4–6 dental implants in the maxilla and mandible with concomitant osteoplasty and placement of a fixed full arch restoration. Standardized

protocols included- pre-operative patient and family counselling, optimization of nutrition, pre-operative anxiolytic, multimodal pain therapy focused on narcotic reduction, and use of slow-release local analgesia. Patient acceptance was found to be nearly 100%, with improved outcomes and a smoother postoperative course.

VX Liu et al. (2017) (16) evaluated the outcomes of enhanced recovery after surgery (ERAS) across 20 hospitals in Northern California targeting 2 populations: 3768 patients undergoing elective colorectal resection and 5002 patients undergoing emergency hip fracture repair and comparing results. These were compared with 5556 patients undergoing elective gastrointestinal surgery and 1523 patients undergoing emergency orthopaedic surgery. Results stated that among patients undergoing colorectal resection, ERAS decreased the rate of hospital mortality (0.17; 95% CI, 0.03-0.86: P=.03) whereas hip fracture was associated with increased rates of home discharge (1.24, 95% CI, 1.06- -1.44; P=.007).

Nikodemski et al. (2017) (17) did a retrospective study on the implementation of ERAS protocols in patients undergoing major gynaecology surgery. It consisted of two sets of 100 consecutive medical records: patients treated before (pre-ERAS) and after (ERAS) adhering to protocols, and following results were seen: Laparoscopic surgery was used in 44% and spinal anesthesia was given for open surgery in 43 study patients. The use of drains was reduced by 23%, bowel preparation was reduced by 15%. Intravenous fluid administration was reduced by 22%. The use of postoperative morphine was minimized to 12 patients. Postoperative nausea was managed with the regular use of anti-emetics. Anti-coagulation was given to 80% of the study group. Difficulties in the introduction of the ERAS protocol were due to refusal by some patients to mobilize and eat early postoperatively. Patients in the ERAS program group were discharged earlier as compared to standard care treatment.

C. Dort (2017) (18) **et al.** performed a systematic review of 215 articles and meta-analysis on perioperative care for head and neck surgery with free flap reconstruction for enhanced recovery. Key elements included perioperative carbohydrate treatment, pharmacologic thromboprophylaxis, perioperative antibiotics, corticosteroid and antibiotic prophylaxis, anxiolytics, goal-directed fluid therapy, opioid spring multimodal analgesia, frequent flap monitoring and avoidance of pre-operative

fasting. Evidence as per this study proved vital role of perioperative guidelines in head and neck surgical procedures for improved recovery state postoperatively.

Pisarska et al. (2017) (19) This systematic review aimed to evaluate current literature on ERAS in esophageal cancer surgery and conduct a meta-analysis on primary and secondary outcomes.13 articles with a total of 2,042 patients were included in the analysis (1,058 ERAS group and 984 treated with traditional protocols) Implementation of ERAS in esophageal surgery indicated reduction of non-surgical complications with negative influence on overall morbidity. Moreover, a reduction in the length of hospital stay was found. But currently, further research with high-quality RCTs is required to fully assess the feasibility of modern perioperative care protocols in esophageal surgery.

Sekar K et al. (2017) (20) compared arch bar, transmucosal screws and eyelets and evaluated the plaque accumulation index as a primary outcome and mucosal damage as the secondary outcome. Arch bar was found to be associated with high plaque accumulation and mucosal damage while placement and removal and therefore more discomfort to the patient. Furthermore, compared with arch bars eyelets had nil injury to the gingival margin and gingival health was easier to maintain. Transmucosal screws were identified as a better method in comparison to arch bar and eyelets when comparing the plaque index.

L.J Rogers et al. (2018) (21) studied compliance with ERAS and its impact on morbidity in resection for primary lung cancer. Data were collected on consecutive patients undergoing lung resection for primary lung cancer between April 2012 and June 2014 at a regional referral centre in the United Kingdom. All patients followed a standardized, 15-element Enhanced Recovery after Surgery protocol. A total of 422 consecutive patients underwent lung resection over 2 years, of whom 302 (71.6%) underwent video-assisted thoracoscopic surgery. Lobectomy was performed in 297 patients (70.4%). Complications were experienced by 159 patients (37.6%). The median length of stay was 5 days (range, 1-67), and 6 patients (1.4%) died within 30 days of surgery. In this study, an inverse relationship between protocol compliance and morbidity was found after adjustment for confounding factors.

Xu et al. (2018) (22) performed randomized control trials to compare the effects of goal-directed fluid therapy [GDFT] versus conventional fluid therapy in colorectal

surgery patients to study the postoperative outcomes of ERAS. This review involved including a total of 1281 patients in which 624 patients received goal-directed fluid group and 657 as control. The GDFT showed lower complication rates (RR=0.84,0.17-0.99, P=0.04), and time to flatus and time to tolerate an oral diet was shorter in GDFT. This study concluded improvement in gastrointestinal function with GDFT over conventional fluid therapy.

T. Imai (2018) (23) evaluated the effect of ERAS protocol with pre-operative dexamethasone administration in major surgery for head and neck cancer patients. A retrospective study including 28 patients was done with free tissue transfer reconstruction cases. Outcomes were compared to previously treated cases of control. Study analysis revealed less body weight fluctuation, lower CRP, high albumin levels, and lower body temperature in the ERAS group. The study highlighted evidence of better hemodynamic stability and less inflammatory response in patients treated with ERAS guidelines.

Bergstrom et al. (2018) (24) studied the impact of ERAS program on patient outcomes, quality and safety measures while implemented on the gynaecology oncology service centre. A retrospective review of 109 patients undergoing elective laparotomy was done in 2016. Patient demographics, surgical variables, postoperative outcomes, and antimicrobial and venous thromboembolism prophylaxis, were compared. The review concluded ERAS patients required fewer narcotics and oral morphine. Compliance with antimicrobial prophylaxis was 97.2%. No difference was found in the length of stay, complication rates and readmission rates. This study revealed that adherence to ERAS protocols can lead to improved results.

Bailey et al. (2018) (25) in their study regarding the question on end for throat packs inserted by anaesthetists mention that as per Athanassoglou et al. throat pack is rarely necessary and agree that throat pack insertion occurs too often, with little or no evidence for their benefit. The most common reason for insertion is to prevent shed blood from entering the stomach and causing postoperative nausea and vomiting. Yet studies have found no difference in the incidence of nausea and vomiting whether or not a throat pack is used. Studies conclude that the presence of a throat pack results in an increase in the postoperative sore throat during the recovery period and this is probably related to the coarse material used for the insertion technique. Another study

included in it compared dry throat packs with wet throat packs and found no differences between the two in terms of postoperative sore throat, nausea or vomiting.

Yi et al. (2018) (26) in their study randomized control trial determined whether active intra-operative warming reduced bleeding in patients undergoing major operations such as open thoracic surgery and hip replacement surgery. The study was a pilot, prospective, parallel two-arm randomized controlled trial. Eligible patients were randomly allocated to two groups including - passive warming (PW), with the application of a cotton blanket (thermal insulation), or active warming (AW), with a forced-air warming system. The primary outcome measured was intra-operative blood loss, and secondary endpoints were surgical-site infection, cardiovascular events, and length of stay in the post-anesthesia care unit, intensive care unit, and hospital. Sixty-two patients were enrolled. Results revealed that forced-air active warming maintained intra-operative normothermia in all AW subjects, whereas intra-operative hypothermia occurred in 21/32 (71.8%) of PW patients ($p = 0.000$). Hence, in conclusion, combined volume of intra-operative blood loss for the two operations (hip replacement and thoracic surgery) was significantly less in the AW group than in the PW group.

Rastogi et al. (2018) (27) compared the embrasure wiring technique versus arch bar for maxillomandibular fixation in mandibular fractures including total of 40 patients. Anatomic locations selected in both the groups (A and B) were isolated parasymphysis fracture (25–35%), whereas combination fractures (angle and parasymphysis) 15 to 25% in both groups. Furthermore, the pre-operative occlusion was deranged in all the patients in both groups. The comparison of time required for MMF in group A with embrasure wiring was 7.85 ± 0.81 minutes as compared with 45.05 ± 5.96 minutes in arch bar group which was proved to be highly statistically significant. In the group treated with arch bar, a high incidence of wire injury during MMF was reported. Similarly, the presence of postoperative infection was noted in three cases in arch bar group (15%) in contrast to one case in group A (5%) perhaps attributed to the traumatic placement of the arch bar and poor oral hygiene). Also, a statistical comparison of the postoperative complications in respect of hardware failure and malocclusion in both the groups (A and B) was found to be nonsignificant ($p > 0.05$), suggesting both provided adequate stability of the fractured segments.

Also, as the arch bar placement intra-operatively increased the cost of anesthesia, the embrasure wiring technique was considered to be a better option.

D.B Jandlai (2019) (28) performed a retrospective cohort study for the implementation of ERAS protocols at a tertiary care centre specific for head and neck surgery. This study included 185 cases including 92 ERAS patients and 93 controls. It aimed at the evaluation of narcotic usage and length of stay. The mean morphine equivalent dose (MED) administered within 72 hrs. postoperatively was low In the ERAS group. Average postoperative pain scores were also found to be lower in ERAS group. Length of stay was shortened for ERAS patients, however, no difference in ICU length stay was seen. This evidence concluded that implementing ERAS protocols decreased the use of narcotics and improved postoperative analgesia.

S. Ali et al. (2019) (8) conducted a study on the development of ERAS protocols for spinal and peripheral nerve surgery patients consisting of 201 patients undergoing surgical care via an ERAS protocol and compared to a total of 74 patients undergoing traditional perioperative care (control group). In the ERAS group, Intravenous opioid medications postoperatively via patient-controlled analgesia was nearly eliminated (0.5% vs 54.1%, $p < 0.001$). The ERAS group demonstrated greater mobilization on postoperative day 0 (53.4% vs 17.1%, $p < 0.001$) and postoperative day 1 (84.1% vs 45.7%, $p < 0.001$) compared to the control group. Postoperative Foley use was decreased in the ERAS group (20.4% vs 47.3%, $p < 0.001$) without an increase in the rate of straight catheterization.

Miller et al. (2019) gave guidelines based on a meta-analysis of randomized trials which reported a lower risk of aspiration (gastric volume less than 25mL and pH greater than 2.5) when clear liquids are given 2 to 4 hours before a procedure compared with fasting overnight. The theory was thought to be that as we continually produce saliva along with endogenous gastric secretions, therefore, after an 8-hours "fast," roughly 500 to 1,250mL of fluid is added naturally to the stomach. This acidic fluid is diluted by whatever we drink. In other words, allowing unrestricted access to clear fluids up to 2 hours before surgery is likely to improve patient comfort and safety as it reduces thirst and hunger, does not increase gastric volumes, and reduces the acidity of gastric contents. Some pre-operative fasting guidelines have changed the wording from "Allow" to "encourage" clear fluids up to 2 hours before surgery

this appears to be safe. Examples of clear liquids include -water, fruit juices without pulp, carbonated beverages, carbohydrate-rich nutritional drinks, and clear tea. Many Enhanced Recovery After Surgery pathways also includes the oral intake of a maltodextrin carbohydrate drink 2 hours before surgery, which has a probable metabolic benefit of reducing insulin resistance in addition to improving patient satisfaction and reducing thirst, hunger, and postoperative nausea and vomiting. Brandstrup et al. showed that the liberal use of IV fluid in abdominal surgery was associated with a significant increase in complications compared with a restrictive approach. Regarding fluid management, however, the amount of fluid given with restrictive fluid management has gradually decreased, and the term "zero balance" is introduced to describe a restrictive regimen aiming to avoid postoperative fluid retention. In many patients recovering from major surgery, the transition from IV to oral fluids can occur within 24 hours. Early transition to oral intake can help preserve gastrointestinal motility, thus limiting ongoing fluid loss into the bowel.

C Zhu et al. (2019) (29) focused specifically on fluid management as part of ERAS in the study. It identified perioperative fluid management as an independent predictor for improved clinical outcome, finding that each additional litre of intravenous (IV) fluid given on the day of surgery lead to a 16% increased risk of postoperative symptoms delaying recovery, and a 32% increase in the risk of postoperative complications. A joint consensus statement was released between the American Society for Enhanced Recovery and Perioperative Quality Initiative to create a framework for perioperative fluid management within ERAS for colorectal surgery. A Cochrane review concluded that compared with a standard fast (nil per oral [NPO] after midnight), a shortened fluid fast which in some included studies involved fluid intake up until 90 minutes before surgery did not result in an increased risk of aspiration or increased morbidity as compared with the previous standard NPO recommendations. Insulin resistance was another factor found which could lead to postoperative hyperglycemia which has been associated with a 30% increase in the risk of a postsurgical infection. Patients in the ERAS group received 875 mL of carbohydrate-rich (157 g) fluid until 2 hours before the surgery, while patients in the conventional group began fasting at midnight and did not receive any carbohydrate-rich fluid. While no difference was found overall between the ERAS and conventional groups.

Altman et al. (2019) (30) performed randomized controlled trials for evaluating early postoperative feeding in gynecologic oncology surgery, including surgery involving bowel resection. Most studies defined this concept as intake of food within 24 hours of surgery and used a protocol of clear fluids immediately after surgery, with timely shifting to a standard diet as tolerated. Many protocols included actively mobilizing the patient within 24 hours of surgery, and most suggested mobilizing for a minimum of 2 hours on the day of surgery, followed by 6 hours on all subsequent hospital days. Early mobilization required increased support from nursing, health care aids, and physiotherapy. Many ERAS protocols now routinely advocate for a narcotic-sparing approach with regularly scheduled doses of NSAIDs and acetaminophen, which has been shown in audits of gynecologic ERAS protocol implementation to decrease opioid consumption and associated adverse effects.

Simpson et al. (2019) (31) -Pain Management in Enhanced Recovery after Surgery (ERAS) Protocols. The study mentions that use of opioid medication for pain management has significant side effects including ileus, respiratory depression, and nausea and vomiting. However, lidocaine, celecoxib, magnesium, and epidural analgesia showed to decrease opioid consumption and decrease the risk of postoperative ileus formation. Postoperative ileus contributes significantly to both cost and LOS in patients undergoing colorectal surgery. One of the most feared complications of narcotic use is opioid-induced respiratory depression. A 2012 meta-analysis by Apfel et al. identified opioid use as one of the four major anesthesia-related factors contributing to PONV. PONV further contributes to prolonged LOS in the postanaesthetic care unit (PACU); in addition, patients often rate PONV as worse than postoperative pain. Vomiting has been associated with aspiration, wound dehiscence, esophageal rupture, and pneumothorax. A 2013 meta-analysis by Apfel et al. showed a decrease in PONV with the use of IV acetaminophen. Cochrane review from 2015 examining 45 trials with 2,502 subjects found that lidocaine infusions significantly reduced postoperative pain in the first 24 hours postoperatively.

Delaplain et al. (2019) (32) This review analyzed the effect of post-operative antibiotics on surgical site infections. 27 studies were included in the meta-analysis. Study found no statistically significant difference among the alone perioperative antibiotic group and with extended antibiotic prophylaxis group in cases of midface fractures. Among the 439 patients, only seven (1.6%) developed a postoperative

surgical site infection. Among orbital fractures, six studies contributed to the incidence of post-operative SSIs in patients with orbital fractures, similar to the patients with midface fractures, the incidence of SSI was low (1.77%) with no significant difference. For mandible fracture cases overall analysis showed no significant association between post-operative surgical site infection rate when any of the antibiotic regimens were examined. Specifically, no significant association was found when a comparison was made between peri-operative and postoperative groups. Study favoured use of post-operative antibiotics limited to 24 hours or less

Habib et al. (2019) (33) in their meta-analysis included 13 studies that evaluated the incidence of SSI (surgical site infections) in cases treated with antibiotics. None of the studies found a significant benefit of postoperative antibiotic prophylaxis in reducing infection rates. Majority suggested that for low-risk facial fracture patients, antibiotic prophylaxis may not be necessary. Results concluded that additional postoperative prophylactic antibiotic therapy in maxillofacial fractures does not reduce the risk of developing SSI's. No significant difference in the risk of SSI between postoperative and peri- or pre-operative antibiotic prophylaxis was found.

Kubitz et al. (2020) (34) implemented ERAS protocols at university heart centre Hamburg, Germany and evaluation of outcomes, which included data collection from 50 patients undergoing minimally invasive valve surgery. The study aimed at key features including physiotherapeutic rehabilitation, minimally invasive surgery, modified cardiopulmonary bypass management, fast-track anesthesia with on-table extubation and early mobilization. The adherence to this protocol was high and no protocol-related complications or in-hospital mortality occurred. The study revealed that protocol is feasible and safe in minimally invasive surgery to improve patient outcomes.

Hajibandeh et al. (2020) (35) performed a meta-analysis and evaluated enhanced recovery after surgery (ERAS) protocols in emergency abdominal surgery. The study included 1334 patients from six comparative studies which revealed that ERAS protocols resulted in favourable outcomes in emergency settings such as by reducing post-operative complications, accelerated recovery of bowel function, and shorter length of hospital stay without increasing the need for readmission or re-operation. But complete pre-operative counselling, which is known to reduce post-operative

stress, pain and anxiety was not found to be possible in the emergency setting. However, details of the procedure, possible perioperative complications, need for creation of stoma and length of hospitalization were explained. Hence, it concludes that although ERAS protocols are commonly used in elective settings, they are associated with favourable outcomes in emergency settings.

Zhang et al. (2020) (36) performed a meta-analysis to evaluate the efficacy and safety of ERAS vs. conventional recovery after surgery (CRAS) on perioperative outcomes of radical cystectomy. Criteria evaluated were -length of hospital time, first timing of regular diet, complications, readmission, ileus, wound infection, mortality and time to first bowel movement. Compared with CRAS it was found that ERAS protocols promote postoperative recovery via faster peristalsis, early resumption of oral intake, and reduction or stoppage of the application of nasogastric tube, reduced length of hospital and readmission, faster return of bowel function, shorter length of hospital stay, and fewer complications. Also additionally, ERAS protocols did not increase the risk of adverse events, when compared with CRAS protocols.

Chen et al. (2020) (37) performed an experimental study to study the effect of enhanced recovery after surgery protocol on patients who underwent off-pump coronary artery bypass grafts. This study included 94 participants including the traditional care group- 47 versus ERAS group- 47. ERAS group patients had a better-improved understanding of CAD, with a significant difference. Meanwhile, the ERAS group had a shorter fasting time and water deprivation time than the traditional group. However, no significant difference in the extubation time of the tracheal tube. LOS-ICU was reduced in the ERAS group compared with that in the traditional group, but no significant difference was observed. Moreover, expenses in ICU were reduced in the ERAS group, but no significant difference was noted. Also, improvement was found in 6-Minute Walk Test on postoperative day 7 suggesting effectiveness of ERAS protocol for patients undergoing OPCABG surgery.

Zhao et al. (2020) (38) studied the efficacy of ERAS protocol and its safety in robot-assisted laparoscopic prostatectomy/laparoscopic radical prostatectomy (RALP/LRP). 7 studies were included in this meta-analysis ERAS program was found to significantly reduce the length of hospital stay and the time to ambulate, defecate, and

flatus in patients undergoing the RALP/LRP, which could be recognized as great clinically efficacy and safety.

Pennington et al. (2020) (39) conducted a quantitative meta-analysis for the evaluation of the ERAS protocol and its benefits in patients undergoing lumbar spine surgery. Parameters such as length of stay complication rate, wound infection rate, 30-day readmission rate, and 30-day reoperation rate were noted. 20 studies were included in the quantitative analysis. The most frequently cited benefits of ERAS protocols were shorter length of hospital stay, lower postoperative pain scores, and decreased complication rates. The meta-analysis demonstrated shorter length of stay for the general spine surgery (mean difference −1.22 days [95% CI −1.98 to −0.47]) and lumbar spine ERAS protocols (−1.53 days [95% CI −2.89 to −0.16]). Neither general nor lumbar spine protocols led to a significant difference in complication rates. Hence concluded that ERAS protocol implementation reduced hospitalization time among adult spine surgery patients and may lead to reductions in complication rates.

Anderson et al. (2020) (40) in their study determined whether throat packs are of benefit to patients undergoing upper airway surgical procedures or not. It included 13 papers. The majority of papers included patients undergoing nasal and paranasal sinus surgery and two included patients having dental extractions. Among the studies included by Basha et al. it showed a significant increase in PONV in patients with throat packs during the recovery period. Meta-analysis of studies reporting incidence of postoperative pain showed significantly lower incidence of pain at 6 hours in patients who did not have a throat pack placed. In conclusion, the review provides no evidence in support of a clinical benefit from throat packs and finds evidence of increased throat pain when they are used. Also, it mentions no clear indication of their routine use in ENT, maxillofacial and dental procedures.

Kim et al. (2022) (41) compared the intermaxillary fixation methods with the use of IMF screws versus arch bars for mandible fractures. A retrospective analysis was done including 57 patients from August 2014 till February 2021. The most common fracture site was the angle (30%), followed by the parasymphysis (25%), the body (23%), the condyle (11%), and the ramus (11%). Patient discomfort and oral hygiene were measured as primary outcomes. They found that it was challenging to manage

oral hygiene while maintaining IMF using an arch bar. Oral hygiene was inadequate in patients with poor compliance. Regarding patient discomfort, patients experienced pain due to gingival or mucosal injury with sharply cut wires. In addition, the wires irritated the oral mucosa and ulcerated the gingiva.

AIMS AND OBJECTIVES

AIM:

Evaluation of efficacy of Enhanced Recovery after Surgery (ERAS) protocol on Recovery and post-trauma outcomes over Standard Care in patients with Maxillofacial Trauma.

OBJECTIVES:

PRIMARY OBJECTIVES:

- Formulation and implementation of ERAS protocol for Maxillofacial trauma patients.
- Evaluation of immediate post trauma outcomes - evaluation of patient's anxiety, pain control, post-operative complications and length of stay.

SECONDARY OBJECTIVES:

- Evaluation of post-surgery psychological and somatic anxiety.
- Evaluation of Overall patient satisfaction and comfort.
- Evaluation of return-to-work days and cost analysis.
- Evaluation of patient compliance to ERAS protocol.

RESEARCH QUESTION:

Is recovery faster with implementation of Enhanced Recovery after Surgery Protocol (ERAS) in Maxillofacial trauma?

NULL HYPOTHESIS:

Recovery is same with Enhanced Recovery after Surgery Protocol (ERAS) and regular Standard Care in Maxillofacial trauma.

MATERIALS AND METHODS

METHODOLOGY

STUDY DESIGN:

A prospective Randomized controlled study was conducted in the Department of Dentistry in AIIMS, Jodhpur after approval from the Institutional Ethical committee. The Ethics committee approval number is AIIMS/IEC/2021/3359

SAMPLING FRAME:

In this study 123 patients were screened and 74 patients with maxillofacial trauma were recruited from March 2021 to August 2022.

INCLUSION CRITERIA:

1. Patients with maxillofacial trauma including isolated midface, mandible or panfacial fractures.
2. Patients with ASA I and II categories in the age group between 18-65 years, of either sex
3. Patients who have given written consent for participation
4. Absence of pre-existing maxillofacial pathology

EXCLUSION CRITERIA:

1. Patients in age range greater than 18 and less than 65 years.
2. Patients with systemic conditions such as uncontrolled diabetes mellitus, hypertension, cardiorespiratory conditions, previous history of cerebrovascular accidents, myocardial infarction, and coronary artery disease.
3. Patients with physical assault cases.
4. Patients who are intubated/tracheostomized
5. Patients with concomitant head injuries, orthopaedic trauma, cervical spine injuries , debilitating thoracic or abdominal trauma
6. Patients with psychiatric illness

In this study, maxillofacial trauma patients reporting to Emergency and Trauma Centre of AIIMS Jodhpur were assessed. Patients were examined for pre-existing

medical conditions, past history and detailed physical evaluation of other injuries. After stabilization, patient with trauma confined to the maxillofacial region were advised to participate and enroll in the study based on inclusion and exclusion criteria.

Patient were randomly divided into either of two groups using computer generated codes sealed in opaque envelopes.

