

Evaluation of the Efficacy and Safety of Opioid-Free Anesthesia Compared with Conventional Opioid-Based General Anesthesia in Patients Undergoing Elective Laparoscopic Cholecystectomy

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ABSTRACT

Background: Opioids are commonly used during general anaesthesia but are associated with adverse effects such as postoperative nausea and vomiting, respiratory depression, delayed recovery, and increased opioid consumption. Opioid-free anaesthesia (OFA) using multimodal non-opioid agents has emerged as an alternative approach to improve perioperative outcomes. This study aimed to compare the efficacy and safety of opioid-free anaesthesia with conventional opioid-based anaesthesia in patients undergoing elective laparoscopic cholecystectomy. **Materials and Methods:** This prospective randomised controlled comparative study was conducted in the Department of Anaesthesiology at CSI Redfern Memorial Hospital, Hassan, over a period of 2 years. A total of 74 patients undergoing elective laparoscopic cholecystectomy were randomised into two groups: Group OFA (n=37) received dexmedetomidine and lidocaine-based opioid-free anaesthesia, while Group OBA (n=37) received conventional fentanyl-based opioid anaesthesia. Intraoperative hemodynamic parameters, recovery profile, postoperative pain scores, rescue analgesic requirement, postoperative nausea and vomiting, patient satisfaction, and adverse events were assessed. **Results:** Both groups were comparable in baseline demographic and clinical characteristics. Patients in the OFA group demonstrated significantly better intraoperative hemodynamic stability with lower heart rate and mean arterial pressure changes during intubation, pneumoperitoneum, and extubation ($p<0.001$). Recovery was faster in the OFA group, with reduced extubation and orientation times ($p<0.001$). Postoperative pain scores were significantly lower, and time to first rescue analgesia was prolonged in the OFA group ($p<0.001$). The incidence of postoperative nausea and vomiting was significantly reduced in the OFA group compared with the OBA group (8.1% vs 29.7%, $p=0.02$). Patient satisfaction was also significantly higher among patients receiving opioid-free anaesthesia ($p=0.04$). Both techniques showed acceptable safety profiles. **Conclusion:** Opioid-free anaesthesia provides superior perioperative outcomes compared with conventional opioid-based anaesthesia in elective laparoscopic cholecystectomy. It offers improved hemodynamic stability, better postoperative analgesia, faster recovery, reduced opioid-related complications, and higher patient satisfaction while maintaining safety.

Keywords: Opioid-free anaesthesia; Opioid-based anaesthesia; Dexmedetomidine; Laparoscopic cholecystectomy; Postoperative analgesia; Recovery profile.

INTRODUCTION

Laparoscopic cholecystectomy is the treatment of choice for symptomatic gallstone disease and is one of the most commonly performed minimally invasive surgical procedures worldwide. Compared with open cholecystectomy, the laparoscopic approach offers several advantages, including smaller incisions, reduced postoperative pain, shorter hospital stay,

earlier mobilization, and faster return to routine activities. However, the creation of pneumoperitoneum, endotracheal intubation, and surgical stimulation produce significant hemodynamic changes due to sympathetic activation, making optimal anaesthetic management essential for maintaining cardiovascular stability and ensuring smooth postoperative recovery [1].

Opioids have long been regarded as an integral component of balanced general anaesthesia because of their potent analgesic properties and their ability to attenuate perioperative stress responses. Agents such as fentanyl are routinely administered during laparoscopic procedures to provide intraoperative analgesia and blunt sympathetic responses. Despite their effectiveness, opioids are associated with several well-recognised adverse effects, including respiratory depression, postoperative nausea and vomiting (PONV), delayed recovery, sedation, ileus, urinary retention, opioid-induced hyperalgesia, tolerance, and the potential for prolonged postoperative opioid use [2–4]. These limitations have prompted increasing interest in opioid-sparing and opioid-free anaesthetic techniques.

Opioid-free anaesthesia (OFA) is a multimodal anaesthetic strategy that eliminates intraoperative opioid administration while maintaining adequate analgesia through the use of non-opioid agents acting at different sites of the nociceptive pathway. Drugs commonly incorporated into OFA protocols include dexmedetomidine, lidocaine, ketamine, magnesium sulfate, paracetamol, non-steroidal anti-inflammatory drugs, and regional anaesthetic techniques. This multimodal approach aims to improve perioperative analgesia, reduce opioid-related complications, enhance postoperative recovery, and improve overall patient outcomes [5].