1. **Group I (ERAS)**: Patient were treated as per Enhanced Recovery Surgery Protocols (ERAS protocol) for maxillofacial trauma management
2. **Group II (Control):** Patients were given standard care for maxillofacial trauma management

SAMPLE SIZE CALCULATION

$$k = \frac{n_2}{n_1} = 1$$

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2/K)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

$n_1 = (8.82^2 + 4.65^2)\ (1.96 + 0.80)^2 / 1.71^2$

$n_1 = n_2 = 37$

$\Delta = |\mu_2 - \mu_1|$ = absolute difference between two means

σ_1, σ_2 = variance of mean #1 and #2

n_1 = sample size for group #1

n_2 = sample size for group #2

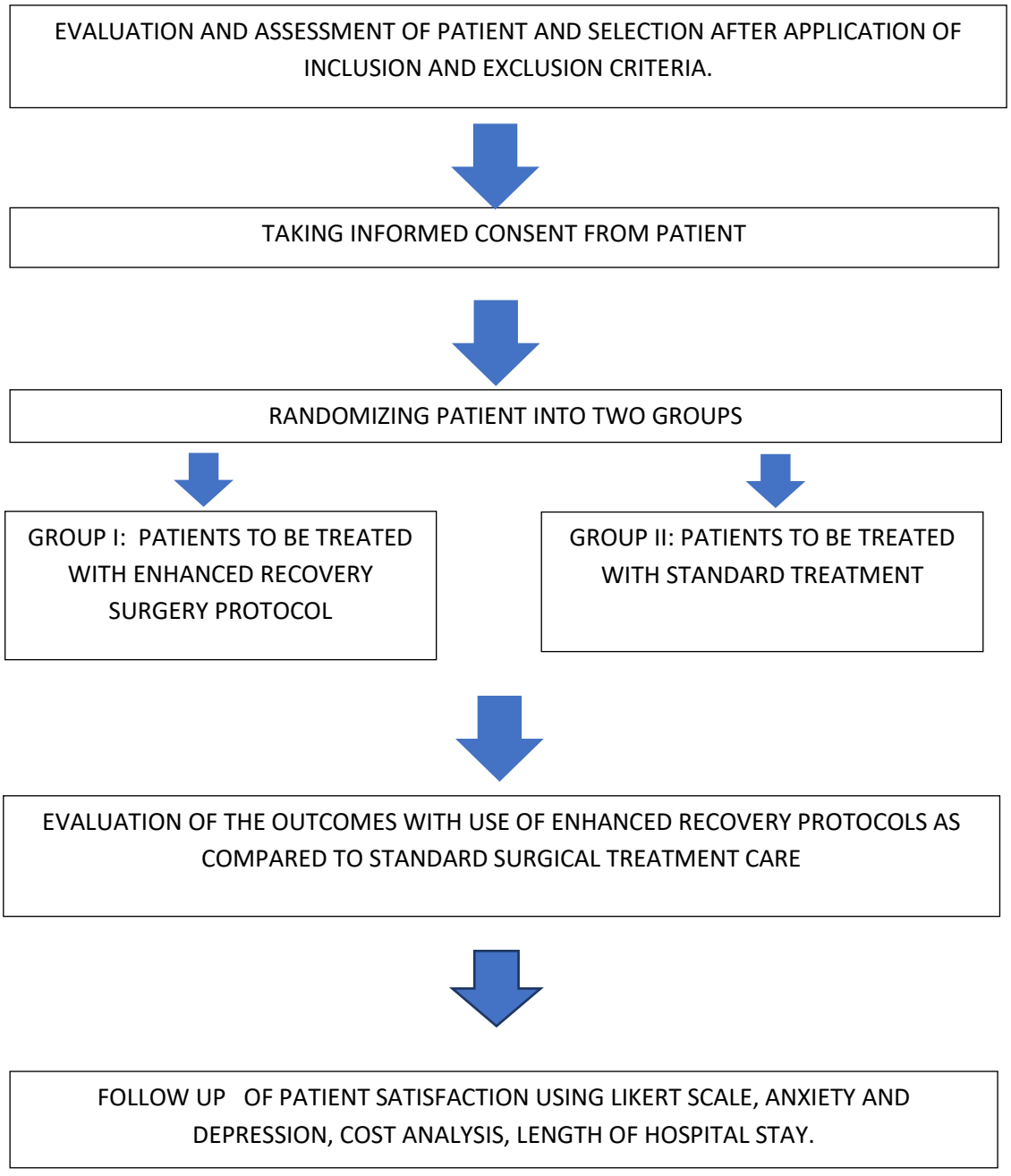
α = probability of type I error (usually 0.05)

β = probability of type II error (usually 0.2)

z = critical Z value for a given α or β

k = ratio of sample size for group #2 to group #1

METHODOLOGY FLOWCHART



After patient stabilization following ABCDE protocol, patients were managed for maxillofacial trauma. ERAS protocol was formulated and following parameters were modified and implemented accordingly.

Evaluation was done in both the groups at following time frames.

T0- Pre-operative evaluation (After patient stabilization and admission to ward)

T1- Presurgical evaluation

T2- Intra-operative evaluation

T3- Post-operative assessment at 24 hours, at 5th day after surgery, after 2 weeks of surgery

ERAS PROTOCOL

PRE-OPERATIVE (T0):

1. Detailed pre-operative patient and caregiver counselling verbally and additionally by a video presentation and handbook supplements was done, explaining the treatment, surgical procedures and alternatives in patient's own language to reduce anxiety after admission. Patient was also educated about surgical procedure, plates and screws, their cost factor, length of stay and complications associated with surgery such as pain, paraesthesia, vision abnormalities, etc.
2. Stabilization of fracture was done using bridle wiring within 2 hours of patient stabilization under local anesthesia with adrenaline 1: 100000 to reduce the mobility and pain of fractured segments.
3. Optimization of medical conditions was done by focusing on early cessation of alcohol, smoking and tobacco before surgery for better prognosis by psychiatric evaluation and reinforcement to help the patient to quit smoking and tobacco use. Daily reinforcement was done for the same and handouts for immediate and delayed consequences of tobacco and smoking were shared with him.
4. No pre-operative I.V fluids were given in the ERAS group unless required.
5. Intravenous antibiotics were continued till 72 hours from the day of admission or surgery in ERAS group.

6. Diet and nutrition counselling was done prior to surgery by referring the patient to a diet counsellor for the need to assess allowance of type of food intake- solid/semisolid/ liquid diet, depending upon the severity of trauma, allowing proper nourishment. Alternatives for solid feeding was advised to the patient's caregiver. Reinforcement of oral feed in possible form was done twice a day and was encouraged to maintain a diet chart.

7. Maintenance of oral hygiene was emphasized by prescribing chlorhexidine mouthwash to reduce the risk of infections in oral cavity and maintaining clean surgical site to ensure better postoperative healing. Periodic reinforcement of oral hygiene by counselling and evaluation (twice a day) was done. Oral prophylaxis was performed pre-operatively in ERAS group.

8. For multimodal Pain management nonsteroidal anti-inflammatory drugs (Inj. Diclofenac 75mg BD was used till 72 hours after admission/ surgery to control pain. After 72 hours intravenous analgesics were converted to oral and Tab.Acelofenac with seratiopeptidase combination was used on SOS basis and number of tablets were calculated. Tramadol was used as a rescue analgesic and number of tablets were calculated.

PRE-SURGICAL (T1):

1. Prolonged period of fasting was avoided by defining time frames – Solid food was allowed up to 6 hours and clear fluids were given till 2 hours prior to surgery (7 am for 1st case and at OT call for subsequent cases.

2. Oral feeds intake was confirmed prior to surgery and was categorized into Adequate or Inadequate. In ERAS group patients were repeatedly motivated for oral feeds.

3. Carbohydrate loading was done using apple juice 400mL as carbohydrate (CHO) supplement drink 2 hours prior for 1st case (7 am for 1st case) and at OT call for subsequent cases followed by evaluating compliance and patient satisfaction.

INTRA-OPERATIVE (T2):

1. Anesthesia drugs that favoured a more awake and oriented state at extubation with minimal complications like post-operative nausea and vomiting were used. Anaesthesiologists were discussed regarding the avoidance of inhalation agents, particularly nitrous oxide.
2. Intravenous Dexamethasone at the rate of 0.25mg/kg was used at the time of induction to control postoperative nausea and vomiting.
3. Intra-operative use of throat packs was avoided in ERAS group.
4. Arch bar/eyelets/direct interdental wiring placement for the purpose of maxillomandibular fixation was performed intra-operatively in ERAS group.
5. Crystalloid fluids were administered by using restrictive fluid strategy at a rate of 2mL/kg/hour compensating for intra-operative fluid losses and considering the discretion of the anaesthesiologists.
6. Normothermia was maintained to prevent hypothermia by using fluid warmers.
7. Vancomycin 1gram in 50 mL normal saline was used for irrigation prior to suturing.
8. 0.5% Bupivacaine was used locally at the site of surgical intervention at the end of surgery before extubation for post-operative pain control.

POSTOPERATIVE (T3):

1. Early shifting of patients back to the ward after extubation preferably within 2 hours was done.
2. Early return to oral feeds was encouraged and intravenous fluid administration was minimized. Rate of fluids were decreased to 1mL/kg/hour and shifted to oral fluids within 2 hours after complete recovery from anesthesia, provided no nausea and vomiting was seen. If the patients were unable to start oral feed, only then intravenous fluids were given as per the anaesthesiologist's discretion as standard care till start of oral feeds.

3. No postoperative antibiotics were given in ERAS group unless required. Any antibiotic upgrade needed was noted.

4. Intravenous and urinary catheters were removed early within 24 hours of surgery to avoid chances of urinary tract infections and early return of the bladder to normal function.

5. Rescue tablets of antiemetics consumed in ERAS group were noted.

6. For Post-operative pain control NSAIDS (Acelofenac plus paracetamol with Seratiopeptidase) in ERAS group till 5 days was given. Opioid analgesics like Tramadol 50mg were prescribed as rescue tablets and calculated.

7. Patients were encouraged for early ambulation preferably within few hours/ same day after surgery.

8. Throat pain or discomfort was evaluated and noted in both groups and categorized into mild, moderate and severe.

9. Patient compliance for the start of oral feeds was noted for both groups which included timelines: within 12 hours, 12-24 hours or > 24 hours after surgery.

10. Post-operative swelling and complications were noted and categorized into mild, moderate and severe.

11. Infection at the surgical site was evaluated and need for an antibiotic upgrade was noted.

12. In ERAS group patients were discharged within 24-48 hours after surgery.

13. Arch bars /eyelets were removed at discharge/5th day unless needed for post-operative occlusion settling.

14. At a period of 2 weeks after surgery, overall satisfaction rate was measured and compliance of counselling for quitting of habit and oral hygiene maintenance was done.

15. Total cost analysis for the management of maxillofacial trauma including hospital stay was calculated and timeline for the patient's ability to return to normal life was also noted.

COMPARISON OF STANDARD AND ERAS PROTOCOLS

AFTER PATIENT STABILIZATION (T0)		
	STANDARD TREATMENT	**ERAS PROTOCOL**
Admission Information, Education and Counselling	Verbal explanation of the treatment options, procedure, complications, costing, dietary modifications and oral hygiene instructions. Followed by written informed consent	Standard treatment + Color printed handout supplements along with video presentation and sharing of video was done for better patient understanding
Antibiotics	Intravenous injection - Cefoparazone plus sulbactam 1.5gm along with Inj. metronidazole 500mg I.V TDS till day of surgery.	Intravenous antibiotics given till 72 hours from day of admission/ surgery which ever earlier.
Optimization of medical comorbidities	Patient assessed and optimized for associated medical comorbidities including diabetes, hypertension, bleeding disorders, asthma and assessment and correction of anaemia	Same as Standard treatment
Tobacco, smoking and alcohol cessation	Counselling the patient methods for tobacco and smoking cessation verbally and educating patient on effects of tobacco, smoking on healing post-operatively	Standard treatment + psychologist counselling along with Handouts supplements and daily reinforcement.
Stabilization of fractures by bridle wiring	No fixed timeline for reduction of fractured segments.	Fracture reduction within 2 hours of patient stabilization.
Diet and nutrition counselling	Nutrition and diet counselling verbally focusing upon type of allowed diet (liquid/semisolid) depending on the severity of trauma.	Standard treatment +Dietician reference along with diet diary. Twice reinforcement per day. Emphasis made on oral feed.
I.V fluids	Infusion of conventional fluids N.S/DNS/at rate of 1mL/kg/hr	No pre-operative Intravenous fluids given in ERAS group unless needed.
Oral hygiene	Debris score is calculated and chlorhexidine mouthwash is	Standard treatment + Oral prophylaxis done+

	prescribed, explaining on need for better oral hygiene	maintaining oral hygiene diary with reinforcement twice per day followed by evaluation.
Pain control	Injection Diclofenac 75mg I.V aq BD. was given till surgery. Additional Diclofenac injections were given along with ongoing analgesics if required for pain control after arch bar placement and calculated. Tab. Tramadol 50 mg SOS given as rescue tablets. Number of rescue tablets were calculated	Injection Diclofenac 75mg I.V aq BD. was given till 72 hours after admission/surgery. After 72 hours oral analgesics (Acelofenac and paracetamol with seratiopeptidase combination) were provided on SOS basis and I.V analgesics were stopped. Tab. Tramadol 50mg SOS was given as rescue analgesic and calculated.
PRE SURGICAL EVALUATION (T1)		
Anxiety Reduction protocol	Supplementation of single dose of Tab. Alprazolam 0.5 mg HS before surgery	Same as standard treatment
Pre-operative fasting with defined timelines	Patient was kept on NPO from midnight and clear fluids allowed till 2 hours prior surgery	Standard with defined timelines. Solid intake 6 hours prior and 2 hours prior (at 7 am) for clear fluids for 1st case and clear fluid till OT call for consecutive cases were ensured.
Carbohydrate loading	No carbohydrate loading is done as per conventional protocol	Carbohydrate loading by supplementation with 12.5 % maltodextrin /grape juice/apple juice(400mL) at 2 hours prior (at 7 am) for 1st case and at OT call for subsequent cases.
Restrictive I.V fluid therapy	Infusing with conventional fluids NS/RL/DNS.	No pre-operative fluid given in ERAS group unless required. Emphasis on oral intake made

INTRA-OPERATIVE MANAGEMENT (T2)		
	STANDARD TREATMENT	**ERAS PROTOCOL**
Control of Post-operative Nausea Vomiting	Injecting Single dose of inj. Dexamethasone, I.V 0.1mg/kg after induction	Same as standard protocol
I.V fluids	Infusing with conventional fluids NS/RL/DNS as per anesthesiologist discretion	Discussion done with anesthesiologist regarding implementation of restrictive fluid therapy. Infusion at rate of 2mL/kg/hour, compensating losses and I.V bolus given if required. Balanced Crystalloid solution used.
Temperature regulation	Regular measures for maintaining Intra-operative body temperature	Discussion with anesthesiologist for Maintenance of normothermia with warmers and warm I.V fluids
Throat pack	Throat pack used intra-operatively	Throat pack was not used
Arch Bar placement	Done pre-operatively under LA	Done intraoperatively under GA to reduce patient discomfort
Local antibiotic	Irrigating wound with Normal Saline and betadine locally prior closure	Injection Vancomycin 1 gm in 50 mL saline locally irrigated prior to suturing.
Local anesthetic administration	No local anesthesia injected at surgical site	Injecting 0.5% bupivacaine at site of surgical intervention at end of surgery

POST-OPERATIVE MANAGEMENT (T3)		
	STANDARD TREATMENT	**ERAS PROTOCOL**
Shifting of patient to ward after extubation	Patient shifted to ward within 4 hours of surgery	Early shift of patient to ward within 2 hours
Fluids optimization	No strict guidelines as per regular post-operative care.	Intravenous fluids given at rate of 1mL/kg/hour and encouraging early shift to oral feeds within 2 hours of complete recovery of anesthesia. Balanced Crystalloid solution was used
Antibiotics	Intravenous infusion of inj. Cefoparazone plus sulbactam 1.5 gm I.V BD+ Inj. Metronidazole 500mg I.V till discharge followed by oral antibiotics for 5 days Need for antibiotic upgrade noted.	No post-operative antibiotics given in ERAS group unless required. Any antibiotic upgrade was noted.
Post-operative analgesics	Injection Diclofenac + inj. Paracetamol 75mg BD till discharge. Tab Diclofenac plus paracetamol TDS prescribed post discharge till total 5 days of surgery. (Tab tramadol 50mg) as rescue given both pre and post discharge. Number of rescue analgesic tablets were calculated.	Tab Acelofenac plus paracetamol + Seratiopeptidase BD till 5 days after surgery. Number of rescue analgesic tablets (Tab tramadol 50mg) consumed were calculated.
Start of oral feeds	In standard intravenous fluids were infused NS/DNS/RL till 12-24 hours of surgery then patient was shifted to oral feeds	Patient shifted to clear oral feeds 2 hours after complete recovery from anesthesia if no episode of nausea/vomiting. Intravenous fluids were stopped as oral feeds were

		started. Fluids were given orally beyond 2 hours post-surgery orally if needed.
Early removal intravenous and urinary catheter	No timeline for early removal of catheter and intravenous lines.	Done within 24 hours
Anti-emetics	Injection Ondansetron 0.1mg/kg I.V SOS	Same as standard treatment
Post-operative steroid	Inj. Dexamethasone 8mg I.V T.D. S then dose tapered gradually over 2- 3 days	Post-operative steroids not used in ERAS group
Early arch bar removal	Standard 2-4 weeks	Arch bar removed at time of discharge/5th day unless needed for post op occlusion settling.
Discharge	No specific timeline for discharge.	Early discharge within 24 – 48 hours

PARAMETERS ASSESSED

Following parameters were assessed:

ASSESSMENT PRIOR TO SURGERY

1. Pain using VAS scale- Average of VAS scale from Day 0 to Day of surgery
2. Number of analgesics and rescues analgesic consumed daily
3. HAD scale (Hospital anxiety and Depression Scale)
4. Pre-operative I.V fluids used- Total I.V fluids from Day 0 to Day of surgery
5. Assessment of oral intake:

Timeline	Score
Within 6 hours	0
6-12 hours	1
12-24 hours	2
> 24 hours	3

6. Oral hygiene maintenance by OHIS debris score

OHIS index	Index	Score
Good	0-0.7	0
Fair	0.7-1.8	1
Poor	1.9-3.0	2

7. Patient compliance 2 hours before surgery
   - For clear fluids before 2 hours - mentioning Yes/ No
   - For carbohydrate loading – Yes / No
8. Patient satisfaction using Likert scale
   - **ASSESSMENT AFTER 24 HOURS OF SURGERY**:
   1. Pain by VAS scale
   2. Number of analgesics and rescues analgesic consumed daily
   3. Evaluation of number of post-operative nausea vomiting and episodes

4. Evaluation of patient compliance post-surgery

Timeline	Score
Within 6 hours	0
6-12 hours	1
12-24 hours	2
> 24 hours	3

5. Post-operative Total I.V fluid consumption in total 24 hrs.
6. Evaluation of Throat pain and discomfort

Criteria	Score
Mild	0
Moderate	1
Severe	2

7. Post-operative Swelling

Criteria	Score
Mild	0
Moderate	1
Severe	2

- **ASSESSMENT AT POST-OPERATIVE DAY 5**

1. Oedema evaluation. Categorizing into:

Criteria	Score
Mild	0
Moderate	1
Severe	2

2. Infection at operated site/ antibiotic coverage-Yes/No

- **ASSESSMENT AT 2 WEEKS AFTER SURGERY**

1. Patient overall satisfaction by using Likert scale
2. Compliance in quitting tobacco- Yes/No

3. Return to normal life after discharge:

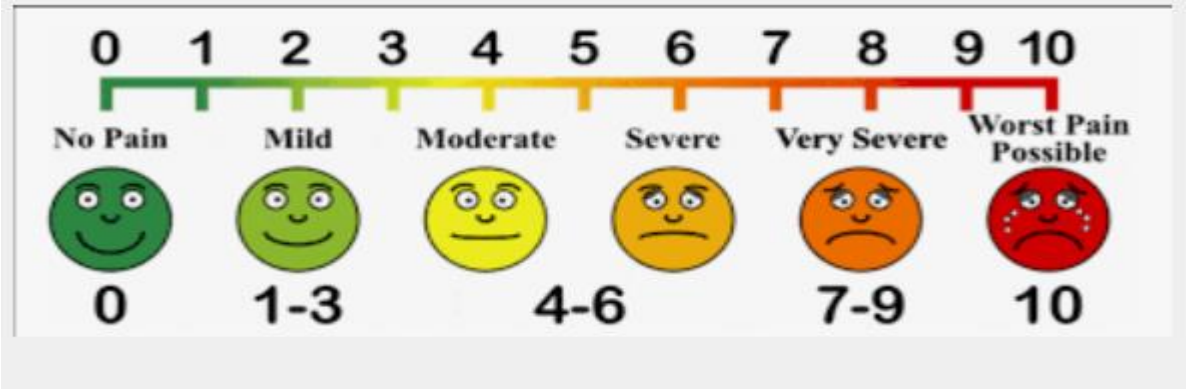
Timeline	Score
Within 7 days	0
Within 15 days	1
>15 days	2

4. Evaluation of discomfort due to arch bar – Yes/No
5. Discomfort with repeated injections –Yes/No
6. Cost factor analysis
7. Oral hygiene by calculating debris score.

OHIS index	Index	Score
Good	0-0.7	0
Fair	0.7-1.8	1
Poor	1.9-3.0	2

TOOLS USED:

1. **VAS Scale:**[Numerical Pain Rating Scale]: Visual Analogue Scale for pain assessment - 10 cm horizontal line with 0- labelled on left and 10 labelled on right. Patients are asked tolerate current level of overall pain on mouth opening and movements. Classified as none 0, mild 1-3, moderate 4-6 severe 6-10



1. **HADS – Hospital anxiety and depression scale**

2. **Likert Scale**: For the assessment of patient satisfaction with ongoing management of his current status and measuring the response to specify their level of agreement or disagreement.

A typical five-level Likert,

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

3. Debris Score:

   Oral hygiene evaluation by Debris index of Oral hygiene index- modified:

   By Jack and Vermillion (1964**)**

   Debris score:

   0= No debris or stain

   1= Soft debris covering not more than one third of tooth surface

   2= Soft debris covering more than one third but not more than two third of tooth surface

   3=Soft debris covering more than two third of exposed tooth surface

Six surfaces were examined- 4 posterior and 2 anterior teeth. 16,11,26,46,31,36 as per FDI numbering system.

In posterior portion, buccal surface of upper 1st molars (16,26)

Lingual surface of lower 1st molars (36,46) was examined.

In anterior portion, labial surface of upper right (11) and lower left central incisors (31) were examined.

Calculating: Total score of all surface was calculated and divided by number of surfaces examined

$$\text{Debris index} = \frac{\text{Total score of all surface}}{\text{Number of total surfaces examined}}$$

Total score:

Good	0-0.7
Fair	0.7-1.8
Poor	1.9-3.0

Edema /Swelling Evaluation

Facial measurements were taken using millimetre ruler at pre-operative period, at 24 hours and on 5th day after surgery. Markings were made on the following facial regions: the angle of mandible, the tragus, the labial commissure, the nasal border, laterally outer canthus of eye and inferiorly soft tissue pogonion.

Following distances were measured:

Distance I: From the angle of mandible to tragus

Distance II: From angle of mandible to outer canthus of eye

Distance III: From angle of mandible to nasal border

Distance IV: From angle of mandible till labial commissure

Distance V: From angle of mandible till soft tissue pogonion

Differences between the measurements were measured before and after the surgery.

Average of five differences was calculated and if <10mm swelling was classified as mild, between the range of 10-20mm was categorized as moderate and for >20mm into severe category.

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D) _____ Anxiety (A) _____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

RESULTS

In our study, a total of 74 patients with maxillofacial fractures requiring open reduction and internal fixation (ORIF) were randomly divided into two groups, ERAS group (Group I) and Control group (Standard care group- Group II). Group I (ERAS group) included 37 patients including 36 males and 1 female (Mean age -31.14 ± 12.510 years). Group II (Control) had 37 patients consisting of 35 males and 2 females. (Mean age-33.73 ± 12.319 years). Baseline demographic characteristics including age, sex, history of addictions, fractured site, and number and pre-operative occlusion status were compared and no significant difference was observed between both the groups($p>0.05$). (Table 1,2) (Figure 1-6)

Table 1: Baseline Characteristics of ERAS and Control treatment group

Parameters		**ERAS Group**	**Control Group**	**p-value**
Age (Mean ±SD) (in years)		31.14 ± 12.510	33.73 ± 12.319	0.372
Gender	**Male**	36	35	0.556
	Female	1	2	
Number of fractured sites	**Single**	8	5	0.359
	Multiple	29	32	
Fractured site	**Midface**	17	13	0.327
	Mandible	11	9	
	Panfacial	9	15	
Pre-operative Occlusion	**Stable**	9	7	0.572
	Derranged	28	30	

In the ERAS group, about 21.6% of the included patients had a single fractured site whereas 78.4% of subjects had multiple fragmented sites. While in the control group, about 13.5% of patients had a single fractured site and 86.5% had multiple fractured sites.

The ERAS group study selection included about 45.9% of subjects who presented with midface fractures, 29.7% with mandibular fractures and 24.32% having panfacial

fractures. Similarly in the control group, 35.1% of total subjects had midface fractures, 24.3% had mandibular fractures and 40.54% had panfacial category fractures.

Majority of the patients among both groups on presentation had derranged pre-operative occlusion. Relatively fewer patients, about 24.3% of patients in the ERAS group and 18.9% among the control group had relatively stable occlusion whereas 75.7% of patients in ERAS and 81.1% among the control group had derranged pre-operative occlusion status.

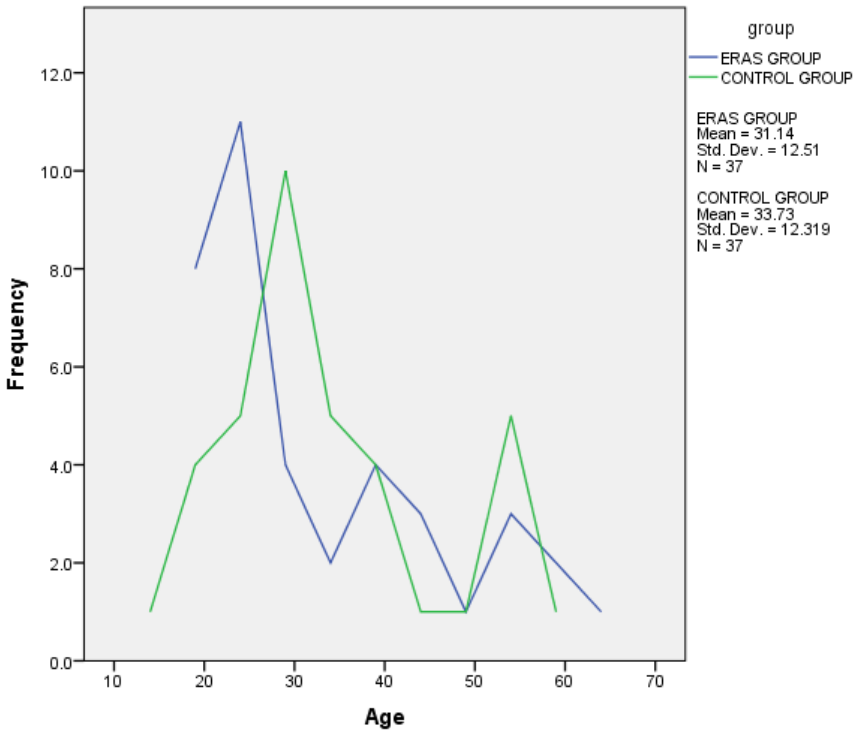


Figure 1: Age group distribution

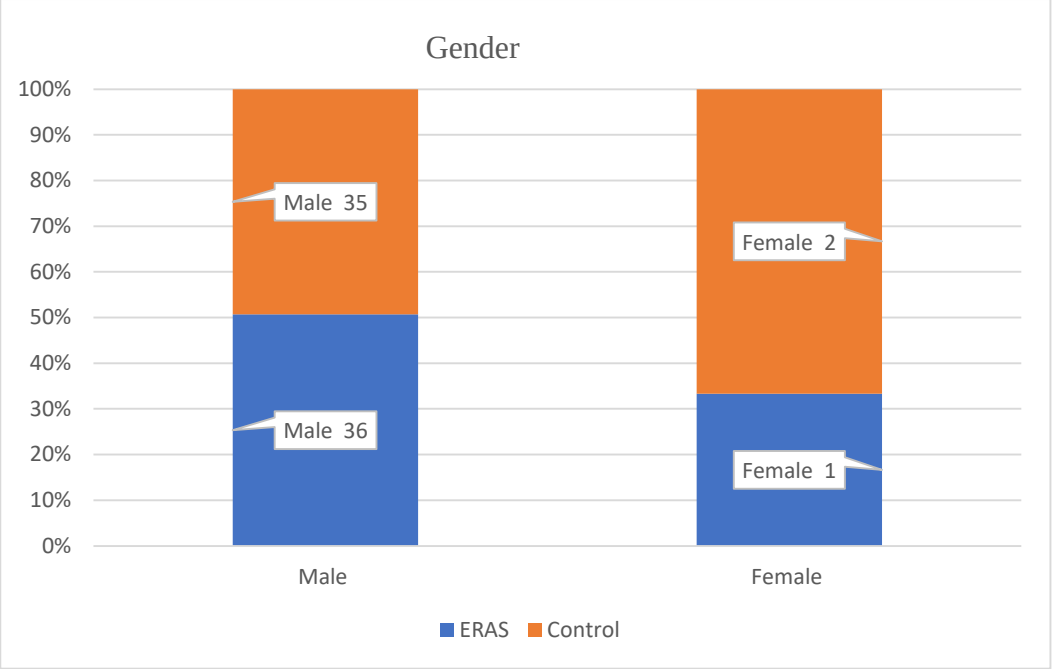


Figure 2: Gender distribution among subjects

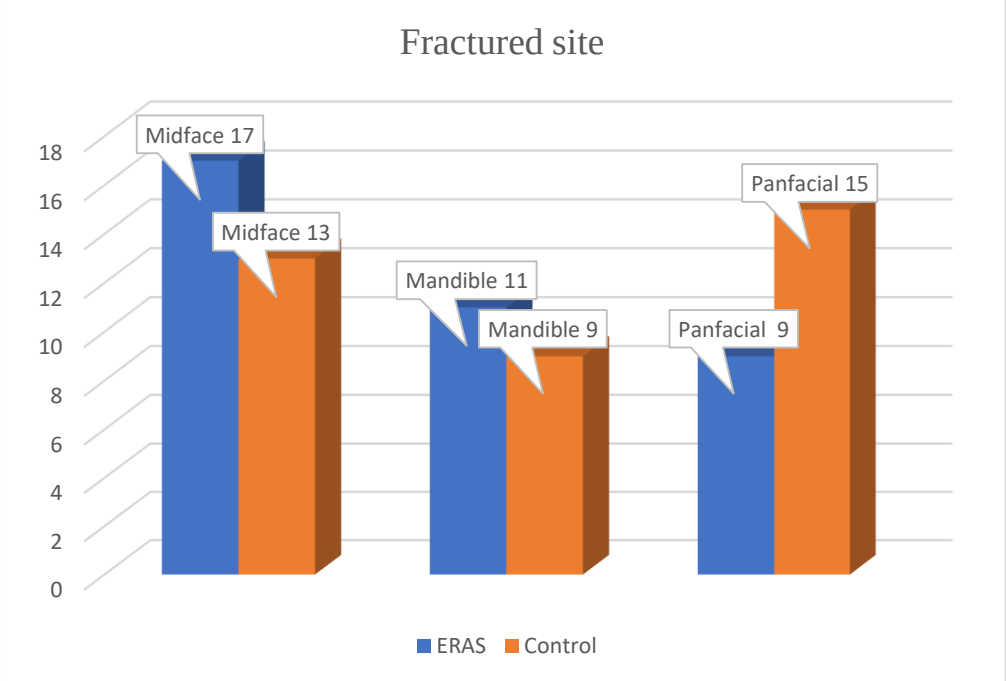


Figure 3: Distribution of fractures as per involvement of facial thirds

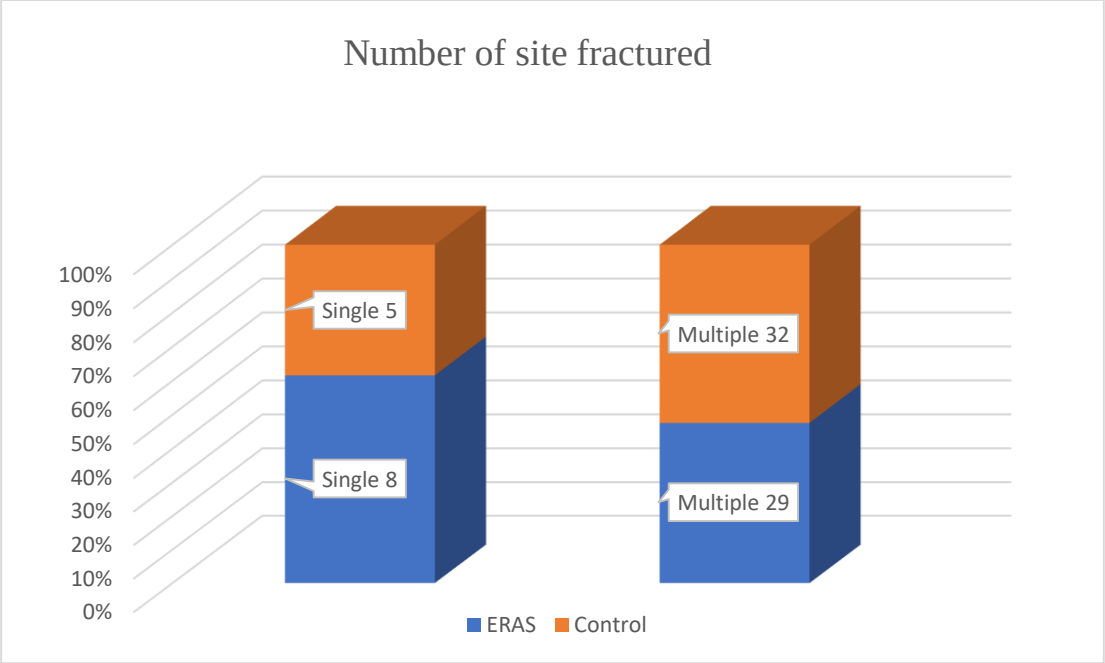


Figure 4: Distribution of number of fractured/fragmented sites

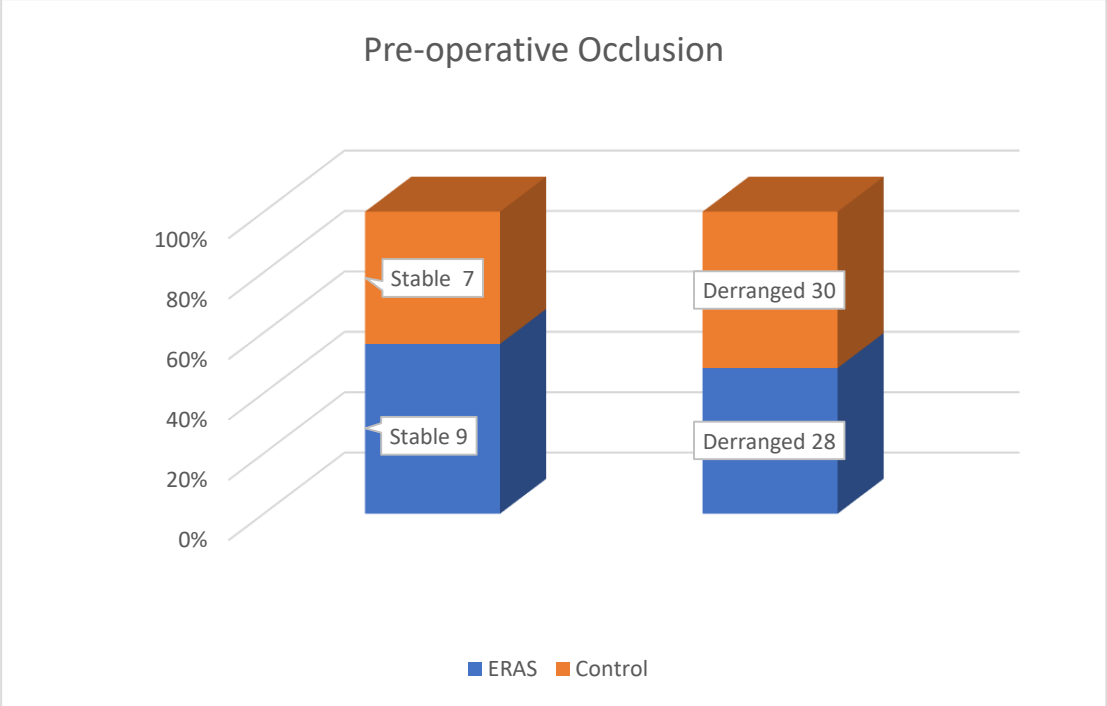


Figure 5: Pre-operative occlusion status

Table 2: Distribution of history of habits/ addictions among groups

Parameters	**ERAS Group**	**Control Group**	**p- value**
No deleterious habits	10	8	0.982
Alcohol	7	7	
Tobacco	10	12	
Smoking	1	1	
More than one habits	9	9	

On evaluating the addiction history, in ERAS group 27% of total subjects had no history of deleterious habits whereas, 18.9% had habit of alcohol, 27% had of tobacco, 2.7% had regular habit of smoking and 24.3% of patients had more than one deleterious habit. While in control group, 21.6% of subjects had no history of deleterious habits, 18.9% had habit of alcohol, 32.4% had of tobacco, 2.7% had smoking as a regular habit and 24.3% of subjects had more than one deleterious habit.

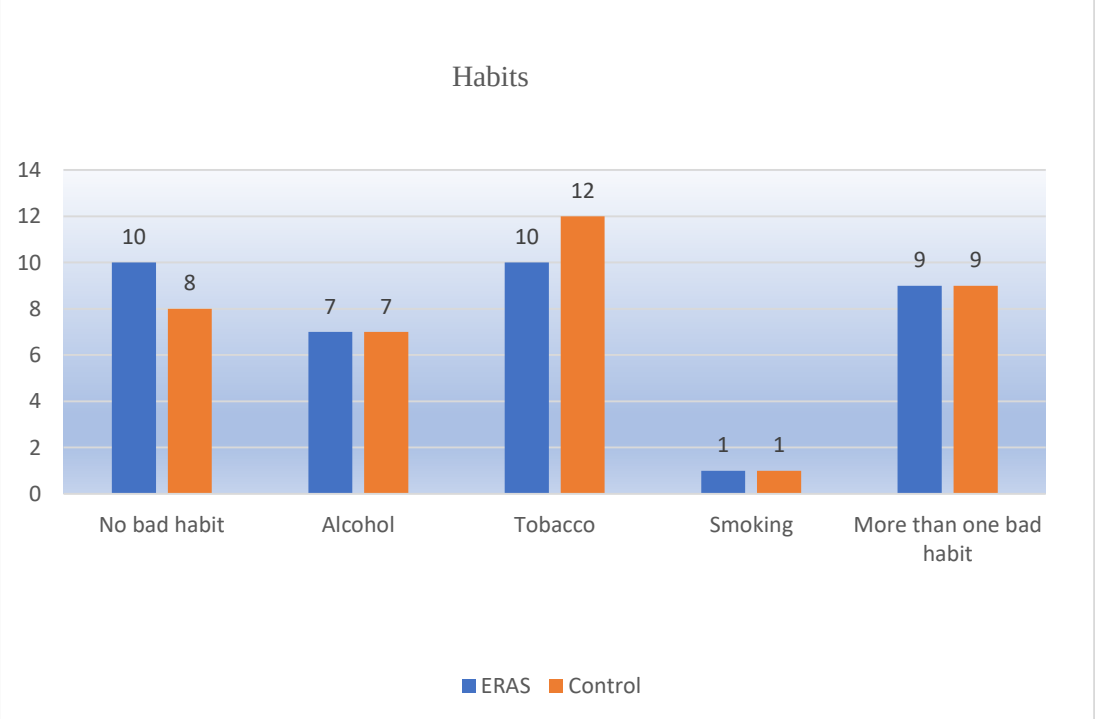


Figure 6: Distribution of habits/addictions

Table 3: Pre-operative parameters after patient stabilization till surgery

Parameters	ERAS Group (Mean ±SD)	Control Group (Mean ±SD)	p-value
Pain by VAS scale	4.73 ± 0.871	4.86 ± 1.032	0.545
Total number of I.V analgesics used till 72 hours in ERAS and till surgery in control	6 ± 0 **	10.97 ± 4.972 #	0.001 *
Additional analgesics on SOS basis	0.27 ± 0.652 (Oral) ***	0.65 ± 1.136 (IV after arch bar placement)	0.096
Rescue analgesics (Tramadol)	00 ± 00	00 ± 00	-------
Pre-operative I.V fluids (mL)	00 ± 00	632.43 ±267.762	0.001*

****Till 72 hours of admission then shifted to oral analgesics on SOS (as per need) basis**

***** After 72 hours till surgery on SOS basis**

 # IV continued till surgery

PAIN EVALUATION (VAS scale)

Pain levels were evaluated using VAS score pre-operatively using a grading scale ranging from 0-10. The average daily VAS score from Day 0 till the day of surgery was calculated (Table 3). Minimum and maximum scores of daily VAS score noted in the ERAS group were 3 and 6 respectively. While in the control group the lowest and highest scores noted were 3 and 8 respectively. The Mean of VAS scores of

subjects among ERAS group was 4.73 ± 0.871 S. D. and for the control group was 4.86 with S.D. of 1.032. No pre-operative significance was noted among both groups considering pre-operative pain. (p value =0.545)

TOTAL ANALGESICS AND RESCUE ANALGESICS

Pre-operative total number of analgesics used via intravenous route till 72 hours after admission /surgery in both groups were calculated. Mean analgesic injections given to patients among the ERAS group till 72 hours were 6.0 with an S.D. of 0. Whereas mean analgesics injections given among the control group were 10.97 with an S.D. of 4.97. Intravenous analgesic consumption showed a statistically significant difference between the two groups (p value=0.001*). After 72 hours of admission patients in the ERAS group were shifted to oral and analgesics were provided as per the need. Among the control group I.V analgesics were continued on twice per day dose till surgery. Also, additional dose of I.V analgesics if had to be supplemented after arch bar placement in control group was noted. (Table 3). Result of mean additional oral analgesics used after 72 hours in ERAS group noted was 0.27 ± 0.652 S.D. For the control group the mean of additional intravenous analgesics given after arch bar placement noted was 0.65 ± 1.136 S.D.

PRE-OPERATIVE INTRAVENOUS FLUIDS

The volume of intravenously infused pre-operative fluids was 632.43mL with S.D. of 267.762mL among the control group whereas in the ERAS group, no pre-operative fluids were given resulting in a statistically significant difference. (Mean ± SD- 00 ± 00) (p value= 0.001*) (Table 3)

Table 4: Comparison of ordinal variables in Pre-operative phase using Chi-square test

Parameters	**ERAS Group**	**Control Group**	**Chi square Value**	**Df**	**"p" value**
Anxiety by HAD scale					
0-7	32	28			
8-10	5	9	1.410	1	0.235
11-21	0	0			
Oral Hygiene Index					
0-0.6	7	2	3.704	2	0.157
0.7-1.8	19	19			
1.9-3	11	16			
Starting of oral feeds					
Within 6 hours	31	1	66.696	3	0.001*
Within 6-12 hours	6	1			
Within 12-24 hours	0	21			
Greater than 24 hours	0	14			
Pre-operative compliance for oral carbohydrates (Apple juice/ coconut water)			74.00	1	0.001*
Yes	37	0			
No	0	37			

Comparison of ordinal variables using Chi-**Square test**

HOSPITAL ANXIETY AND DEPRESSION (HAD) AND ORAL HYGIENE INDEX (OHIS)

Upon rating of pre-operative levels of anxiety and depression, no statistically significant difference was found among both groups. (p value= 0.235)

Among all the included study patients, about 86.5% of patients in the ERAS group had normal ranging HAD scores between 0-7, and 13.5% had borderline HAD range between 8-10. While in control group 75.7% of subjects had normal HAD score between 0-7 and 24.3% had borderline 8-10 HAD score. (Table 4) (Figure7). None of the patients among both groups had pre-operative HAD scores within the range of severe category (11-21).

Pre-operative oral hygiene status among both groups was similar with no statistically significant difference (p value=0.157). About 18.9% of subjects in ERAS group had 0-0.6 (Good) OHIS scores, 51.4% of subjects had 0.7-1.8 (Fair) OHIS scores and 29.7% of them had 1.9-3(Poor) OHIS scores. Among the control group, 5.4% of subjects had 0-0.6 (Good) OHIS scores, 51.4% had 0.7-1.8 (Fair) OHIS scores and 43.2% had 1.9-3(Poor) OHIS scores. (Table 4) (Figure 8).

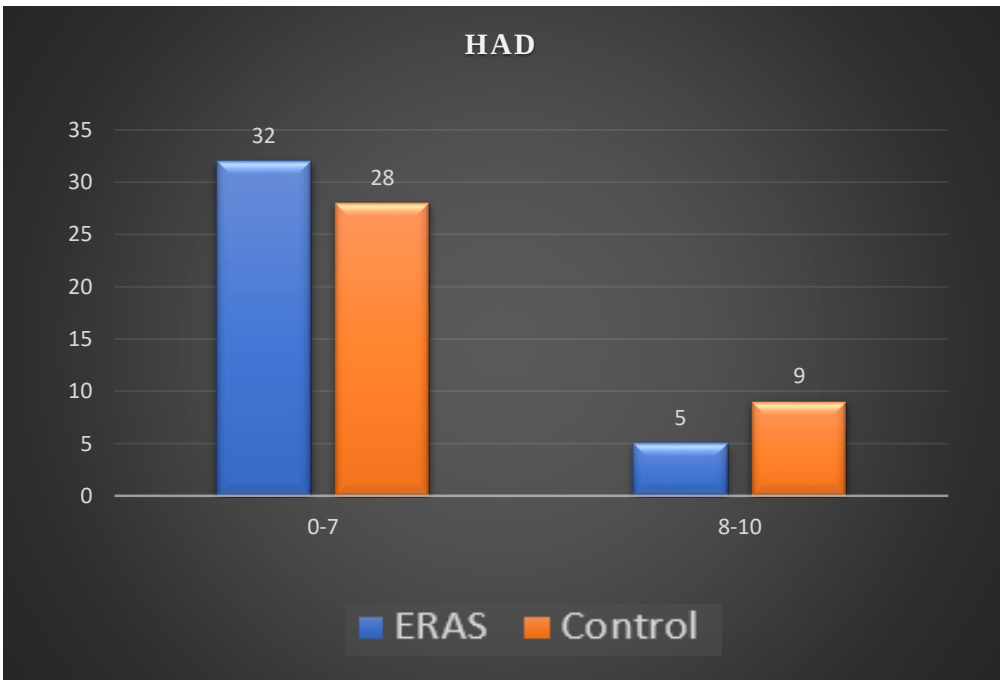


Figure 7: Comparison of HAD Score

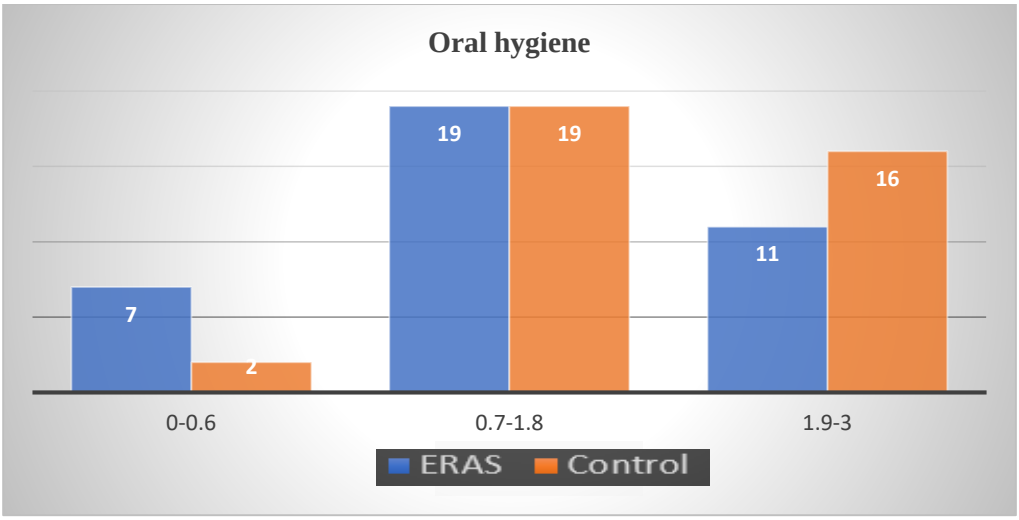


Figure 8: Comparison of pre-operative oral Hygiene Index

STARTING OF ORAL FEEDS AND PRE-OPERATIVE COMPLIANCE FOR ORAL CARBOHYDRATES [T1]

A statistical significant difference was noted among both the groups considering the timing of starting of oral feeds and pre-operative oral carbohydrates/coconut water intake compliance. (p value= 0.001*) (Table 4) About 83.8% of patients in ERAS group pre-operatively after trauma started oral feeds within 6 hours after admission and 16.2% could start oral feeds within 6-12 hours. Whereas in the control group, 2.7% of patients started oral feeds within 6 hours after admission, 2.7% started within 6-12 hours after admission and 56.8% of them started oral feeds after 12-24 hours. (Table 4) (Figure 9)

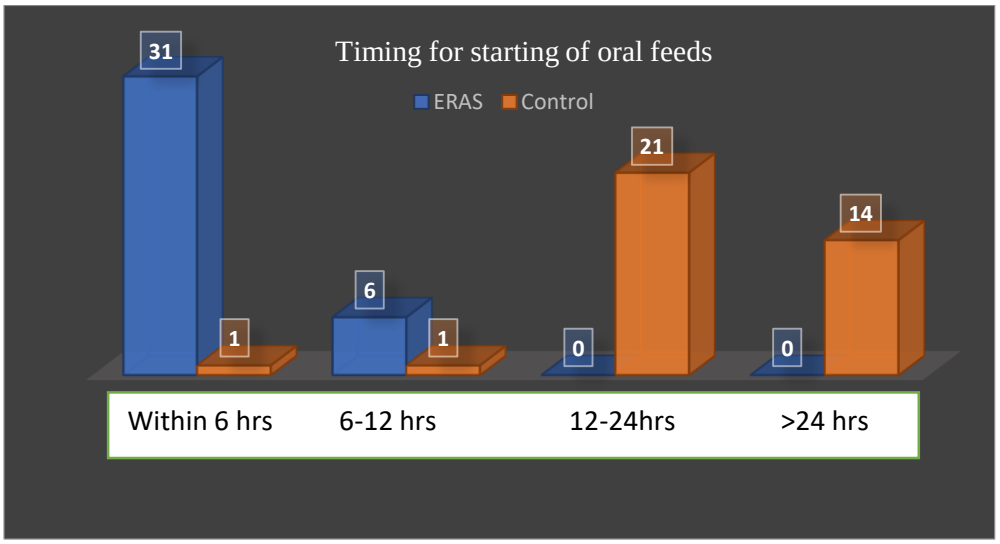


Figure 9: Comparison of Timing for starting of oral feeds

Table 5: Immediate post-operative assessment of parameters after surgery

Parameters	ERAS group	Control Group	
	(Mean ± S.D)	**(Mean ± S. D)**	**p value**
Pain by VAS scale	3.51±0.961	3.57±1.191	0.655
Total number of analgesics after surgery till discharge	4.21 ±0.621 (Oral)	8.08 ± 3.551 (I.V)	0.001*
Rescue Analgesics (Tramadol)	00 ± 00	00 ± 00	---------
Total Post op IV fluids(mL)	0.03±0.164	1683.78 ± 337.074	0.001*

POST-OPERATIVE PAIN EVALUATION (VAS SCORE)

The mean VAS score of patients in ERAS group noted was 3.51 with an S.D. of 0.961 and among control group was 3.57 with an S.D. of 1.191, signifying no significant difference in post-operative pain levels noted at a period of 24 hours after surgery. (p value= 0.655). Scores of minimum and maximum postoperative VAS scores in ERAS group 24 hours after surgery were noted as 3 and 5 respectively. Whereas in control group the lowest and highest noted VAS scorings were 3 and 8 respectively.
(Table 5)

This section describes the comparison of ERAS with control group for outcomes of pain levels. For assessment of comparison among both the groups repeated measure ANOVA test was used.

Table 6: Comparison of ERAS with Control group in relation to pain

Group	Pain scores at admission period	Pain score at 24 hours after surgery
	(Mean ±SD)	**(Mean ±SD)**
ERAS Group	4.73 ± 0.871	3.51 ± 0.961
Control Group	4.86 ± 1.032	3.57 ± 1.191

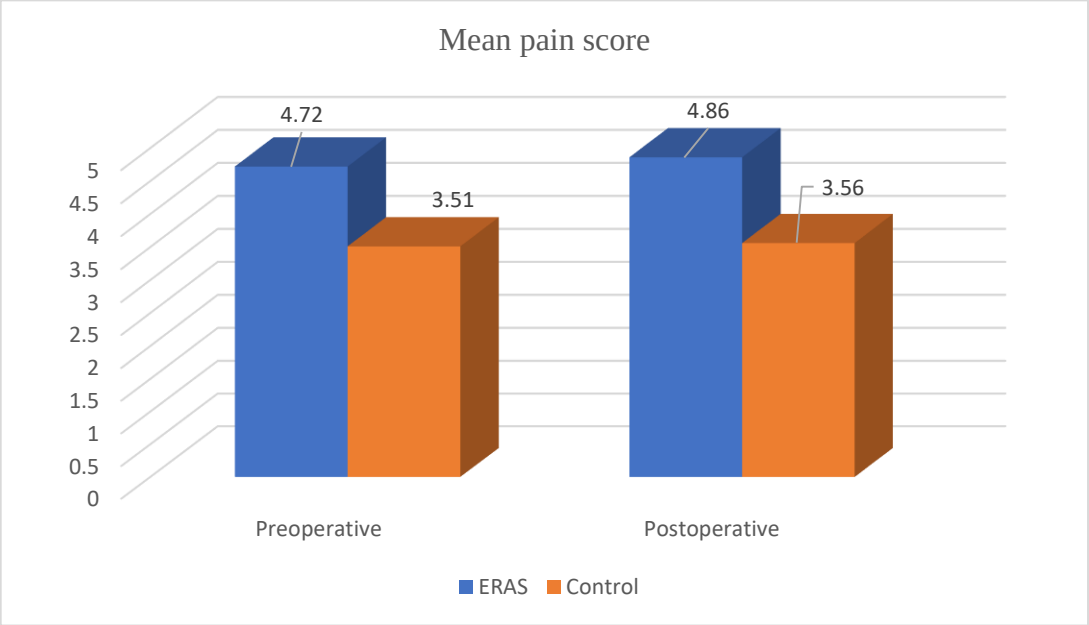


Figure 10: Mean baseline and postoperative pain scores among both groups

Table 7: Pairwise comparison for pain at pre-operative period and at 24 hours after surgery

Pairwise Comparisons							
Time	**Group**	**Group**	**Mean Difference**	**Std. Error**	**Sig.**	**95% Confidence Interval for Difference**	
						Lower Bound	**Upper Bound**
Pre-operative	ERAS	Control	0.135	0.222	0.545	-0.578	0.307
At 24 hours	ERAS	Control	0.054	0.252	0.831	-0.556	0.448

Comparison of variables using repeated AONVA test

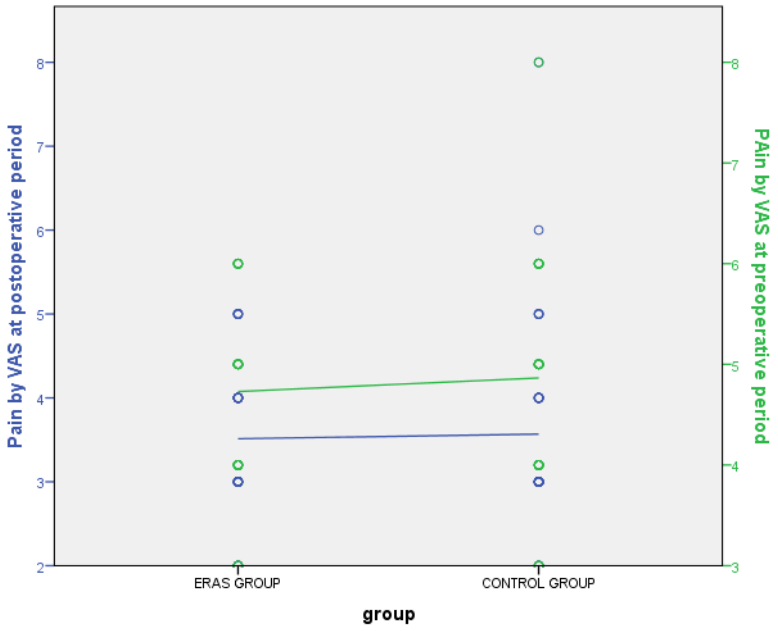


Figure 11: Multidimensional bar graph to compare pre-operative pain and postoperative pain among ERAS and control groups

Pairwise comparison of data of both groups pre-operatively shows no statistically significant difference found at 0.05 level of significance in levels of pain with a mean difference of 0.135, standard error 0.222 and "p" value 0.545. (Table 7). Similar results are observed post-operatively at the time period of 24 hours after surgery with a mean difference of 0.054, standard error 0.252 and "p" value 0.831. (Table 7)

TOTAL ANALGESICS AND RESCUE ANALGESICS USED

Results of mean oral analgesics given to patients among the ERAS group after surgery noted till discharge were 4.21 with an S.D of 0.621 and for the control group were 8.08 with an S.D of 3.551 resulting in a statistically significant difference. (p value=0.001*) (Table 5)

POST-OPERATIVE INTRAVENOUS FLUIDS

The postoperative volume of intravenous fluids used among ERAS group is 0.03mL with an S.D of 0.164mL and among the control group is 1683.78mL ± 337.074 mL S.D. (p value= 0.001*). (Table 5) revealing statistically significant difference.

Table 8: Post-operative assessment of ordinal variables at 24 hours after surgery using Chi-square test

Parameters	ERAS Group	Control Group	Chi square Value	Df	"p" value
PONV episodes					
No	35	31	2.242	1	0.134
Yes	2	6			
Restart of oral feeds					
Within 6 hours	37	0			
Within 6-12 hours	0	1	74.00	3	0.001*
Within 12-24 hours	0	28			
More than 24 hours	0	8			
Throat pain					
No	33	2	52.098	1	0.001*
Yes	4	35			
Severity of throat pain					
No pain	33	2	52.919	3	0.001*
Mild Pain	4	22			
Moderate pain	0	11			
Severe pain	0	2			

Discomfort in swallowing					
No discomfort	37	10	42.511	3	0.001*
Mild discomfort	0	25			
Moderate discomfort	0	1			
Severe discomfort	0	1			
Anxiety by HAD scale					
0-7	37	25	14.323	2	0.001*
8-10	0	11			
11-21	0	1			
Post-operative swelling					
No swelling	11	10	2.130	3	0.546
Mild swelling	18	15			
Moderate swelling	9	5			
Severe swelling	4	2			
Discharge timings					
Within 24 hours	20	0	49.643	2	0.001*
Within 24-48 hours	12	2			
More than 48 hours	5	35			

Comparison of ordinal variables using Chi-**Square test**

Results show similar incidences of PONV episodes among both groups with no statistically significant difference. About 94.6% of patients among ERAS group and 83.8%of patients among the control group did not experience any PONV episodes. (p value =0.134) (Table 8).

Postoperatively 100% of patients among ERAS group restarted oral feed within 6 after the surgery. While in control group, 2.7% of patients started oral feed within 6-12 hours after surgery, 75.7% of them started oral feed within 12-24 hours after surgery and 21.6% started after 24 hours of surgery resulting in a statistically significant difference. (p value=0.001*) (Table 8).

The severity of throat pain evaluated at 24 hours post-surgery was noted higher amongst the control group as compared to the ERAS group as only 10.8% of patients reported throat pain among ERAS group whereas 94.6% of patients among the control

group had complained of throat pain. Only 10.8% of patients suffered from milder intensity pain among ERAS group. None of the patients in ERAS group reported moderate or severe intensity of throat pain. Whereas, 59.5% of patients of control group experienced mild pain, 29.7% had moderate pain and 5.4% of them had severe throat pain. (p value=0.001*) (Table 8).

Hospital Anxiety and Depression score (HAD) was significantly lowered postoperatively in ERAS group in comparison to control group. 100% of subjects showed normal ranging 0-7 HAD scores among ERAS group. Whereas 67.6% of subjects in control group had normal 0-7 HAD scores and 29.7% had borderline 8-10 scores. (p value=0.001*) (Table 8). Only 1 subject among the control group had HAD score within the range of 11-21.

Statistically, no significant difference was found in comparison of post-operative swelling at surgical site. In ERAS group at a period after 24 hours of surgery, 29.7% of subjects developed no swelling, 48.6% had mild swelling, 24.3% had moderate swelling and 10.8% of them had severe swelling at surgical site. While in control group about 27% of subjects developed no swelling, 40.5% had mild swelling, 13.5% had moderate swelling and 5.4% of subjects had severe swelling evident. (p value=0.546) (Table 8)

Results were in favor of reduced hospital stay among ERAS group as evident from statistically significant difference. In the ERAS group 54.1% of subjects were discharged within 24 hours after surgery, 32.4% were discharged within 24-48 hours after surgery and 13.5% were discharged after 48 hours of surgery. While, none of subjects were discharged within 24 hours among control group, 5.4% were discharged within 24-48 hours after surgery and 94.6% of total subjects were discharged after 48 hours of surgery. (p value= 0.001*) (Table 8)

Table 9: Pairwise comparison for anxiety at pre-operative period and at 24 hours after surgery

Pairwise Comparisons							
Time	Group	Group	Mean Difference	Std. Error	Sig.	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
Pre-operative	ERAS	Control	0.108	0.091	0.241	-.0290	0.074
At 24 hours	ERAS	Control	0.351	0.088	0.001	-0.528	-0.175

Comparison of variables using repeated AONVA test

Pairwise comparison of both groups showed no statistically significant difference in pre-operative anxiety levels among both groups whereas, after 24 hours of surgery, there was a statistically significant difference noted in level of anxiety among ERAS and control group with a mean difference of 0.351, standard error 0.088 and "p" value 0.001. (Table 9)

Table 10: Post-operative assessment and comparison of ordinal variables at period of 5 days after surgery using Chi-square test

Parameters	ERAS Group	Control Group	Chi square Value	Df	"p" value
Post-operative edema			0.00	1	1.00
No edema	33	33			
Edema present	4	4			
Surgical site infections			0.158	1	0.691
No	34	33			
Yes	3	4			
Need of antibiotics additional coverage			0.319	1	0.572
No	30	28			
Yes	7	9			
OHIS -oral hygiene index			33.990	2	0.001*
0-0.6	28	5			
0.7-1.8	9	16			
1.9-3	0	16			

Comparison of ordinal variables using Chi-**Square test**

POST-OPERATIVE EDEMA

Similar rates of frequency of post-operative edema at surgical site was noted on evaluation in both the groups.

In about 10.8% of subjects in both ERAS and control group mild edema was noted resulting in no statistically significant difference. (p value= 1) (Table 10)

SURGICAL SITE INFECTIONS

A total of 8.1% of subjects developed post-operative surgical site infection among ERAS group and 10.8% among the control group. Resulting in no statistically significant difference among both the groups. (p value= 0.691). (Table 10)

NEED FOR ANTIBIOTIC COVERAGE

Around 18.9% of patients from ERAS required antibiotic coverage compared to 24.3% among control group. It was noted that the requirement of antibiotic coverage exceeded the incidence of surgical site infections which could be explained in cases with longer duration of surgical procedure, occurrence of dehiscence where need for antibiotic supplementation / upgradation was validated. (p value= 0.572) (Table 10).

Results have shown no statistically significant difference found among ERAS and control groups regarding "Post-operative edema, surgical site infections and need of antibiotics." at a follow up period of 5 days after surgery. (p value= 0.001) (Table 10)

POST-OPERATIVE ORAL HYGIENE

Data presented shows statistically significant difference among ERAS and control groups regarding "Status of oral hygiene" at a period of 5 days after surgery (Table 10), (Figure 12).

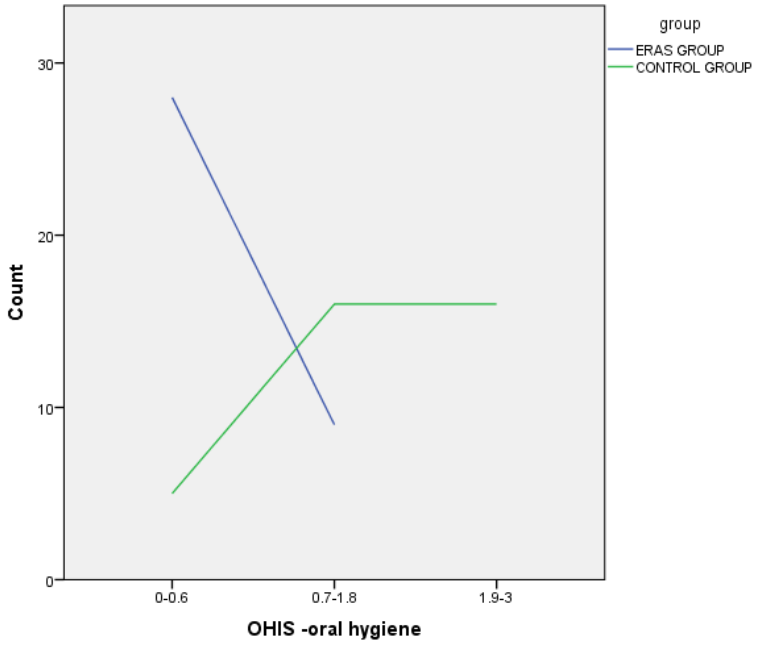


Figure 12: Comparison of post-operative oral hygiene status among ERAS and control group in post-operative period assessed at 5 days after surgery

Table 11: Pairwise comparison of ERAS with control group in relation to oral hygiene

Pairwise Comparisons							
Time	Group	Group	Mean Difference	Std. Error	Sig.	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
Pre-operative period	ERAS	Control	0.270	0.151	0.077	-0.571	0.030
After 5 days of surgery	ERAS	Control	1.054	0.136	0.001	-1.325	-0.783

Comparison of ordinal variables using repeated AONVA test

A pairwise comparison of both groups shows no statistically significant difference in the status of oral hygiene pre-operatively while upon evaluation after 5 days of surgery it reveals a statistically significant difference found in status of oral hygiene among ERAS and control group with a mean difference of 1.054, standard error 0.136 and “p” value 0.001**(Table 11)

Table 12: Post-operative assessment of ordinal variables at 2 weeks after surgery using Chi-square test

Parameters	**ERAS Group**	**Control Group**	**Chi square Value**	**Df**	**"p" value**
Overall Satisfaction			39.357	3	0.001*
Fully unsatisfied	0	0			
Unsatisfied	0	2			
Average	2	22			
Satisfied	7	10			
Fully satisfied	28	3			
Discomfort due to arch bar			39.871	1	0.001*
No	30	3			
Yes	7	34			
Return to normal life (within days)			70.105	1	0.001*
Within 7 days	37	1			
More than 15 days	0	36			
Was communication from health care team adequate and completely understandable?			4.229	1	0.040*
Yes	37	4			
No	0	33			
Able to quit deleterious habit/addictions			49.340	2	0.001*
Unable to quit habits	1	28			
Able to quit habits	27	1			
No history of previous deleterious habits	9	8			
Pain/ discomfort due to multiple needle pricks			52.94	1	0.001*
No pain	34	3			
Pain	3	34			

Comparison of ordinal variables using Chi-**Square test**

Parameters	**ERAS Group (Mean ±SD)**	**Control Group (Mean ±SD)**	**p-value**
Cost Analysis (INR)	303.37±99.88	655.94±104.53	0.001*

OVERALL SATISFACTION AND COMMUNICATION FROM DOCTORS SIDE

Overall patient satisfaction was noted to be higher among the ERAS group with a resultant statistically significant difference. Among ERAS group 5.4% of subjects had average level of satisfaction and 75.7% were fully satisfied with the provided medical services. In control group, 59.5% of subjects had average level of satisfaction and 8.1% were fully satisfied. (p value= 0.001*) (Table 12) (Figure 13)

About 100% of patients in ERAS group perceived that the communication from the doctor's side was adequate and fully understandable. While 10.8% of patients felt communication from doctor side was adequate and fully understandable among the control group. (p value =0.040*) (Table 12)

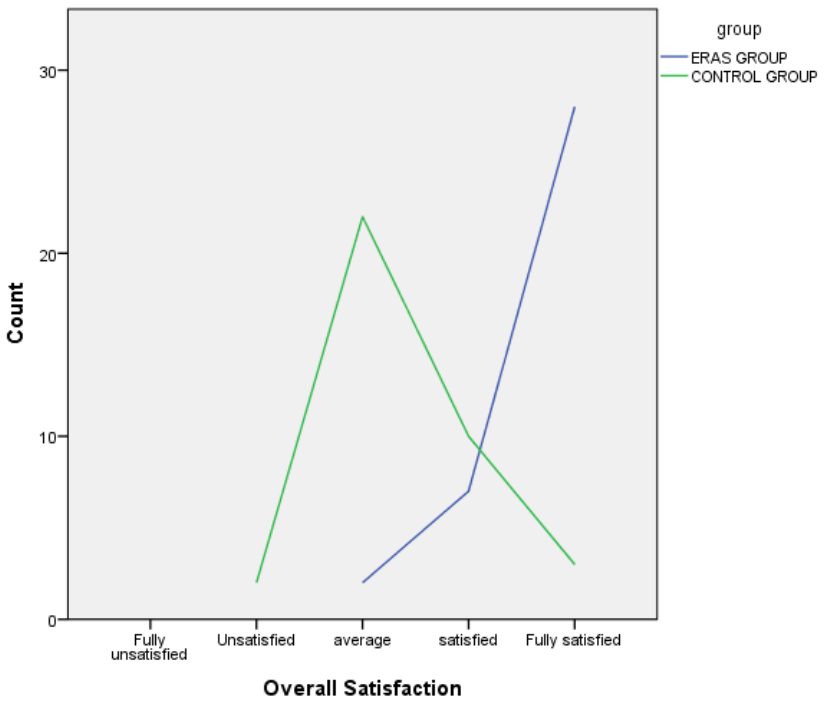


Figure 13: Comparison of Overall satisfaction rates among ERAS and Control group assessed at a period of 2 weeks after surgery

DISCOMFORT WITH ARCH BAR AND PAIN /DISCOMFORT WITH MULTIPLE NEEDLE PRICKS

Discomfort due to arch bar was comparatively reduced among ERAS group with just 18.9% of subjects reporting discomfort due to arch bar. Whereas majority of patients in control group (97.3%) of subjects experienced discomfort with intraorally placed arch bar with resultant statistically significant results. (p value = 0.001*). Also, similar results with significant difference were noted for pain due to multiple needle pricks and punctures in control group. (p value = 0.001) (Table 12) (Figure 14,15)

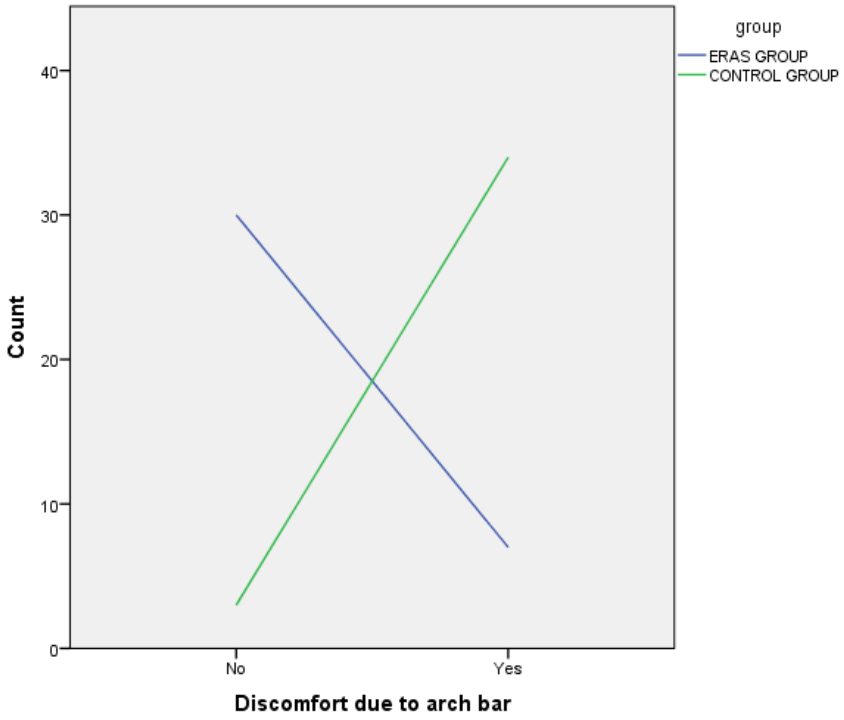


Figure 14: Comparison of discomfort with arch bar among both the groups

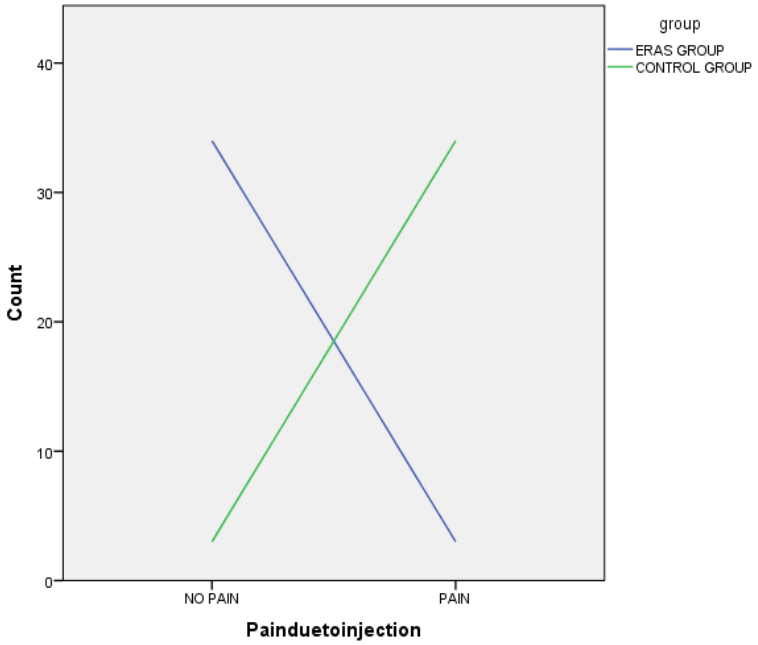


Figure 15: Comparison of pain/discomfort with multiple needle punctures among both groups

RETURN TO NORMAL LIFE

Results showed up that 100% of patients in ERAS group returned to normal life within 7 days. While, 2.7% of patients returned to normal life within 7 days, and 97.3% returned after 15 days in control group. (p value =0.001) (Table 12)

ABLE TO QUIT HABITS /ADDICTIONS

Statistically significant difference was noted among both the groups on evaluating the ability and willingness to quit habits post-operatively. (p value=0.001) (Table 12) (Figure 16). 27 out of 37 patients in ERAS group were able to quit deleterious habits in contrast to 1 out of 37 patients of control group.

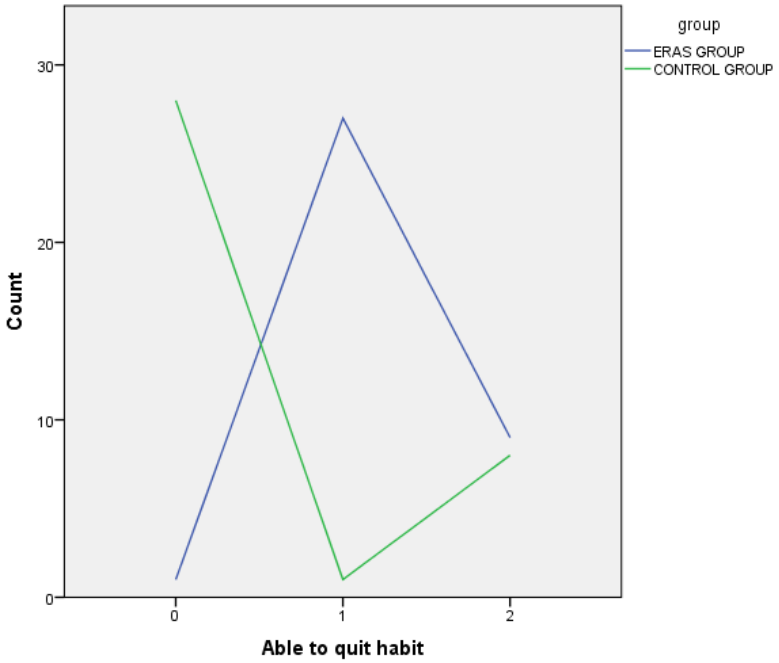


Figure 16: Comparison of patient's ability in quitting of habit among both the groups

COST ANALYSIS

Significant reduction in the hospital stay costings in ERAS group was noted as compared to control group with statistically significant difference. Mean financial expenses of subjects among ERAS group was 303.37 INR with S.D. of 99.88 And mean financial expenses among control group was 655.94 INR with S.D. of 104.53. (p value= 0.001*) (Table 12)

DISCUSSION

Trauma is one of the major leading causes of death among humanity contributing significantly to mortality and morbidity throughout the world and in large numbers in developing countries. The maxillofacial region being the most prominent is more vulnerable to trauma (42). Reports reveal that 20% to 60% of all road traffic injuries (RTA's) involve some form of maxillofacial injury (43). Maxillofacial injuries can occur as an isolated injury or in association with multiple concomitant injuries to the head, chest, abdomen, spine and long bones caused by physical force, foreign objects, animal bites or burns. Incidences of maxillofacial trauma have been exponentially increasing in recent times with road traffic accidents being the leading cause responsible for 1 million death per year and 20-50 million death rates across the world. As per the Indian scenario, 0.2 million deaths in 2017 were reported due to road traffic accidents. The reasons for higher frequency of road traffic accidents in developing countries like India include inadequate road safety awareness, poor road conditions, violation of speed limit, not wearing seat belts or helmets, and use of alcohol or other intoxicating agents (44) Other etiology responsible for trauma includes interpersonal violence, sports injuries, industrial accidents and gunshot injuries.

Victims of such maxillofacial facial injuries not only just sustain physical trauma, scars or disfigurements, but also carry their resultant emotional and psychological impact. Psychological impairments such as posttraumatic stress syndrome and depression are common after sustaining such facial injuries (45). Several authors have documented that around 10-70% of facial trauma patients showed such signs of sadness and anxiety. Facial fractures also cause impaired masticatory function due to occlusion derangement leading to dietary restrictions, poor function of traumatized areas leading to poor masticatory ability, severe pain and aesthetic impairment ultimately leading to poor quality of life. The management of injuries to the maxillofacial complex remains a challenge for oral and maxillofacial surgeons, demanding both skill and a high level of expertise. Open reduction and internal fixation of fractures has been considered as gold standard and has reported results with a satisfactory restoration of facial appearance and of function till date. Recently with ever-increasing patient expectations, patients demand an immediate

return to normal aesthetic and functional results. Also, patients enter each decision for surgery with expectations regarding the effectiveness of the procedure and their postoperative recovery.

Enhanced recovery after surgery (ERAS) programs are evidence-based protocols designed to standardize and optimize perioperative medical care. They are formulated with patient-centric approaches. Enhanced recovery after surgery (ERAS) protocols are multimodal care pathways designed to reduce the profound stress response following surgery. The key elements of ERAS protocols include pre-operative counselling, optimization of nutrition, standardization of analgesics and anesthetic regimens and early mobilization and discharge (46) (47). These protocols named ERAS enhanced recovery programs (ERPs) or "fast-track" programs were initiated by Professor Henrik Kehlet in the 1990s and have become an important focus of perioperative management after colorectal surgery (48), vascular surgery (49), thoracic surgery (50) and more recently radical cystectomy. These programs have focused on attempting to modify the physiological and psychological responses to major surgery. Every step of perioperative care includes strategies to reduce the surgical stress response by modifying the inflammatory and metabolic changes. These protocols have primarily originated from modifications within individual conventional perioperative care strategies in the hospital setting. It requires a multidisciplinary approach with proper coordination between the patient, the surgeon, the anesthesiologist, the nursing staff, and the caretaker of the patient. Essential overall perioperative care includes pre-operative, intra-operative and postoperative components.

ERAS care includes the procedures as per predefined protocols starting from pre-admission to discharge till the follow-up of the patient. Meticulous planning at pre-admission, pre-operative evaluation and optimization along with protocol-based intra-operative and postoperative management have shown to fasten recovery and discharge of the patients when applied in various fields including colonic surgeries**,** neurosurgery**,** head and neck surgeries**,** gynecologic surgeries, hepatic surgeries, cardiac surgeries, etc (51). Such protocols have not been formulated previously for maxillofacial trauma cases undergoing open reduction and internal fixation. Hence in our study, we have formulated ERAS protocols and implemented and simultaneously evaluated their efficacy.

In the present study a total of 123 patients with maxillofacial trauma were evaluated over a period of 18 months. And after the application of inclusion and exclusion criteria, a total of 74 patients were finally included in the study. Patients with other concomitant head injuries, long bone, cervical spine, thoracic or abdominal injuries, intubated/tracheostomized, with uncontrolled systemic diseases, and psychiatric illness were screened and excluded from the study. Patients included in the study were randomized into two groups employing computer-generated digital codes. Group I acted as ERAS group (intervention group) whereas Group II was kept as control group (Standard regular care group). In Group I patients undergoing open reduction and internal fixation were treated as per the newly formulated enhanced recovery protocols at pre-operative, intra-operative and postoperative phases. In our study, patients were found to be homogeneously distributed in both groups as evident from statistically insignificant differences observed in relation to various demographic variables like age, gender and baseline parameters like number of fractured sites, involvement of facial thirds, pre-operative occlusion and with history of habits and addictions (p value > 0.05). Thus, this indicated sufficient substantiated evidence that our randomization was successful in reducing the patient-related confounding factors. (Table 1,2). Majority of the maxillofacial fractures included in our study were young males of 2nd and 3rd decade. ERAS group included 36 males and 1 female whereas control group included 35 males and 2 females (p value=0.556). This occurrence was in congruence with the differential socialization and gender constraints of our society. (Table 1) (Figure 2).

Maxillofacial fractures are classified according to the involvement of facial thirds. Fractures with involvement of all thirds of face including upper third (frontal bone), upper midfacial region (involving the zygomaticomaxillary region and naso-orbital ethmoidal region and lower third (mandibular) region are regarded as panfacial category. With regards to fractured site, both groups had similar distribution and randomization into midface, mandible and panfacial fractures resulting in statistically insignificant difference. (p-value= 0.327) (Table 1) (Figure 3)

Considering the fragmentation of fractured site, results showed no statistically significant difference between both the groups suggesting equal single and multiple site distribution. Whereas the overall results of study showed higher incidences of multiple site involvement as compared to single site. 78.4% of samples had multiple

fractured site among ERAS group whereas 86.5 % of samples among the control group had involvement of multiple sites. (p value =0.359) (Table 1) (Figure 4). This similar distribution of fractured sites among both the groups might have been the reason for non-significant difference in mean VAS score at admission.

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Maxillofacial trauma is often associated with functional deficits with malocclusion being the most common sequela after trauma. Literature have reported the incidence of malocclusion following trauma ranging between 5-20 % manifesting in the maxillary arch, mandibular arch, anterior and/or posterior dentoalveolar segments, or any combination of these (52). In our study, results were in favor of equal distribution of patients with stable and derranged occlusion among both the groups (p value=0.576) (Table 2) (Figure 5). Overall results revealed higher incidence of malocclusion rates post trauma ranging from 75-80% in both ERAS and control group. Higher malocclusion rates in our study, when compared to the literature were because of the selective inclusion of only those patients who required open reduction and fixation of fractured segments. Whereas for the milder cases where occlusion tended to be stable and in case of minimally displaced fractures, where they could be

managed by closed reduction or non-surgical intervention were already excluded from the study.

Habits such as tobacco (smokeless), alcohol, and smoking are proven to be detrimental leading to poor surgical outcomes such as post-operative infections, non-union, malunion and wound dehiscence. Studies have revealed that smoking is associated with higher rates of non-union and deep surgical site infections after surgical management. Smoking cessation (four weeks before surgery) has shown a decreased rate of postoperative wound infection (53). Pre-operatively among the selected cases there was an equal distribution of patients with history of these above mentioned habits/ addictions among both the groups (p value=0.982) (Table 2) (Figure 6). Of around 75% of total admitted patients in our study had history of habits, either single or in combination and reported with poor oral hygiene.

Pre-operative Care

Patient education and counselling

In our protocol pre-operative management in ERAS group included psychologically preparing the patient for the surgery by providing detailed pre-operative counselling and informing the details of the procedure, length of stay, associated risk factors, nutritional needs, cost factors and treatment outcomes. Efforts were made to understand the patient's expectations and minimize the admission and surgery related anxiety by verbal communication with patient and caregiver in his own language and by means of handbook supplementation and by sharing informative video of instructions in ward after admission.

Patients and caregivers were encouraged for equal participation in decision making. By handing over the audio-visual videos and handbooks patients were able to go through the information repeatedly which developed more clarity regarding the do's and don'ts as compared to the control group which lacked structured reinforced guidance and clarity. Simple diagrammatic handouts in local language ensured better understanding of ongoing and expected events among the ERAS group. Handouts also consisted of patient's daily diary which emphasized on recording of daily health progress and emphasized on attaining preset targets.

Communication channel was better established with these manuals as compared to just verbal communication which frequently leads to non-compliance with given instructions to patients and caregivers as they may fail to register the significance of finer details. This better communication was reflected as reduction in anxiety status of patient and caregivers by lowering of Hospital Anxiety and Depression Scale (HAD) post-surgery and increased overall compliance and patient satisfaction rates. Psychiatric counselling and habit cessation was done prior to surgery for ERAS patients with addictions. Daily reinforcement of the same and handouts for immediate and delayed consequences of tobacco and smoking were handed over to patients and caregivers. Associated post-operative risks and prognosis were explained to patient if he was addicted to any of the habit. Results proved better outcomes were noted with the counselling and habit cessation sessions with statistically significant improvement in oral hygiene status of patients in post-operative phase among ERAS group as compared to the standard care group. This was also reflected in our study results as no statistically significant difference was noted with regards to the incidence of post-operative surgical site infections and need for antibiotic upgrade among both the groups despite of the fact that no post-operative antibiotics were used in majority of cases in ERAS group.

Significant complaints after maxillofacial trauma include facial edema with associated soft tissue injuries and severe pain. Pain is frequently associated with mobility of fractured segments, particularly in cases with mandibular and dentoalveolar segments. To evaluate subjective pain based on the difference in the patient's perception several scales were introduced in the clinical practice to objectify the pain. Many pain measuring tools are mentioned in the literature like Visual analog scale (VAS), Wong-Baker Faces Pain Scale, Comfort scale, McGill Pain Scale, Numeric Rating Scale (NRS), Color Analog Scale and Mankoski Pain Scale. McGill pain scale and Brief Pain inventory scale are complex and are difficult to understand. In our study, we have utilized VAS (Visual Analogue scale) for perioperative pain evaluation which is a comparatively easy and widely used scale in clinical settings. Scores are based on self-reported measures of symptoms that are recorded with a single handwritten mark placed at one point along the length of a 10-cm line that represents a continuum between the two ends of the scale- “no pain” on the left end (0 cm) of the scale and the “worst pain” on the right end of the scale (10 cm) (54).

Generally, the acute inflammatory response peaks within 24–48 hours after trauma and disappears at about 1-week post-fracture (55). The chemical mediators which are released during the inflammatory phase such as bradykinin and histamine stimulate the nerve endings and cause pain while the mobile segments are manipulated (56). The results of our study at admission showed no statistically significant difference in VAS score among both groups. However, measures were taken to reduce the pain and patient's discomfort by temporarily stabilizing the fractured dentate segments under local anesthesia. The time frame for stabilizing fractured segments was specified in our formulated ERAS protocols. In ERAS group within 2 hours after the patient's stabilization in emergency room, the fractured site was temporary stabilized with bridle wiring. By adhering to this time specific criteria's, the patients among ERAS could start early oral intake and were better able to tolerate liquid /soft semi solid diet because of reduction in pain. And majority of patients among ERAS group started oral feeds within span of 6-12 hours post-admission denoting statistically significant when compared to control group when nutritional status was considered. (p-value =0.001*) (Table 4) (Figure 9)

As per the previous primary studies of ERAS society prime significance is given to "Multimodal analgesia"/Balanced analgesia which involves using combinations of nonsteroidal anti-inflammatory drugs (NSAIDs) and paracetamol, anticonvulsant agents, and calcium channel blockers, which all target different pain receptors and pain transmission pathways peripherally and centrally. Using combinations of nonopiate medications and regional analgesia allowed clinicians to avoid or significantly reduce systemic opiate consumption altogether, reserving them as a last resort only. The goal is to optimize pain control while minimizing unpleasant and harmful drug side effects, particularly those caused by opiates. ERAS Society particularly recommends that transition from the intravenous to oral routes should be expedited, if possible, to reduce risks from cannula use, cannula site thrombophlebitis, and facilitate early discharge. Also, opioids have shown to produce side effects such as itching, nausea, bowel ileus, constipation, urinary retention, hypotension, respiratory depression, confusion and hallucinations, and tolerance. Hence, their avoidance of use has been suggested.

After admission patients in both the groups were kept under the coverage of intravenous analgesics and antibiotics till 72 hours from day of admission/surgery

which ever earlier. After 72 hours/after surgery pain management was done by converting intravenous to oral administration of analgesics if needed among ERAS group, else analgesics and antibiotics were stopped. Whereas in the control group patients were kept under coverage of intravenous analgesics and antibiotics of similar dosage from the day of admission till day of surgery and the same was continued post-operatively till discharge. In case of pain after discontinuing I.V analgesics (after 72 hours) oral tablets (combination of Acelofenac and Seratiopeptidase) were provided to ERAS group patients till surgery and noted. In both the groups rescue tramadol was reserved only in cases where pain was not controlled by intravenous/oral NSAIDs. In control group post arch bar placement most of the patients required supplementation of I.V analgesia after procedure. Mean of I.V analgesics supplemented after arch bar besides regular dose of analgesics noted was 0.65 with S.D of 1.136. Mean of additional oral analgesics required after 72 hours in ERAS group on SOS basis was 0.27 with S.D of 0.652. Prolonged intravenous use among control group led to increased discomfort and pain with each injection and also the need for change of cannula site as intravenous medications were continued for longer period in control group. For the pain evaluation, daily VAS score was calculated and a mean value was derived. Whereas among ERAS group the pain associated with the change in cannula sites was minimized with shifting to oral route from intravenous after 72 hours of admission/ surgery whichever earlier and also early discharge contributed significantly to it. Minimum and maximum value of daily VAS score noted in ERAS group was 3 and 6 respectively. While in control group the lowest and highest score noted were 3 and 8 respectively. Our study results have shown statistically significant difference in total number of analgesics used (p value=0.001*) (Table 3,5) at pre-operative phase and on evaluation at 24 hours after surgery. Pre-operatively this reduction could have been resulted from our early fractured segment stabilization and placement of arch bar intraoperatively under general anesthesia thereby minimizing discomfort due to multiple injections and pain associated with wire prick injuries. Pain control was readily achieved in ERAS group with I.V analgesics during initial 72 hours of admission/surgery Beyond 72 hours oral tablets were required in few cases. None of the patients among both the groups required the need for supplementation for opioids as rescue analgesics as pain was manageable with NSAIDS. Postoperatively this reduction in VAS score resulting in

similar pain control among both groups could have been attributed to use of local infiltration of surgical site with long acting local anesthetic 0.5% Bupivacaine.

After admission patients in ERAS group were encouraged and reinforced for starting of oral feeds as early as possible and intravenous fluids were discontinued in majority of cases within 6 hours of admission to ward. Whereas in control group although patients were advised to start oral feeds at earliest but due to lack of repeated encouragement and subsequent reinforcement start of oral intake was delayed and intravenous fluids were continued till needed. Policy of "Restricted fluid therapy" was implemented in ERAS group. This early start of oral feeds led to improved nutritional status of traumatized patients prior to surgery as compared to control subjects.

Multiple randomized controlled studies have shown that greater perioperative fluid administration in major abdominal surgeries has been associated with increased complication rates, prolonged duration of recovery, and increased hospital length of stay. Studies have recommended for a more "restrictive" approach for fluid management as compared with the traditional "liberal" approach. Meta-analysis by Varadhan and Lobo have defined a restricted fluid therapy as less than 1.75 L/day and a liberal fluid therapy as greater than 2.75 L/day .Restricted fluid therapy had 59% fewer complications and a 3- to 4-day reduction in hospital stay (57).

As per the standard pre-operative protocol intravenous fluids are started 6-8 hours prior to surgery when the patient is nil per oral. As per our ERAS protocol we allowed patients to take clear fluids till 2 hours before surgery with carbohydrate loading for morning first cases and on OT call in subsequent cases, this resulted in minimizing the liberal use of intravenous fluids. Volume of pre-operative fluid used among both the groups included fluids administered in ward prior to shifting of patient to OT theater. Amongst control group intravenous fluids were started from overnight. While in ERAS group they had to be started only if patients compliance for clear fluids(which included water, black coffee, tea or fruit juice without pulp) was poor (58).

Our results have shown statistically significant difference with reduction in pre-operative intravenous fluids consumption among the ERAS group as compared to control group (p-value 0.001). The mean pre-operative fluids infused in control group was 632.43mL with SD of 267.7mL. (p value= 0.001*) (Table 2). Minimum and

maximum volume of pre-operative I.V fluids infused among control group was 500mL and 1200mL respectively. Whereas in ERAS group with restrictive fluid therapy approach no pre-operative intravenous fluids were given by ensuring 100% compliance rate in continuing of clear fluids and oral carbohydrate intake. Special emphasis made on early starting of the oral intake have shown to be efficacious in minimizing the complications such as edema, poor wound healing, delayed gastric emptying and fluid overload associated with the liberal use of intravenous fluids.

Trauma results in increased energy and nutritional requirements for wound healing depending on the location and extent of trauma. In hospitalized patients' pre-operative nutritional assessment is essential for the optimal care. Early oral feeding is the preferred mode of nutrition for such patients undergoing surgery. As any surgical procedure as well as trauma itself elicits a series of reactions including release of stress hormones and inflammatory mediators, i.e., cytokines which has a major impact on metabolism. This causes catabolism of glycogen, fat and protein with release of glucose, free fatty acids and amino acids into the circulation compromising healing. As per studies of Cuthbertson et al. they have reported about 20–25% increase in metabolic rate after trauma (59). According to his calculation in a traumatized individual with no oral nutritional support patient loses about 15% of his body mass in 10 days. Hence, maintenance of perioperative nutritional status and especially the degree of diet affects the metabolic response to surgery. Post-operative wound healing is impaired in poorly nourished patients resulting in prolonged stay in hospital and hence oral nutritional feeds are started early as possible. In our study oral feeds were started in 83% of patients among ERAS group preferably within 6 hours after stabilization with regular periodic reinforcement and with start of oral feeds I.V fluids were stopped. Among control group I.V fluids were continued till 12-24 hours post-surgery till adequate restart of oral fluids. Daily reinforcement twice a day for oral feeds in possible form was done in ERAS group. Patient were also asked to maintain a diet chart in provided handbook. Patients were managed with appropriate input from a dietician or nutritionist, and providing ‘‘Immunonutrition" which consisted of nutrition enriched whole protein, liquid nutritional supplements and balanced carbohydrate, essential amino acids (arginine, glutamine, ω-3 fatty acids, and minerals enriched semisolid diet was done (60). Strict diet and nutrition counselling was done daily by diet counsellor for need to assess allowance of type of food intake-

solid/semisolid/ liquid diet, depending upon the severity of trauma, and pain which allowed proper nourishment and rapid recovery post-operatively. Alternatives for solid feeding were advised to patients' caregiver. Statistically significant difference in the starting of oral feeds after admission was noted in comparison of both groups (p value= 0.001*) (Table 4)(Figure 9).Majority of the patients in ERAS group had satisfactory oral intake within 6-12 hours. Whereas the oral intake in control group was restarted within 12-24 hours. This led to reduction in the overall liberal use of intravenous fluids in ERAS group and reduced chances of edema. And also, post-operatively early oral intake improved body function and healing resulting in early return to bowel function post surgically among ERAS group.

Appropriate maintenance of oral hygiene, both prior and after surgery, is an important criterion for the management of maxillofacial fractures. Loss of tissue barriers due to fractures, loose or missing teeth, gingival tears, hematoma, oedema renders inability of patient to maintain oral hygiene by himself and subsequently leads to susceptibility to post-operative infections and dehiscence and increased readmission rates. Pre-operatively both the groups had a statistically insignificant difference in oral hygiene status (p value=0.157) (Table 4)(Figure 8) evaluated by Modified OHIS scale.

In our study in ERAS group, we emphasized on maintenance of oral hygiene by prescribing chlorhexidine mouthwash to reduce the risk of infections in oral cavity and maintaining clean surgical site. Oral prophylaxis was performed with pulsed irrigation devices prior to surgery in ERAS group. Periodic reinforcement of oral hygiene by counselling and evaluation (twice a day) was done till surgery and continued post-operatively.

Routine placement of arch bar in cases of maxillofacial trauma further adds to difficulty in maintenance of oral hygiene. As per our formulated ERAS criteria we considered intra-operative placement of arch bar under general anesthesia both to eliminate pain and discomfort associated with procedure and for better maintenance of oral hygiene .Post-operatively also its early removal along with regular hygiene reinforcements significantly led to improved oral hygiene and patient's compliance as compared to control group (61). With efforts on prioritizing the oral hygiene maintenance there was significant improvement noted in the oral hygiene status post-

operatively in ERAS group which suggested effectiveness of repeated reinforcements and measures taken. (Post-operative p-value 0.001*) (Table 10) (Figure 12). Improved oral hygiene was the main factor that minimized the rates of surgical site infections and need for antibiotic upgrade.

Traditionally, pre-operative fasting guidelines used to be overnight (6-9 hours) prior to surgery. The rationale behind this was to reduce gastric acidity and volume with a consequent decrease in the risk of gastric content aspiration during surgery. However, even this amount of fasting has been associated with greater catabolism and prolonged recovery as a fasted state places the body under greater metabolic stress and reduces its ability to cope with complications. Over the last decade, guidelines for pre-operative fasting period have been modified. As per the latest guidelines often intake of clear fluids such as water, black coffee, tea or fruit juice without pulp is allowed until 2- 3 hours before induction of anesthesia without any associated risks of pulmonary aspiration. This have been shown to reduce the pre-operative discomfort, thirst and dryness of mouth as compared to overnight fasted patients. Among ERAS group patients were nil by mouth for 6 hours for solid foods and allowed clear fluids till 2 hours prior to surgery and compliance was noted. Carbohydrate loading was done mandatorily with apple juice in non-diabetic patients and coconut water in patients with diabetes. Among the control group also, patients were given similar instructions. Nursing staff and caregiver among the ERAS group particularly provided timely reminders for the clear fluids and oral carbohydrate uptake prior to surgery which resulted in significant difference in compliance rates.

As per Cochrane review they have found no increased risk of aspiration in patients who were allowed fluids 2–3 hours prior to surgery compared to patients having undergone a traditional fasting period. Series of catabolic events occurs within the body in response to trauma that leads to a release of stress hormones and inflammatory markers (e.g. cytokines, cortisol, catecholamines and glucagon). These hormones diminish the action of insulin (which is the body's main anabolic hormone) thus leading to a boost in energy substrate mobilization, and catabolism. With the anabolic effect of insulin hindered glucose uptake in peripheral tissue is reduced while production of glucose via gluconeogenesis is enhanced. Both these changes lead to hyperglycemia. In addition, insulin resistance also causes an increase in lipolysis and proteolysis resulting in loss of fat stores and contributing to a negative nitrogen

balance. The combination of protein breakdown, increased gluconeogenesis and inability to utilize glucose leads to a reduction in muscle function. This phenomenon lasts for 3-4 weeks post-surgery and is a major cause of prolonged fatigue following surgery and is found to be a factor determining the length of hospital stay and post-operative recovery.

If this insulin resistance is reduced the carbohydrate uptake, utilization and storage gets improved and protein losses are minimized thus re-establishing the essential anabolic state. For this purpose, in ERAS protocol, we have followed avoiding such prolonged pre-operative fasting periods and used the carbohydrate loading pre-operatively. Continuous saliva production along with gastric contents after prolonged 8 hour fasting period, roughly adds around 500 to 1,250mL of fluid naturally to the stomach. This acidic fluid gets diluted by whatever we take orally. Allowing clear fluid intake 2 hours prior surgery does not lead to increased gastric volumes and in fact reduces acidity of gastric contents. Meta-analysis of prospective control trials has shown a reduction in length of stay by 20% in those receiving pre-operative carbohydrate-rich drinks when compared with a traditional overnight fast and up to 50% reduction in insulin resistance following surgery including abdominal and orthopedic surgery. Improvements in protein metabolism have also been found with a 50% reduction in loss of lean body mass reported when carbohydrate loading was used prior to major abdominal surgery. Carbohydrate loading has also been shown to reduce patient discomfort with regard to thirst, hunger and anxiety while lessening reports of fatigue following surgery (62). Cochrane systematic review by Smith et al. have shown to decreased length of hospital stay without any postoperative complications with pre-operative carbohydrate treatment. Safely this carbohydrate loading can be given in noninsulin dependent diabetic cases. In insulin dependent diabetics cases, pre-operative carbohydrates use has not shown to result in hyperglycemia or delayed gastric emptying. However, blood glucose levels should be monitored at regular intervals (63).

In our study, carbohydrate loading was done by supplementation with 12.5 % apple juice(400mL) / coconut water at 2 hours prior (at 7 am) for 1st case and at OT call for subsequent cases. Results have showed statistically significant difference found among ERAS and control groups regarding “oral feeds and pre-operative compliance for oral carbohydrates” in pre-operative period. (p value= 0.001*) (Table

4). Modified pre-operative fasting guidelines with additional carbohydrate loading 2 hours prior surgery in ERAS group also helped in regulation of the heat production. Carbohydrate loading instructions with 400mL (Real) apple juice and coconut water in diabetics were given to both the groups. But among the control group because of lack of repeated reminders and reinforcement a statistically significant difference was noted with compliance on comparison. Patients' compliance was noted better among the ERAS group and 100% of subjects among the ERAS group followed instructions which were provided and reinforced verbally and by provided handouts. (Table 4). Carbohydrate loading and avoidance of prolonged fasting may have contributed in early discharge of our ERAS patients.

Intra-operative Care

Throat packs are routinely used in maxillofacial surgeries in patients undergoing procedures under general anesthesia. They are often used in the form of a long roll gauze material with a radio-opaque tag. Throat packs helps in prevention aspiration or ingestion of fluid, blood or debris during surgery and therefore reduces the risk of post-operative respiratory complications as well as nausea and vomiting. (40)Throat packs seal the area around the tracheal tube stabilizing the tracheal tube or supraglottic device and preventing its displacement. But the primary disadvantage of throat pack includes the risk of retention and post-operatively potential for airway obstruction and throat pain during initial post-operative phase specially during deglutition. This precludes these patients from taking adequate oral intake.

A recent UK consensus statement and qualitative systematic review states that anesthetist should no longer routinely insert throat packs.(40) Given that retained throat packs pose significant risks, their benefits need to be shown to outweigh these risks if they are to continue to be used in ENT and oral surgery. Among the ERAS study group one of the main attributing factor in early restarting of oral intake was avoidance of intra-operative use of throat pack because of minimized incidences of throat pain and discomfort on swallowing.

As the use of throat packs are thought to prevent the aspiration and ingestion of fluids while surgery there was a belief that they reduced the incidences of post-operative nausea vomiting. But the recent systematic reviews revealed that oropharyngeal packs did not improve or worsen PONV, but resulted in increase of

throat pain. No difference was noted among the patients in whom throat pack was used and among patients where it was not used considering incidences of PONV at 2 hours and 24 hours (64). No studies included in the systematic reviews on use of throat packs in ENT and dental surgeries showed any benefit in reducing PONV with the use of throat packs mentioning no evidence in support of routine use of throat packs (40).

Studies by Fine et al. have reported of higher incidences of throat pain with the use of throat packs till period of 24 hours post-operatively. Meta-analysis of studies reporting incidence of post-operative pain have showed significantly lower incidence of pain at 6 hours in patients among who throat pack was not placed (40).Throat packs have shown to significantly increase the incidence of apthous stomatitis and ulcerations on the lateral surface of the tongue, uvula, soft palate and buccal mucosa because of trauma while insertion and removal causing small abrasions. This leads to post-operative soreness of throat and difficulty in deglutition. Seraj et al. in his study have also assessed airway soiling at the end of the procedure, finding no significant difference in the volume of blood or secretions aspirated from a subglottic port between patients with and without packs. In analogous to these studies in our study also there was a significant reduction in throat pain and discomfort on swallowing found among ERAS group where throat packs were not used as revealed by statistically significant difference between both the groups. (p value= 0.001*) (Table 8). Reduction in throat pain contributed to early start of oral feeds and patients tolerated clear fluids well during early post-operative phase as compared to control group. After 2 hours of complete recovery from anesthesia clear oral fluids were restarted in ERAS group. This also led to minimal use of post-operative intravenous fluids infusion which might have eventually led to decreased chances of fluid overload and reduction in post-operative edema.

With the introduction of newer anesthetic agents, the overall incidence of post-operative nausea vomiting has reduced and is estimated to be around 20–30%. In high-risk patients, the incidence in still as high as 70%, and it is one of the most unpleasant experiences in the post-operative period. As per Apfel et al. risk factors for post-operative nausea vomiting include female gender, a history of motion sickness or PONV, non-smoking status and the use of postoperative opioids. Meta analysis have revealed an overall reduction in risk of PONV by 20% by avoiding agents such as

nitrous oxide (65). In our study among ERAS group, we have used multimodal approach which includes the use of intra-operative antiemetics and a total intravenous anesthesia with propofol instead of inhalational agents. Also, we have avoided the use of the use of nitrous oxide as inhalation agents in ERAS group which has a significant association with increased episodes of post-operative nausea vomiting.

Steroid like dexamethasone in addition to its anti-inflammatory property also has some potential to act as an anti-emetic drug. Precise mechanism of action is not known; however, it has been suggested that the antiemetic effect could be due to the inhibition of prostaglandins, prevention of serotonin release in the gut, reduction in neural 5-hydroxytryptophan levels or release of endorphins. Sore throat and hoarseness are common complications of endotracheal intubation. It may be very distressing for the patient and may lead to sleep disturbances (66). Dexamethasone has also been shown to reduce the incidence of sore throat. Also, intra-operative administration of dexamethasone has reported in reduction of both the incidence (by 36%) and the severity of sore throat in patients undergoing tracheal intubation. Studies have shown that single dose of dexamethasone resulted in earlier oral intake after tonsillectomy surgery. Intra-operative single administration of dexamethasone at induction however was given in ERAS group to control the post-operative nausea vomiting and reduce edema. Edema control and early return to clear fluids was achieved with this strategy. In control group dexamethasone continued for 2- 3 days post-operatively in subsequent tapering doses. However, considering the systemic effects of intravenous steroids on dampening immune system and increased susceptibility of surgical site infections (SSI) we have restricted the use of steroids among ERAS group post-operatively.

In both groups the PONV episodes were similar and with a statistically non-significant difference (p -value 0.134) (Table 8). This reduction in PONV episodes without the use of throat packs can be attributed to the single dose of intravenous dexamethasone 0.25mg/kg at induction and emphasizing particularly for the use of anesthesia drugs that favor more awake and oriented state at extubation with minimal complications like post-operative nausea and vomiting by discussion with anesthesiologist. Also, other factors such as reduction of pre-operative fasting, carbohydrate loading and adequate hydration have influenced patients among the ERAS group in minimizing the PONV episodes. Reduction in PONV episodes was

also achieved among ERAS group without the risk of detrimental effects of prolonged use of steroids. The use of regional anesthetic techniques and the use of non-steroidal anti-inflammatory drugs (NSAIDs) as opioid-sparing strategies and early restarting of oral feeds and normalization of gut have also influenced indirectly in PONV rate reduction.

This reduction in the PONV episodes have helped our patients among ERAS group for early start of oral feeds as compared to control group. Patients were found to tolerate the clear fluids early and restarted the adequate oral intake early. Verbal communication, counselling and regular reinforcements, reduced PONV, absence of throat pain encouraged our patients among the ERAS group for early start of oral intake and thereby minimizing the need of intravenous fluids. Majority of patients among the ERAS group were able to restart the clear oral fluids within 6 hours post recovery from general anesthesia. Patients among control group restarted oral feeds within 12- 24 hours. (p value = 0.001*)(Table 8).Till restart of oral feeds in control group patient's hydration was maintained by infusion of intravenous crystalloid fluids at a rate of 2mL/kg/hour for compensation of intra-operative fluid loss. Whereas among the ERAS group the use of restrictive fluid strategy was readily achieved.

Intra-operative Temperature regulation

Niranjan et al. defines hypothermia as core body temperature below 36°C. About 70% of patient's experiences hypothermia when operations lasts for 2 hours or more. This is of great concern because perioperative hypothermia results in adverse outcomes for patients, such as delayed recovery from anesthesia and increased intra-operative blood loss. Hypothermia at 31.9°C triples the incidence of surgical site infection and increases the duration of hospital stays by 20% (66). In addition to it the patients are also inactive while waiting for surgery and on a prolonged period of fasting of standard 6-12 hours from midnight before which leads to reduction in their metabolism and dysregulation of the mechanism of body's heat production. This increases the chances of intra-operative hypothermia.

In our study special emphasis was given in ERAS group on discussion with anesthesiologist regarding the maintenance of normothermia. Warming mattress were used intraoperatively to maintain normal body core temperature (37) °C which uses low voltage electrically conductive technology to generate a uniform heated surface

and also it consists of control unit to maintain the temperature, as well as an alarm and automatic overtemperature shut-off system to prevent overheating. To maintain normothermia we have administered warm intravenous fluids and blood products and covering the patients promptly after finish of operation with warmed blankets. Improved results were noted in ERAS group as compared to control group with thermoregulation and maintenance of normothermia resulting in reduced infection rates and need for antibiotic upgrade and early discharge ultimately reducing length of hospital stay in our study also.

Arch Bar Placement under General Anesthesia

Routinely arch bar placements are done under local anesthesia which is itself a painful procedure requiring multiple needle pricks while administration of local anesthetics and with passing of interdental stainless-steel wires. Arch bar itself in early acute post trauma phase because of tissue edema and already injured mucosa constantly impinges on lacerated /abraded mucosa and causes discomfort and impairs healing. This increases the patient discomfort and reduces the compliance of patient. Also, arch bar is associated with increased plaque accumulation and ultimately results into poor oral hygiene prior to surgery which predisposes to infection. In our study in ERAS group arch bar placement was done intraoperatively under general anesthesia. Mean timing of application of arch bar among control group was 20 ± 9.9 minutes when performed under local anesthesia whereas it was relatively less required under general anesthesia of around 14.9 ± 5.4 minutes. This noted difference could probably be because of less cooperation of patient when performed under local anesthesia.

Among the ERAS group in majority of cases Ivy eyelets were used in substitution of arch bars as they were less invasive, decreased OT time, post-operatively minimized the chances of ulcerations and discomfort and also removal was easier as compared to conventional arch bars. Mean timing of application of Ivy Eyelets under general anesthesia noted was 9.3 ± 3.2 minutes. In cases with dentoalveolar trauma, fracture of condylar regions or panfacial fractures with severe occlusal derangements where post-operative intermaxillary fixation was expected, arch bar was placed among ERAS group intraoperatively. Early removal of the arch bar/Ivy eyelets on 5^{th} day was considered among the ERAS group in cases with stable occlusion whenever possible.

Pain associated with the multiple gingival and mucosal injuries associated with arch bar in place or during its placement by the passing of stainless-steel wires transmucosally was not observed in ERAS group (p value = 0.001*) (Table 12) (Figure 15,16) when compared to control group. This also reduced the need for additional and rescue analgesics post placement of arch bar. (p value=0.009*) (Table 3). Need for additional analgesic was higher among the control group after placement of arch bar under local anesthesia. Inj. Diclofenac had to be supplemented in each case after the arch bar placement in control group.

Intra-operative local surgical site wound irrigation

Prophylactic intra-operative wound irrigation of the subcutaneous and deeper soft tissues prior to skin or mucosa closure with saline or antiseptic solutions represents an easy and economical option to reduce surgical site infection (SSI) rates and is frequently used in surgical practice. However, the latest official guidelines for the prevention of SSI by the Centres for Disease Control and Prevention (CDC) and the World Health Organization (WHO) conclude that intra-operative wound irrigation only with saline is not efficient and must be done with polyvinylpyrrolidone-iodine (PVP-I) solutions for an added potential benefit (67).

Wound irrigation aims to reduce the microbial burden by removing tissue debris, metabolic waste, and tissue exudate from the surgical field before site closure. Antibiotic agents are widely used in irrigation fluids amongst all surgical disciplines. The combination of intrawound vancomycin powder and betadine irrigation was found to reduce SSI rates after posterior spinal fusion in patients with idiopathic scoliosis (68). In another study of spine surgery patients, the same combination was found to reduce the proportion of gram-positive cultures and MRSA infections. Prophylactic irrigation with vancomycin solution (1000 mg/L; 2 L) significantly decreases the incidence of acute surgical site infection after primary joint replacements in orthopedics surgeries. Thus, this strategy appears to be safe, efficacious, and inexpensive method for reducing the incidence of acute surgical site infection (69).

Vancomycin is a type of glycopeptide antibody. It was initially used to treat inflammation caused by *S. aureus* that was not controlled by penicillin because of patient allergy or bacterial resistance. This drug adheres to the bacterial cell wall and

causes various defects, including changes in the permeability of the bacterial cell membrane and selective inhibition of the formation of several RNAs. The local application of vancomycin ensures that a high concentration of antibiotics accumulates at the surgical site while maintaining low drug concentrations in the blood, killing Gram-positive bacteria in the surgical site while causing little harm to internal organ (70).Topical vancomycin has been hypothesized to achieve a higher local concentration of antibiotic avoiding toxic systemic doses, and decreasing the risk of associated bacterial (71).

In our study copious irrigation of the surgical site was done with betadine followed by saline and local vancomycin antibacterial solutions in ERAS group as compared to only betadine and saline irrigation in control group. Vancomycin powder 1gm mixed with 50 mL saline was used for irrigation purpose prior to closure. Surgical site infection and need for antibiotic upgrade is similar with non-significant difference in both the groups suggesting the efficacy of local irrigation by vancomycin in ERAS group equal to prolonged post-operative I.V antibiotics of control group. Post-operatively the factors contributing to prevention of SSI's that focused upon in ERAS group were hygiene maintenance, daily betadine irrigation of sutured site, proper nutritional support, pre-operative and post-operative optimization of comorbidities and reduced length of stay ultimately reducing chances of nosocomial infections. Also post-operative oral hygiene maintenance counselling played a major role in improvement and minimizing the surgical site infection rates as post-operative antibiotics were not routinely used in ERAS group.

Postoperative Care

Goal of postoperative fluid therapy is to maintain adequate tissue hydration, electrolyte homeostasis while avoiding excess salt and water retention. After surgery patients are more prone to electrolyte changes due to blood and tissue fluid loss and because stress response to surgery which leads to inability of the patients to receive adequate necessary nutrition with most common incidences of post-operative hypocalcemia and hyponatremia.

Fluid requirements intraoperatively are categorized into maintenance therapy and volume therapy. Maintenance therapy is to cover fluid lost by urine output and other insensible losses which is maintained with crystalloid infusions at rate of 1 to 1.5mL/kg/hour. Whereas volume therapy refers to the administration of large boluses of IV fluid (typically 250mL) to assess volume responsiveness and treat objective evidence of hypovolemia to improve intravascular volume and oxygen delivery. Primarily the maintenance IV fluid for any major surgery should be an isotonic balanced crystalloid which is considered as fluid of choice. It should have similar plasma electrolytes contents and acid- base equilibrium such as Ringer's Lactate. Recently there has been an increasingly evidence that 0.9% saline should not be used as it more likely associated with hyperchloremia, metabolic acidosis, and acute kidney injury (71). In cases of maxillofacial trauma majority of requirements are easily fulfilled with maintenance intravenous fluid therapy. However still ERAS emphasizes on stopping of I.V fluids at the earliest by restarting of oral feeds.

In our study patients in ERAS were started with clear oral feeds post-operatively within 6 hours of extubation provided there was no post-operative nausea and vomiting. And post-operative I.V fluids were stopped, provided vitals were stable. Whereas in control group post-operative I.V fluids were rushed till next 12 - 24 hours till adequate oral fluids were restarted which resulted in statistically significant difference in volume of I.V fluids used. (p value=0.001*) (Table 5). Difference among both the groups in starting of oral diet was majorly due to multiple reinforcements in ERAS group post-operatively to start clear fluids as early as possible after recovery.

Oral hygiene maintenance even after the oral prophylaxis is challenging. In ERAS group we have emphasized on regular counselling for maintenance of oral hygiene post oral prophylaxis. Repeated reminders for using of chlorhexidine mouthwash twice per day after feeds were given to patients by doctors and caregiver's ensured adequate hygiene maintenance. Daily twice irrigations were performed in ERAS group. Whereas in control group poor hygiene maintenance, no regular reinforcements, pre-operative arch bar placements further detoriated the oral hygiene. Better oral hygiene index scores were thus noted in ERAS group post-operatively with modified OHIS index.

In our study on admission among both the groups there was no difference among the selected cases considering the status of oral hygiene. (p value=0.157). However, at a period 5 days after surgery results have revealed significant improved oral hygiene status recorded with modified oral hygiene index among the ERAS group. (p value= 0.001*) (Table 10) (Figure 12). Better oral hygiene would also have contributed in minimizing surgical site infections.

Infections occurring as a post trauma sequalae leads to significant morbidity and increased healthcare costs. Overall, infection rates after maxillofacial fractures widely vary across studies ranging from 0% to 62% (72). To prevent such infections, systemic antibiotic prophylaxis is an accepted strategy in day-to-day clinical practice. However, the optimal type and duration of prophylaxis still remains controversial. Furthermore, with the emergence of increasing antimicrobial resistance surgeons are becoming more aware of the importance of limiting the antibiotic use.

Recent international surveys among maxillofacial trauma surgeons indeed concludes that most of them continue antibiotic prophylaxis longer than proposed, which leads to overuse of antibiotics (73) (15). Prolonged systemic antibiotic prophylaxis can lead to adverse effects such as rashes, diarrhea and *clostridioides difficile super* infections, nausea, vomiting and abdominal pain, malaise, and fatigue (74) (75).The overuse and improper use of antibiotics are considered important drivers for the emergence and spread of antimicrobial resistance(AMR).AMR occurs as a natural evolutionary response to antimicrobial exposure, whereby microorganisms acquire the ability to withstand antimicrobial drugs via mutations in chromosomal genes and by horizontal gene transfer. Therefore, significant efforts

have been placed on the development of restricted antibiotic policies to ensure use of antibiotics. Antibiotics also have an additional financial costing to both patient and healthcare provider.

Morris and Kellman in their study defines timings of prophylactic antibiotics as -pre-operative (from time of injury up to 2 hours prior to surgical intervention), perioperative (from 2 hours prior to surgical intervention until completion of surgery) and postoperative (from the completion of the surgical procedure). Habib et al. defines post-operative antibiotics when continued for more than 24 hours. Whereas as per his meta-analysis post-operative (24–72 hours) regimens and extended (>72 hours) courses of post-operative antibiotics failed to reduce the rate of surgical site infections (33).

Systematic review by Dawood et al. concludes that antibiotic prophylaxis beyond 24 hours postoperatively did not lower the incidence of SSIs regardless of the location of the facial fracture (76). A recent systematic review by Delaplain et al. confirmed a higher rate of surgical site infection with the use of post-operative antibiotics for more than 72 hours (32).

Therefore, significant efforts have been placed on the development of restricted antibiotic policies and procedures, to ensure use of antibiotics is restricted to cases when the incidence and risk of infection are high and the consequences of infection are significant.

Recent meta-analysis by Habib et al. signified that the extended use of postoperative antibiotics did not significantly decrease the likelihood of infection rates in patients with mandibular fractures. Post-operative antibiotics when used for greater than 24 hours did not showed any additional benefit (33). Post-operative short (1 day) course of antibiotic treatment showed similar results as extended course. Hence, study concluded that antibiotic prophylaxis beyond 24 hours postoperatively was not associated with a lower incidence of SSIs, regardless of the location of the facial fracture(32).Therapeutic guidelines recommends that antibiotic prophylaxis should not be used unless there is a clear indication to do so. The optimal time for pre-operative intravenous administration should be within 60 minutes prior to surgical incision. And a single pre-operative dose of antibiotic is sufficient for the majority of procedures. Therefore, significant efforts have been placed on the development of

restricted antibiotic policies and procedures, to ensure use of antibiotics is restricted to cases when the risk of infection is high and the consequences of infection are significant. Following these guidelines in our study among ERAS group post-operative antibiotics were not used until needed.

In our study in ERAS group for the optimization of infection patients were kept on pre-operative antibiotics till 72 hours after admission/surgery whichever earlier and were instructed to use chlorhexidine mouthwash twice daily. As a standard protocol single dose of pre-operative antibiotics were administered 1-hour prior to incision which included Inj. Cefosulbactum 1.5gm I. V and Inj. Metronidazole 500mg I.V. Post-operative extended use of antibiotics were not considered among ERAS cases except in cases of pre-existing infections, prolonged duration of surgery (of more than 6 hours) and contaminated wounds. Whereas in control group antibiotics were given extensively via intravenous route from day of admission till discharge irrespective of wound type, duration of surgery, open or closed fractures type, anatomic location and contamination. Our results have revealed no statistically significant difference among both the groups in terms of incidences of surgical site infections and need for antibiotic upgrade. Infection rates were similar in both the groups. Like previous mentioned studies our results also supported the conclusion that prolonged use of post-operative antibiotics are unwarranted.

This suggested the prolonged use of antibiotics had no role in minimizing the infection rates. Rather they can increase other complications of thrombophlebitis, pain due to multiple skin puncture increased, healthcare expenditure costs, weakening of immune system on long run and increased the risks of developing of antimicrobial resistance. Infections rates were well controlled among majority of patients in ERAS group even with the use of short course of antibiotics.

No significant increase in infection rates were noted among ERAS group inspite of no use of postoperative antibiotics in majority of cases. Statistically insignificant difference was noted among both groups on comparison for the need of antibiotic coverage (p-value= 0.572) (Table 10) and rates of surgical site infections (p value= 0.691) (Table 10). In specific cases with extensive facial trauma with soft tissue avulsions or in cases of long duration surgeries, antibiotics were given postoperatively in ERAS group also (4 cases). Among 5 cases in control group for

above similar reasons antibiotic upgrade by addition of Inj. Amikacin was considered. For these specific cases antibiotic coverage was given with Inj. Cefosulbactum, Inj. Amikacin and Inj Metrogyl till discharge even in absence of any clinical signs of infection.

For another 3 cases in ERAS group and 4 cases in control group signs of early infection were noted on follow up. For these surgical site infections Tab. Clindamycin 300mg BD in both the groups. Postop postoperatively on 5^{th} day after surgery on evaluation prophylactic antibiotics were administered in 4 cases in ERAS group and 5 cases in control group having susceptibility of developing infections even in absence of any clinical signs of infection. Hence, antibiotic upgrade/addition included both the patients requiring prophylactic antibiotic and in whom early signs of infection were noted.

Prolonged pre-operative and post-operative steroids were not used among ERAS group. Single dose of intravenous dexamethasone was used at the time of induction among ERAS group to control post-operative edema and prevent PONV. Oral Seratiopeptidase was used in ERAS group for reduction of edema. Whereas in control group intravenous Dexamethasone 8mg TDS with subsequent tapering was used for edema control in both pre and post-operative period. Recent systematic review and meta-analysis by Sivaramakrishnan G et al. reports efficacy of oral seratiopeptidase as comparable to corticosteroids with better safety profiles. In spite of not using prolonged steroids, patients among ERAS group reported marginally higher but non-significant difference in edema when compared to the control group. (Table 10)

As one of the key components of ERAS includes pain management by multimodal analgesia, standardized analgesic regimens were administered to patient for implementation of opioid sparing analgesia. As the pre-operative pain predicts patients' surgical course and can lead to increased post-operative pain, psychologic fear factors exacerbating pain were readily controlled with pre-operative and immediate post-operative adequate patient counselling.

In our study for evaluation of anxiety in subjects pre and post-surgery we have used Hospital Anxiety and Depression Scale (HADS) introduced by Zigmond and Snaith. Major perk of using this scale is relatively easy to use and less time

consuming. It assesses both anxiety and depression which are seen in majority of cases to coexist. Questionnaire consisted of seven interview questions for anxiety and seven of depression taking roughly around 2- 5minutes.0-7 scoring indicated normal patients whereas 8-10 and 11-21 scoring indicated borderline and severely affected anxiety and depression cases respectively.(77) There was reduction in anxiety score post surgery noted in ERAS group. (p value=0.001*) (Table 8,9). Results revealed a positive correlation between decreased anxiety and post-operative pain control with lesser need of analgesics noted in ERAS group.

Among ERAS group we have employed local infiltrative technique anesthesia with 5mL of 0.5 % bupivacaine into the tissues prior to surgical site closure. Injecting local anesthetics directly to wounds provided analgesia by blocking pain transmissions from nociceptive afferents receptors at surgical site incisions and inhibited local inflammatory response to injury, thereby reducing the release of inflammatory mediators and reducing post-operative edema.

There was no statistically significant difference noted in the post-operative pain levels by VAS score among both the groups at 24 hours (p value 0.655) (Table 6) (Figure 10). Adequate pain control with just oral analgesics in ERAS group in combination with long-acting local anesthetic bupivacaine and anxiety reduction measures suggests successful implementation of ERAS programmes. Whereas among the control group intravenous analgesics were utilized till discharge. Early removal of the cannula and shifting to oral analgesics among ERAS group resulted in early discharge and also increased patient compliance. There was a significant difference noted considering the use of analgesics in both the groups. In our study in none of the patient's opioids medications which was reserved as rescue analgesic was used. Eliminating the opioid use in ERAS group also benefitted in promoting early mobilization, bowel motility and prevention of nausea vomiting and also preventing the consequences of long-term opioid use.

Arch bar/Ivy loop placement intraoperatively and their early removal of arch bar in ERAS group further added to pain control as impingements by wires, traumatic ulcerations, wire adjustments on traumatized mucosa could be avoided. This indirectly led to reduction in consequences like poor oral hygiene, delayed healing, dehiscence and risks of surgical site infections.

Early shifting of patient to ward, preferably within 2 hours after stabilization was encouraged after extubation. In ERAS group IV cannulas, surgical drains and urinary catheters hindering in early mobilization were quickly removed post-surgery thus reducing morbidity and promoting early discharge and chances of hospital acquired nosocomial infections. Studies reveal that prolonged use of urinary catheters leads to increased risk of catheter associated urinary tract infection by 5 % per day. Also, around 3.6% of those developing catheter associated urinary tract infection develop urosepsis and require prolonged hospitalization (78). Policy of early removal of intravenous and urinary catheter post-surgery within 24 hours to minimize chances of urinary tract infections and early return of bladder to normal function was employed in ERAS cases. Though majority of our patients among the both groups did not require catheterization, still if in case of insertion in longer surgeries their early removal within 24 hours was considered in ERAS group. However the early removal of IV cannula in ERAS group played a major role in unhindered early mobilization after surgery as no postoperative IV antibiotics, analgesics or intravenous fluids were administered. This led to early mobilization of patient and successful ambulation thereby preventing post-surgical complications of thromboembolisation and attempted towards early return to normal body function. Early ambulation was further encouraged by counselling which favored ERAS results thereby decreasing patients' hospital stay and increasing patient satisfaction with quality of treatment which ultimately decreased total hospital stay costing as compared to the control group.

Early discharge criteria and Cost analysis

ERAS implementation benefitted both to the patients and the health services as a whole. Significant reductions in median length of hospital stay causes a significant reduction in hospital costs. This led to more availability of hospital beds and huge number of patients were benefitted by this availability.

As per studies by Anderson et al. they defined discharge criteria which comprised of ability of patients to tolerate solid food, complete mobilization and transition of analgesics to oral. Whereas Delaney et al. defined additional discharge criteria particularly concerning on passage of flatus or stool and patient agreement with the scheduled discharge (79). Bradshaw et al. criteria consisted of return of normal body temperature, gastrointestinal function used three discharge criteria for

ERAS patients including normal body temperature, return of gastrointestinal function and ability to tolerate oral diet (80). Our formulated fast track (ERAS) programmes optimized perioperative care and accelerated recovery, reduced morbidity and shortened mean hospital stay.

Patients among ERAS group were relatively discharged early with majority of subjects being discharged within 24-48 hours after surgery when compared to control group. In control group most of the patients were discharged after 48 hours.This resulted in statistically significant difference in post-surgical discharge timings. This was achieved with early mobilization, early removal of cannulas, catheters and surgical drains, avoidance of intravenous antibiotics and analgesics and early return to oral diet. (Table 12)

Cost analysis comparison of two groups in our study was calculated as summation of charge of hospital stay per day and prescription cost. Hospital stay per day costed Thirty five rupees (Rs 35/-) in general ward and antibiotic and analgesic costing both in hospital and after discharge were included in control group whereas for ERAS group hospital stay charges and only analgesic costings during hospital stay and at discharge were main expenses. Average hospital stay among ERAS group was 4-5 days whereas for control group it was 8-9 days. Statistically significant difference was noted with resultant reduction in cost factor among ERAS group (p value= 0.001*) (Table 12). Early discharge significantly resulted in decreased financial burden in ERAS group. Indirectly this reduction also benefited patients by early return to job and avoidance of loss of wages per day.

Adequate Communication

Similar instructions and explanations were given to patients and their caregivers in both the groups. However, in ERAS a supplementation in form of easily understandable handouts and repeated reinforcements at each step was done both by doctors and nursing staff. This attributed to a better compliance and a statistically significant difference in overall satisfaction reported by patients in ERAS group. All patients in ERAS group had reported complete satisfaction with the communication provided to them. However, only 4 patients in control group were fully satisfied with the provided communication. Especially in set ups with patients having low educational and socioeconomic status multiple repetition of instructions and

information needs to be done. In such cases chances of instructions not perceived completely are high. Communication in health care is a topic of great discussion everywhere. Poor communication can result in compromise in patients' safety while a good communication can enhance patients' overall perception of healthcare. There is a room for improvement for both content and timelines of communication. That is why even during undergraduate and post graduate training communication as an essential skill emphasized considerably these days. (Table 12) (81).

Ability to return to normal life

At a follow up period of 2 weeks ERAS group patients showed remarkably increased patients satisfaction rates (p value= 0.001*) (Table 12) (Figure 13). On discharge patients among both groups were explained regarding both their post-operative after care at home and steps for early return to normal life. Results revealed that all patients among the ERAS group returned to their normal life within 7 days of discharge. Whereas with lack of repeated reinforcements time of discharge, patients among control group had not returned to normal life even at 2 weeks. Factors attributing to early return to normal life among ERAS group were early discharge, early removal of arch bar and thereby reducing discomfort, no prolonged use of intravenous medications, minimal oral medications on discharge and reduced levels of anxiety. Thus, our study suggests effective implementation of ERAS protocols in routine practice in the field of maxillofacial surgery. Successful multidisciplinary collaboration is the prime requirement for its success in clinical settings. Improvement in the quality of care and patient outcomes was established with the use of ERAS guidelines.

CONCLUSION

1. Distribution of sociodemographic features and baseline parameters including age, sex, location and number of fractured sites, occlusion and subjects presenting with habits were comparable among both the groups with non-significant difference suggesting successful randomization.
2. Pre-operatively evaluated parameters such as levels of pain, anxiety and oral hygiene were similar among both the groups with no statistically significant difference found.
3. The pain evaluation by VAS score at 24 hours after surgery showed no statistical difference among both the groups suggesting equal efficacy of combination of oral analgesics and local infiltrated anesthetic bupivacaine in ERAS group to I.V analgesics administered post-operatively in control group.
4. Pain both pre-operatively and postoperatively was managed by NSAIDS use. Tramadol which was reserved as rescue analgesic was not required in any of cases among both the groups. This supported success of opioid sparing strategy which is promoted in ERAS protocols.
5. In pre-operative and post-operative period at 24 hours after surgery there was a statistically significant difference noted for the intravenous fluids administered among both the groups. ERAS group was kept on restrictive fluid therapy by shifting to oral feeds at the earliest. This promoted and facilitated for early discharge among ERAS group.
6. Post-operative period at 24 hours after surgery showed significant reduction in the anxiety levels among the ERAS group indicating towards success of employed counselling methods.
7. Oral hygiene index evaluation in the post-operative follow up period of 5 days after surgery showed significant improvement in oral hygiene status among the ERAS group. This could have been a significant contributing factor for the reduction of surgical site infections despite avoidance of post-operative antibiotics and lesser need for antibiotic upgrade in ERAS group.

8. PONV episodes at 24 hours of surgery were comparable among both the groups with no statistically significant difference which suggested that single dose of pre-operative administered dexamethasone at induction and starting of oral feeds orally were sufficient in minimizing the PONV episodes in ERAS group.
9. Statistically significant difference was noted for throat pain and discomfort on swallowing post-operatively among ERAS group where throat pack was not used.
10. No statistically significant difference was noted in post-operative edema at the operated surgical site at 24 hours after surgery and after 5 days of surgery indicating similar efficacy of oral seratiopeptidase in controlling of edema in ERAS group when compared to 4-5 days of steroid use in control group.
11. No statistically significant difference was noted in surgical site infections and the need of antibiotic upgrade among both the groups. Restricted antibiotic use in ERAS group showed similar effectiveness as extended course used in control group.
12. Comparison of pain and discomfort with arch bar and multiple needle pricks showed statistically significant difference among both the groups with resultant reduction in the discomfort rates reported by ERAS group subjects.
13. Post-operatively statistically significant difference was noted in the ability of patients in quitting of habits/ addictions among both groups. Majority of patients among ERAS group were able to quit their habits when evaluated at follow up period of 2 weeks after surgery.
14. Analysis of parameters such as post-surgical discharge timings, communication from doctor's side, hospital stay cost analysis and requiring days for return to normal life showed statistically significant difference signifying there were early hospital discharge rates, adequate communication from doctor's side, reduction in hospital cost expenditure and early return to normal function in ERAS group.

15. Overall satisfaction rate comparison showed statistically significant difference with high patient satisfaction rate reported at final follow up among the ERAS group.

16. This study is a qualitative study with the modifications aiming on improvement of quality of care and comfort provided to the patients which involves minor alterations in the traditional care provided. Statistically significant results among ERAS and control group for few parameters were expected. For instance, volume of I.V fluids used, discomfort and impingements with arch bar, at follow up periods in control group were bound to be certainly high as compared to ERAS group where in majority cases we had avoided I.V fluid administration and removed arch bar on discharge. Our study particularly aims to represent that ERAS emphasis on small factors which does not change the outcomes drastically but strict adherence to these small yet key factors, can surely bring change in post-operative quality of life, patients perception and overall satisfaction. We need to revaluate our standard regular practice and reconsider what practices to be discontinued, retained and modified.

Future Implications

1. Some modifications to our standard care practice is required as ERAS have proven to effectively alter patients response to surgery, minimize post-operative stress, enhance recovery and drastically improve patients perception towards traumatic insults and quality of care in total.

2. Adherence to ERAS protocol may require intensive team efforts with cooperation from even patients and their caregivers.

3. Initially adherence implementation may be difficult but as these ERAS protocols will get standardized with frequent implementation, improvement of patient care is expected.

STRENGTH OF STUDY

1. This study might be the first in literature where ERAS protocols have been formulated and implemented among the maxillofacial trauma cases. We have formulated and modified conventional fast track ERAS protocols specifically considering the care required for maxillofacial trauma patients undergoing open reduction and fixation.

2. There is no randomized clinical control trial comparing the efficacy of ERAS protocols with standard regular care in patients with maxillofacial fractures.

3. We have obtained ethical clearance from Institutional Ethical Clearance Committee (IEC) and study was conducted strictly adhering to methodology as per protocol.

4. We have evaluated all relevant parameters like pain, anxiety, rescue analgesics and intravenous fluids use, oral hygiene, timing of shift to oral fluids, compliance for presurgical oral carbohydrates, throat pain and discomfort, PONV episodes, post-operative edema, surgical site infections, need for antibiotic upgrade, discharge timings, overall satisfaction, effectiveness of counselling in quitting habits, discomfort with multiple injections, cost analysis and return to normal life.

5. The major strength of our study is its robust study design. It is a randomized controlled trial with adequate concealment of allocation with computer generated codes in sealed envelopes which have minimized the patient selection bias.

6. In our study, randomization was successful as the both the groups were similar with regards to base line demographic variables.

7. There was homogenous distribution in both the groups and further non-significant difference in trauma characteristics in form of type of fractures, site of fractures, occlusion status and oral hygiene status.

8. Study includes both subjective and objective parameters evaluated at specific time periods.

9. All included patients among study completed predetermined follow up period.

LIMITATIONS

1. Our present study required both formulation and implementation of ERAS protocol for maxillofacial trauma. As it was the first study of ERAS protocol in field of maxillofacial trauma, sample size included in our study was small. Though our results with this sample size have shown promising differences in intervention group, further multicentric studies with comparatively larger sample size are required for assessing feasibility and related outcomes of ERAS protocols.

2. Protocol for antibiotic standardization and reducing antibiotic use to minimum could not be done in our study. The most significant factor limiting strict use of single antibiotic loading dose only prior to incision was delay in surgery due to increased patients load and operation theater unavailability.

3. ERAS protocols require modification which further requires multiple checks and balances at frequent time periods in order to improve the patient care when compared to existing standard surgical practice. Hospital settings with overburdened clinical load and limited manpower resources can be a hinderance in successful implementation of ERAS protocols.

4. Successful habit's de- addiction evaluation requires longer follow up periods. In our study till 2 week follow up period we could accomplish habit's de addiction and motivation for the same was persisting with the measures taken among ERAS group. Similar results were noted for the maintenance of oral hygiene also. Ill effects of both these factors could be negated successfully in ERAS group in our study with no major surgical site infections or complications noted.

5. Precise estimation of actual cost analysis was not done in our study. Inclusion of patients daily earning loss while hospital stay until they returned back to normal work was not calculated.

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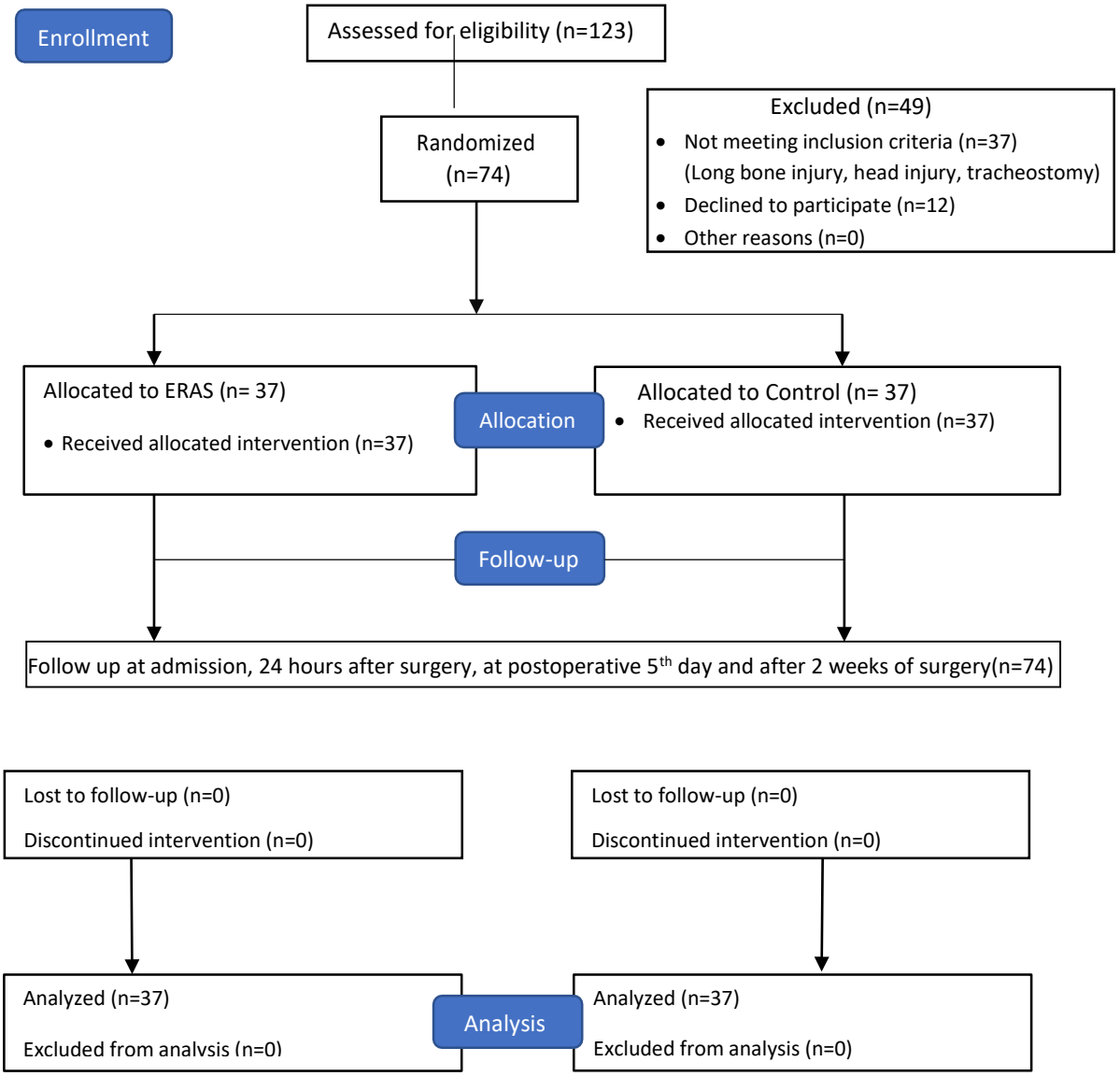
ANNEXURE I: CONSORT FLOW DIAGRAM

The present study was conducted in the Department of Dentistry of AIIMS, Jodhpur according to following CONSORT flow diagram.

CONSORT FLOW DIAGRAM



ANNEXURE II: INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2021/3524 **Date: 12/03/2021**

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2021/3359**

Project title: **"Efficacy of enhanced recovery after surgery (ERAS) protocol in maxillofacial trauma: A randomized controlled trial"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**M.D.S. Dissertation**
Student Name:	**Dr. Astha Jani**
Guide:	**Dr. Ankita Chugh**
Co-Guide:	**Dr. Kirti Chaudhry Dutt & Dr. Pradeep Kumar Bhatia & Dr. Pravin Kumar**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation.

If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member Secretary

Member secretary
Institutional Ethics Committee
AIIMS Jodhpur

Basni Phase-2, Jodhpur, Rajasthan-342005; **Website:** www.aiimsjodhpur.edu.in; **Phone:** 0291-2740741 Extn. 3109
E-mail : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com

ANNEXURE III A: PATIENT INFORMATION SHEET (ENGLISH)

Oral and Maxillofacial Surgery

Department of Dentistry

All India Institute of Medical Sciences, Jodhpur

PATIENT INFORMATION SHEET

TITLE**:** **Efficacy of Enhanced Recovery after Surgery (ERAS) Protocol in Maxillofacial Trauma: A Randomized Controlled Trial**"

You have been requested to volunteer for a research study, in which data would be collected from patients with maxillofacial fractures. The data collected will include personal details such as address, contact numbers, educational qualification, socioeconomic status. The surgical treatment will be provided as per requirement, and would carry its own risks and benefits. The risks and benefits of the treatment provided do not have any correlation with this study. Parameters such as pain, anxiety score, oral hygiene, compliance for oral feed, infection, swelling, throat discomfort, discomfort due to arch bar placement along with cost analysis will be assessed pre- and post-operative respectively and questions evaluating the satisfaction with symptom state will be put forth. This study will require additional follow up visits/expenses/invasive procedures. All the data collected shall be kept confidential and will be used only for the purpose of research.

For further queries, contact:

Dr. Astha Jani

Post graduate student

Phone number -9265067931

Department of Dentistry

Section of Oral and Maxillofacial Surgery

AIIMS, Jodhpur

ANNEXURE III B: PATIENT INFORMATION SHEET (HINDI)

ओरल एंड मैक्सिलोफेशियल सर्जरी

दंत चिकित्सा विभाग

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर

मरीज़ सूचना पत्र

TITLE: **Efficacy of Enhanced Recovery after Surgery (ERAS) Protocol in Maxillofacial Trauma: A Randomized Controlled Trial**

आपसे एक शोध अध्ययन में सम्मिलित होने का अनुरोध है। जिसमें मैक्सिलोफेशियल फ्रैक्चर वाले रोगियों से डेटा एकत्र किया जाएगा। एकत्र किए गए डेटा में पता, संपर्क नंबर, शैक्षिक योग्यता, सामाजिक आर्थिक स्थिति जैसे व्यक्तिगत विवरण शामिल होंगे. सर्जिकल उपचार आवश्यकता के अनुसार प्रदान किया जाएगा। प्रदान किए गए उपचार के जोखिम और लाभों का इस अध्ययन के साथ कोई संबंध नहीं है। ऑपरेशन से पहले और बाद में पैरामीटर्स जैसे दर्द, तनाव, मौखिक स्वच्छता, मौखिक फ़ीड के लिए अनुपालन, संक्रमण खतरा, सूजन, गले में तकलीफ, आर्च बार लगने के कारण बेचैनी के साथ-साथ लागत विश्लेषण का मूल्यांकन किया जाएगा। लक्षण स्थिति के साथ संतुष्टि का मूल्यांकन करने वाले प्रश्न सामने रखे जाएंगे। एकत्र किए गए सभी डेटा को गोपनीय रखा जाएगा और इसका उपयोग केवल अनुसंधान के उद्देश्य के लिए किया जाएगा।

अधिक प्रश्नों के लिए, संपर्क करें:

डॉ। आस्था जानी

ओरल और मैक्सिलोफैशियल सर्जरी

मोबाइल: 9265067931

पोस्ट ग्रेजुएट छात्र

ANNEXURE IV A: INFORMED CONSENT FORM (ENGLISH)

Oral and Maxillofacial Surgery
Department of Dentistry
All India Institute of Medical Sciences, Jodhpur
INFORMED CONSENT FORM

TITLE: **Efficacy of Enhanced Recovery after Surgery (ERAS) Protocol in Maxillofacial Trauma: A Randomized Controlled Trial**

I declare that on date..... All the details of this information sheet given to me has been explained in language that I comprehend best. I have been informed that Enhanced recovery after surgery (ERAS) Protocols will be implemented on me for early and improved recovery and parameters such as pain, anxiety score, oral hygiene, compliance for oral feed, infection, swelling, throat discomfort, discomfort due to arch bar placement along with cost analysis will be done pre- and post-operative respectively.

I understand that all information related to me in this research will be kept safe by the responsible staff of AIIMS Jodhpur. I allow them to see all the information related to me. I have been told that all the information related to me will be kept confidential. I have also been told that the results of this research can be published in any book or journal and can be displayed in any conference. I have also been told that my name or any other identity will not be used without my consent. I am participating in this research with my consent and I am aware that I can refuse to participate in this research at any time without any reason.

I agree to participate in this research.

(Signature)

Place: Date:

Name of the Participant: _____

Son/Daughter/Spouse of: _____

Complete postal address: _____

_____

This is to certify that the above consent has been obtained in my presence.

1) Witness – 1

Name:

Address:

2) Witness – 2

Name:

Address:

Signatures of the principal investigator:

ANNEXURE IV B: INFORMED CONSENT FORM (HINDI)

ओरल एंड मैक्सिलोफेशियल सर्जरी

दंत चिकित्सा विभाग

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर

TITLE: **Efficacy of Enhanced Recovery after Surgery (ERAS) Protocol in Maxillofacial Trauma: A Randomized Controlled Trial**

सहमति पत्र

मैं घोषणा करता/करती हूं कि दिनांक ..... सभी विवरण मुझे दिए गए है। इस सूचना पत्र को मुझे मेरी भाषा में समझाया गया हैऑपरेशन के पूर्व और बाद किया जायेगा मुझे सूचित किया गया है कि एनहांस्ड रिकवरी प्रोटोकॉल मेरी जल्दी और बेहतर सुधार के लिए मुझ पर लागु किये जायेंगे। दर्द विश्लेषण स्कोर, मौखिक स्वच्छता, मौखिक फ़ीड के लिए अनुपालन, संक्रमण, सूजन, गले में तकलीफ, आर्च बार लगने के कारण असुविधा के साथ लागत विश्लेषण ऑपरेशन के पूर्व और बाद किया जायेगा । मैं समझता /समझती हूं कि इस शोध में मुझसे संबंधित सभी जानकारी एम्स जोधपुर के जिम्मेदार कर्मचारियों द्वारा सुरक्षित रखी जाएगी। मैं उन्हें मुझसे संबंधित सभी जानकारी देखने की अनुमति देता हूं ।मुझे बताया गया है कि मुझसे जुड़ी सभी जानकारियों को गोपनीय रखा जाएगा। मुझे यह भी बताया गया है कि इस शोध के परिणाम किसी भी पुस्तक या पत्रिका में प्रकाशित किए जा सकते हैं और किसी भी सम्मेलन में प्रदर्शित किए जा सकते हैं । मुझे बताया गया है कि मेरे नाम या किसी अन्य पहचान का उपयोग मेरी सहमति के बिना नहीं किया जाएगा। मैं अपनी सहमति से इस शोध में भाग ले रहा हूं और मुझे जानकारी है कि मैं बिना किसी कारण के इस शोध में भाग लेने से इनकार कर सकता हूं।

मैं इस शोध में भाग लेने के लिए सहमत हूं।

हस्ताक्षर)

जगह तारीख:

प्रतिभागी का नाम: _____

पुत्र / पुत्री / पति / पत्नी: _____

पूरा डाक पता.

ANNEXURE V: CASE RECORD FORM

CASE RECORD FORM

Sr. No: Clinic No:

Name: CR no:

Address: Age/Sex:

Contact number:

Date:

Occupation:

Randomization code: Group allotted:

Yes No

Inclusion criteria:

1. Patients with Maxillofacial trauma
2. Patients in the age group between 18-65 years, of either sex
3. Patients who have given written consent for participation
4. Absence of pre-existing maxillofacial pathology

Exclusion criteria:

Yes No

1. Patients in age range greater than 18 and less than 65
2. Patients with systemic conditions such as
   uncontrolled diabetes mellitus, hypertension,
   cardio respiratory conditions,
   previous history of cerebrovascular accidents,
   myocardial infarction, coronary artery disease.
3. Patients with physical assault cases.

4. Patients who are intubated / tracheostomized
5. Patients with concomitant head injuries, orthopaedic trauma, cervical spine injuries or debilitating thoracic or abdominal trauma
6. Patients with psychiatric illness

ASSESSMENT PRIOR TO T1: (PRESURGERY)

Habits evaluation: Time period Frequency

Smokeless Tobacco:	Yes No		
Alcohol:	Yes No		
Smoking:	Yes No		

Fractured sites:

Midface	
Mandible	

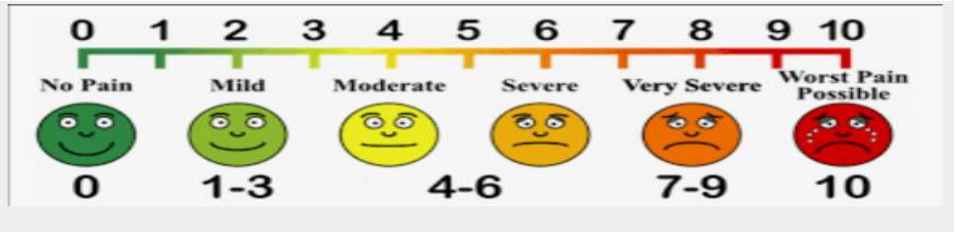
Number of fractured sites:

Pre-operative Occlusion:

Adequate	
Deranged	

Parameters:

1.Pain by VAS Scale**:**



Daily VAS score :

DAY 1	2	3	4	5	6	7	8

Average of VAS score:

2. Number of additional analgesic tablets: Consumed per day

DAY 1	2	3	4	5	6	7	8

Number of rescue analgesics if any.

3. Anxiety by HAD (Hospital anxiety and depression) Scale

4. Oral hygiene evaluation by Debris index of Oral hygiene index- modified:
   By Jack and Vermillion (1964**)**

Total score

Good	0.0-0.6
Fair	0.7-1.8
Poor	1.9-3.0

8. Oral feeds:

Within 6 hours after injury
Within 6-12 hours
12-24 hours after injury
>24 hours after injury

9. Pre-operative I.V fluids**:**

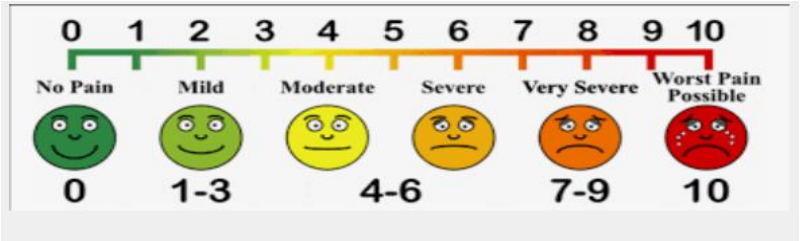
10. Patient compliance 2hours before surgery:

Yes No

Pre-operative fasting/clear fluids	
Carbohydrate loading:	

ASSESSMENT AT 24 HRS.: (Post surgery)

1. Pain by – VAS scale:



VAS SCORE :

2. Total Number of analgesics after surgery till discharge

   Total number of rescue analgesic tablets consumed if any:

3. Episodes of Post-operative nausea vomiting**:**

Yes	No	Number of episodes

4. Patient compliance: oral feed started within

Within 6 hours	
Within 6-12 hours	
12-24 hours after surgery	
>24 hours after surgery	

5. Post-operative total I.V fluids consumed-

6. Throat pain

Yes	No
Mild	
Moderate	
Severe	

7. Discomfort in swallowing:

Yes	No
Mild	
Moderate	
Severe	

8. Anxiety score by HAD scale: -

9. Swelling:

Mild	
Moderate	
Severe	

10. Discharge timings:

Within 24 hours	
24-48 hours	
>48hours	

ASSESSMENT AT DAY 5:

1. Post-operative complications:

- Oedema:

Mild
Moderate
Severe

- Infection at surgical site: Yes/ No
- Need for antibiotic upgrade: Yes/ No

2. Oral hygiene debris index**:** Debris score:

Good	0.0-0.6
Fair	0.7-1.8
Poor	1.9-3.0

AT 2 WEEKS AFTER SURGERY:

1. Overall Patient satisfaction for treatment and recovery using Likert scale:
   1- Strongly agree
   2- Disagree
   3- Neutral
   4- Agree
   5- Strongly agree

2. Did pre-operative counselling help in motivating to quit tobacco? Yes /No
3. Discomfort due to arch bar – ulceration/impingement- Yes/No
4. Do you feel you had to bear Discomfort with repeated injections – Yes/No
5. Could you return to your normal life? Yes/ No

   Within 7 days:

   Within 15 days

   >15 days

6. Do you feel communication from health care team was adequate and completely understandable - Yes /No?

Cost analysis

a. Days of hospital stay X Cost of stay per day	
b. Post op prescription	

Total costing: a+b

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D) _____ Anxiety (A) _____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

ANNEXURE VI A: ENHANCED RECOVERY AFTER SURGERY PATIENT INFORMATION HAND-OUTS (ENGLISH)

ENHANCED RECOVERY AFTER SURGERY PATIENT INFORMATION HAND-OUTS

- This booklet will help you to understand the Enhanced recovery after surgery protocols followed at hospital AIIMS Jodhpur which will play a key role in speeding up your recovery.
- This programme is different from traditional treatment care as it will focus upon small factors, their influences and small modifications which will improve your recovery from traumatic impact.
- You upper /lower jaw has been fractured which will require surgery to rejoin the fractured segments.
- Before surgery you will be admitted in the ward and prepared for the surgery.

BEFORE OPERATION

- Within 2 hours after stable medical condition, the fractured site will be stabilized intraorally by wires under local anesthesia which will help in holding of fractured segments and help to relieve pain which is caused because of mobility.

Nutrition

- Before the operation it is beneficial for you to try and make yourself as fit as possible.
- You can do this by taking adequate oral diet which will help to maintain weight and healthy condition.
- Take good quantity of proteins(dals/eggs/chicken/soyabean), fruits and vegetables in your diet. Foods like Maida, junk foods, aerated drinks to be avoided.

[Picture Courtesy: https://healthcenter.uga.edu/]

Tobacco cessation

- If you have any habits such as tobacco, smoking, alcohol it is advisable to quit as smoking, alcohol and other habits can significantly slower the wound healing after surgery and can aggravate other health related issues.
- It can also increase the chances of post-operative infections which can result in failure of operation.
- For this you will be referred to a psychologist opinion who will help you and guide you through the process.
- There can be withdrawal symptoms but the concerned psychologist will take care of it. You may inform us for any issues.

[Picture Courtesy: https://www.istockphoto.com/]

Medications

- In the ward you will be given medications for pain relief and antibiotics to avoid chances of infections.
- You will have a drip put into your arms and fluid will be given through this to ensure you do not become dehydrated.

Oral hygiene

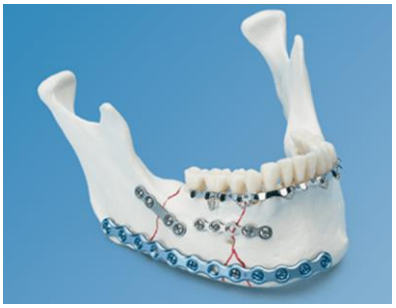
- Pre surgery scaling will be done for cleaning your teeth as a part of maintaining oral hygiene and chlorhexidine will be prescribed which you have to use twice per day.
- Also, a temporary arch bar and will be fixed to maintain occlusion while in operation which may remain till 2 weeks after surgery. We will remove it at earliest possible

- This can lead to discomfort, pain, impingement on surrounding structures and even difficulty in eating and maintaining oral hygiene.
- Chlorhexidine Mouth wash and warm saline rinses will help you in keeping your mouth clean and reduce chances of infection

Informed Consent

- Before going into surgery, you will be asked to sign a consent form which will mentions your willingness and consent to let us operate for surgery.
- Consent will include that – the operation will be carried under general anesthesia in which you will not perceive any pain or sensation

- To rejoin the fractured segment outside plate will be inserted and plated by drilling the bone and fixing in correct position.
- Titanium Plate of accepted standards will be used.



[Picture Courtesy -www.jnjmedtech.com]

- Incision will be given to access the site inside the mouth or on face sometimes depending upon the fracture or need.
- Sometimes it can also be done through existing wounds.
- Scar on face will usually be in hidden areas and will be minimally seen by 6 months.
- The plate will be in the place and will not have the need to be removed until in some cases of infection. The plate and screw charges have to be paid to the hospital.
- After surgery there are some chances of complications like pain, temporary loss of sensation of specific part operated and swelling. All these settles in time period of 3-10 days in usual course. Required medications will be provided as needed. We will be following policy of minimal needed antibiotics and IV fluids as they not only cause problems like antibiotic resistance but also are not very good for body if taken beyond strict needs. In

event of any prolonged complications appropriate treatment including medications and readmission may be done.

DAY OF YOUR OPERATION

- Your pre assessment will be done one day before your surgery.
- Eating and drinking before your operation: you can eat solid foods like rice chapatti etc until 6 hours before your surgery.
- If you are planned as first case of the day then till 7am you can have clear fluids like water, coconut water, apple juice. No milky fluids are allowed.
- At 7am a carbohydrate rich drink clear apple juice (400mL) will be given to you. This will help in improving your recovery. You will be given some medications before surgery which will to prevent the chances of vomiting after surgery along with pain relief medications and antibiotics.

- Even some tubes can be inserted into your bladder to monitor urine output.
- Continuous monitoring of blood pressure, pulse, temperature and oxygen levels will be done.

DAY AFTER OPERATION

After operation you will be shifted early again back to ward and allowed to rest.

- Liquid clear fluids like water, coconut water, apple juice can be started 2 hours after surgery if you are fully awake and have no complaints of nausea and vomiting.

  After complete anesthesia recovery fluids running through drips will be removed and you will be allowed to eat / drink orally fully.

- Regular pain killers and antibiotics will be started in tablet form from day 1. Also, the tubes will be removed from bladder within 12 hours which will ease your discomfort.

- You will be encouraged to start walking within 4-6 hours after surgery.
- You will be sent home early as soon as you recover mostly within 24-48 hours after surgery
- Before we send you home, we would ideally like you to:
- Be walking, eating and drinking, have passed urine, controlled pain, and no temperature.
- You will be recalled at 5th day and at 2 weeks of your surgery for early removal of arch bar and post-operative counselling and to evaluate post-operative findings.
- Thereafter you may report in case of some problem or issues.

[Picture Courtesy- https://townofwindsorct.com/]

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ANNEXURE VI B: ENHANCED RECOVERY AFTER SURGERY PATIENT INFORMATION HAND-OUTS (HINDI)

मरीज सूचना पुस्तिका

यह पुस्तिका मे दी गयी जानकारी आपकी सर्जरी के बाद जल्द रिकवरी में आपकी मदद करेगी, जो आपके ठीक होने में तेजी लाने में महत्वपूर्ण भूमिका निभाएगी।

यह कार्यक्रम अस्पताल के पारंपरिक उपचार से अलग है क्योंकि यह छोटे कारक को ध्यान में रखके मरीजों के दर्द को कम करने और जल्द सुधार करने में मदद करता है।

सूचना

आपका ऊपरी/निचला जबड़ा टूट गया है और टूटी हुई हड्डी जोड़ने के लिए सर्जरी की आवश्यकता होगी । सर्जरी से पहले आपको वार्ड में भर्ती किया जाएगा और सर्जरी के लिए तैयार किया जाएगा ।

ऑपरेशन से पहले

• स्थिर चिकित्सा स्थिति के बाद 2 घंटे के भीतर, फ्रैक्चर वाली जगह को लोकल एनेस्थीसिया के तहत तारों द्वारा आंतरिक रूप से स्थिर किया जाएगा जो फ्रैक्चर वाले हिस्सों को पकड़ने में मदद करेगा और गतिशीलता के कारण होने वाले दर्द को दूर करने में मदद करेगा।

पर्याप्त पोषण

ऑपरेशन से पहले जितना हो सके खुद को उपयुक्त रखने की कोशिश करना आपके लिए फायदेमंद होगा।

• पर्याप्त मौखिक आहार आपके वजन और स्वस्थ स्थिति को बनाए रखने में मदद करेगा । जितना हो सके उतना अधिक मौखिक आहार लेने से ड्रिप/सुई से कम दवाई देनी पड़ेगी जिससे आपके दर्द में भी कमी रहेगी और सुई बादल ने की आवश्यकता कम रहेगी ।

आपको आहार विशेषज्ञ के पास भी भेजा जायेगा जो आपको पर्याप्त आहार की जरुरियारत के विषय में बताएँगे और वार्ड में उस प्रकार आहार शुरू किया जायेगा ।

व्यसन त्यागना

अगर आपको तम्बाकू, धूम्रपान, शराब जैसी कोई आदत है तो इसे छोड़ने की सलाह दी जाएगी क्योंकि धूम्रपान, शराब और अन्य आदतें सर्जरी के बाद घाव भरने की प्रक्रिया को को धीमा कर सकती हैं और अन्य स्वास्थ्य संबंधी तकलीफे बढ़ा सकती हैं।

यह सर्जरी के बाद संक्रमण की संभावनाओं को भी बढ़ा सकता है जिसके परिणामस्वरूप ऑपरेशन विफल हो सकता है।

इसके लिए आपको एक मनोवैज्ञानिक की राय के लिए भेजा जाएगा जो आपकी व्यसन मुक्ति में मदद करेगा और इस प्रक्रिया में आपका मार्गदर्शन करेगा।

व्यास मुक्ति के दौरन आपको वापसी के लक्षण हो सकते हैं परन्तु इसके संबंधित चीज़ों का मनोवैज्ञानिक ध्यान रखेंगे।

दवाएं

• वार्ड में आपको दर्द से राहत के लिए दवाएं और संक्रमण की संभावना से बचने के लिए एंटीबायोटिक्स दी जाएंगी।

मौखिक स्वच्छता

मौखिक स्वच्छता बनाए रखने के एक भाग के रूप में सर्जरी से पहले आपके दांतों की सफाई

(स्केलिंग)की जाएगी और माउथवॉश का उपयोग दिन में दो बार करना होगा।

• धातु के तार मुह में ऑपरेशन के दौरान बंधे जाएंगे. बहोशी में बंधे जाने पर आपको दर्द महसूस नहीं होगा और तार आपके डिस्चार्ज करने पर हटाएंगे जिसे चूबन और दर्द में राहत रहेगी ।

सूचित सहमति

सर्जरी में जाने से पहले, आपको एक सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जाएगा, जिसमें आपकी सर्जरी के लिए सहमति का उल्लेख होगा।

ऑपरेशन सम्पूर्ण बहोशी के तहत किया जाएगा जिसमें आपको कोई दर्द या सनसनी महसूस नहीं होगी।

हड्डी को फिर से सही जगह जोड़ने के लिए हड्डी पर बाहरी टाइटेनियम की प्लेट लगेगी जाएगी ।

टाइटेनियम प्लेट शरीर के साथ कोई प्रतिक्रिया नहीं करती जिस वजह से उनको निकालने की अवश्यकता नहीं रहती ।

जिन पेशेंट में जैसे सर्जरी के बाद इंफेक्शन, सुनापन के लक्षण दिखने को मिलते हैं उन पेशेंट्स में प्लेट्स हड्डी जुडने के बाद 6 महीने -1 साल के बाद निकली जा सकती है।

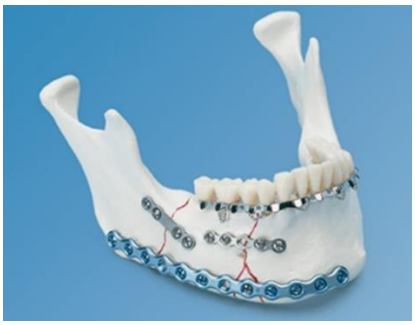
फ्रैक्चर या आवश्यकता के आधार पर मुंह के अंदर या चेहरे पर चीरा लगाया जाएगा।

· कभी-कभी यह मौजूदा घावों के माध्यम से भी किया जा सकता है।

चेहरे पर के निशान समय के साथ 6 माह में कम होने लगेंगे।

सर्जरी के बाद कुछ जटिलताएं होने की संभावना होती है जैसे कि दर्द, सूजन, नासो को दबाव /छोट पोहंचना। जरूरत पड़ने पर जरूरी दवाएं उपलब्ध कराई जाएंगी।

हम कम से कम आवश्यक एंटीबायोटिक दवाओं और IV तरल पदार्थों की नीति का पालन करेंगे क्योंकि वे न केवल एंटीबायोटिक प्रतिरोध जैसी समस्याएं पैदा करते हैं बल्कि शरीर की रोग प्रतिरोधक की को काम करते है ।



ऑपरेशन के दिन

ऑपरेशन से पहले खाना-पीना: आप अपनी सर्जरी से 6 घंटे पहले तक ठोस आहार जैसे चावल की रोटी आदि खा सकते हैं।

तरल साफ पदार्थ आप ऑपरेशन के दो घंटे पहले तक ले सकते हैं जैसे की पानी, नारायण पानी, सेब का जूस। ऑपरेशन से पहले नारियल पानी या सेब का जूस लेने से अपनी भूख कम रहेगी । दूध, चाय आदि पदार्थ के सेवन की अनुमति नहीं है ।

आपको सर्जरी से पहले दर्द निवारक दवाओं और एंटीबायोटिक दवाओं के साथ कुछ दवाएं दी जाएंगी जो सर्जरी के बाद उल्टी की संभावना को रोकेंगी।

सर्जरी के बाद

ऑपरेशन के बाद आपको जल्दी वापस वार्ड में शिफ्ट कर दिया जाएगा और आराम करने दिया जाएगा ।

पानी, नारियल पानी, सेब का रस जैसे साफ तरल पदार्थ सर्जरी के बाद उल्टी की अनुभूति ना होने पर 2 घंटे बाद शुरू किए जा सकते हैं ।

पहले दिन से नियमित दर्द निवारक और एंटीबायोटिक्स टैबलेट के रूप में शुरू हो जाएंगे। साथ ही, 12 घंटे के भीतर मूत्राशय से ट्यूब को हटा दिया जाएगा, जिससे आपकी परेशानी कम हो जाएगी।

सर्जरी के 4-6 घंटे के भीतर आपको चलने के लिए प्रोत्साहित किया जाएगा।

· जैसे ही आप सर्जरी के 24-48 घंटों के भीतर ठीक हो जाते हैं, आपको जल्दी घर भेज दिया जाएगा ।

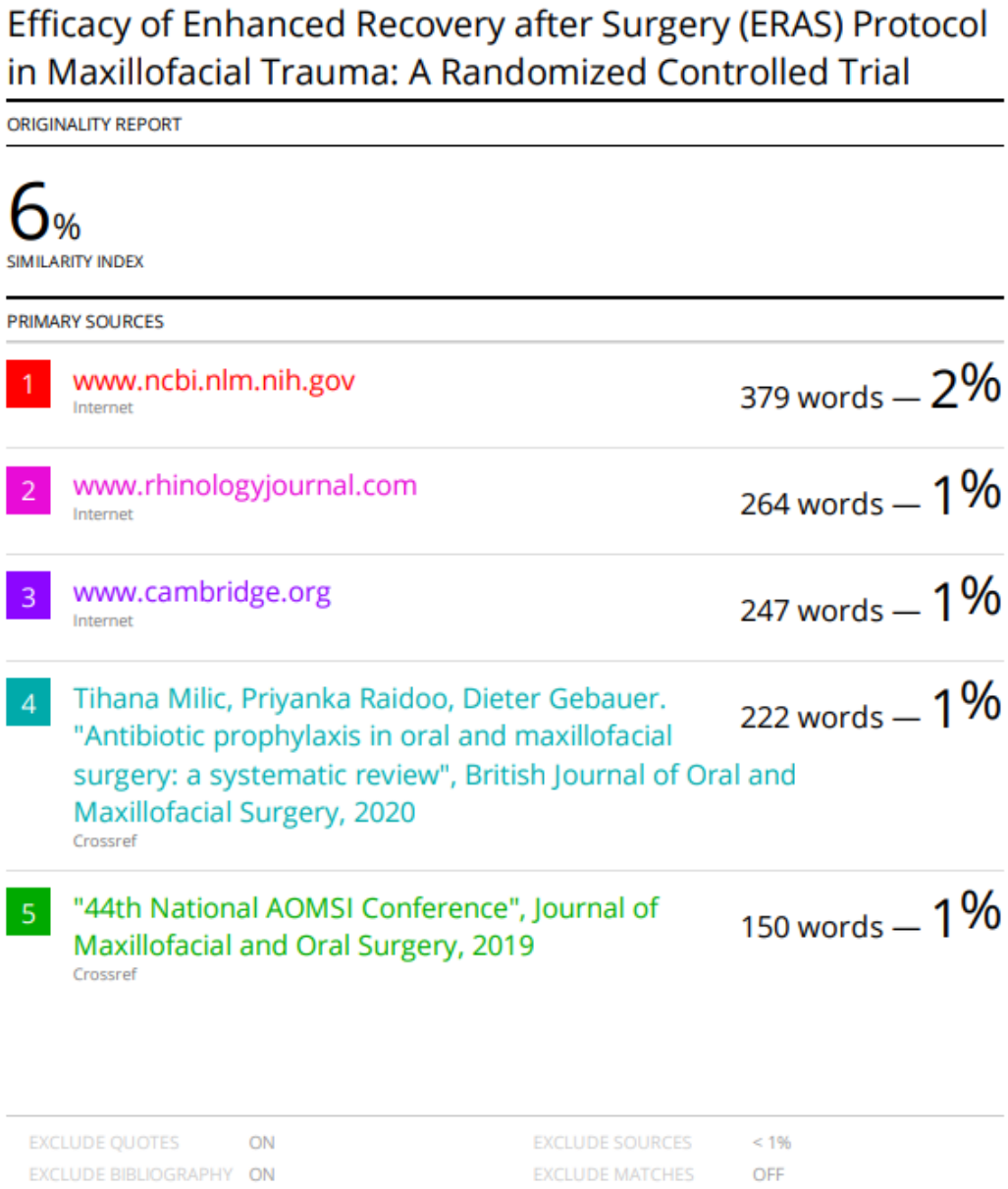
इससे पहले कि हम आपको घर भेजें, आदर्श रूप से हम चाहेंगे कि आप:

· चलना, खाना-पीना, पेशाब ठीक से करे और नियंत्रित दर्द की स्थिति में रहे ।

आपको 5वें दिन और आपकी सर्जरी के 2 सप्ताह बाद जांच के लिए वापस बुलाया जाएगा ।

हम आपके शीघ्र स्वस्थ होने की कामना करते हैं।

ANNEXURE VII: PLAGIARISM CERTIFICATE



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