Among the various agents used in opioid-free anaesthesia, dexmedetomidine has gained considerable attention because of its sedative, analgesic, anxiolytic, and sympatholytic properties. As a highly selective α_2 -adrenergic receptor agonist, dexmedetomidine attenuates the stress response associated with laryngoscopy, intubation, and pneumoperitoneum while producing minimal respiratory depression. Intravenous lidocaine further enhances analgesia through its anti-inflammatory, antihyperalgesic, and analgesic effects, contributing to reduced postoperative pain and opioid requirements [6,7].

Enhanced Recovery After Surgery (ERAS) protocols strongly recommend multimodal analgesia and opioid minimisation to facilitate early postoperative recovery. Opioid-free anaesthesia complements these recommendations by promoting early ambulation, faster gastrointestinal recovery, reduced incidence of PONV, shorter hospital stay, and improved patient satisfaction [8].

Several randomized controlled trials have evaluated opioid-free anaesthesia in laparoscopic surgery and other surgical procedures. Most studies have reported superior intraoperative hemodynamic stability, lower postoperative pain scores, prolonged duration before first rescue analgesia, decreased postoperative opioid consumption, lower incidence of PONV, and improved quality of recovery compared with conventional opioid-based anaesthesia. Nevertheless,

dexmedetomidine-based techniques have occasionally been associated with increased episodes of bradycardia and hypotension, necessitating careful monitoring during anaesthesia [9–12].

Considering the growing emphasis on opioid-sparing perioperative care, the present prospective randomized comparative study was undertaken to evaluate the efficacy and safety of opioid-free anaesthesia compared with conventional opioid-based general anaesthesia in patients undergoing elective laparoscopic cholecystectomy. The study compared intraoperative hemodynamic stability, postoperative pain scores, analgesic requirements, recovery profile, postoperative nausea and vomiting, patient satisfaction, and perioperative adverse events between the two anaesthetic techniques.

Although several studies have demonstrated the benefits of opioid-free anaesthesia, evidence from Indian tertiary care centres remains limited, particularly in patients undergoing elective laparoscopic cholecystectomy. Furthermore, variations in anaesthetic protocols and patient populations necessitate additional prospective comparative studies to establish the efficacy and safety of OFA in routine clinical practice.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomised, controlled, comparative study was conducted in the Department of Anaesthesiology at CSI Redfern Memorial Hospital, Hassan, over a period of 2 years. The study was designed to evaluate the efficacy and safety of opioid-free anaesthesia (OFA) compared with conventional opioid-based general anaesthesia (OBA) in patients undergoing elective laparoscopic cholecystectomy.

Study Population

A total of 74 patients scheduled for elective laparoscopic cholecystectomy under general anaesthesia were included in the study. Patients were randomly allocated into two equal groups of 37 patients each. Group OFA received opioid-free anaesthesia, while Group OBA received conventional opioid-based general anaesthesia.

The sample size was calculated based on previous studies considering postoperative VAS score as the primary outcome, assuming an effect size of 0.7, power of 80%, and alpha error of 5%. A minimum of 34 patients per group was required. To compensate for possible dropouts, 37 patients were included in each group.

Inclusion and Exclusion Criteria

Patients aged 18–65 years, of either gender, belonging to ASA physical status I or II, and willing to provide written informed consent were included in the study. Patients with ASA grade III or IV, emergency

surgeries, known allergy to study drugs, chronic opioid use, significant hepatic, renal, cardiovascular or respiratory disease, pregnancy, lactation, morbid obesity (BMI >35 kg/m²), neurological or psychiatric illness, and those requiring conversion to open cholecystectomy were excluded.

Preoperative Evaluation

All patients underwent detailed pre-anaesthetic evaluation one day before surgery, including medical history, physical examination, airway assessment, and routine laboratory investigations. Investigations included complete blood count (CBC), random blood sugar (RBS), liver function tests (LFT), renal function tests (RFT), serum electrolytes, coagulation profile (when indicated), electrocardiogram (ECG), and chest radiograph whenever clinically indicated. Baseline heart rate, blood pressure, oxygen saturation, body weight, and body mass index were recorded, and patients were kept fasting according to standard preoperative fasting guidelines.

Randomization

Patients were randomized into either the OFA or OBA group using a computer-generated randomisation sequence. Allocation was concealed using sequentially numbered, sealed opaque envelopes, which were opened immediately before induction of anaesthesia.

Anesthetic Technique

Patients in the OFA group received glycopyrrolate and midazolam as premedication, followed by dexmedetomidine (1 µg/kg loading dose over 10 minutes), lidocaine (1.5 mg/kg), propofol (2 mg/kg), and rocuronium (0.6 mg/kg) for induction. Anaesthesia was maintained with an oxygen-air mixture, sevoflurane, dexmedetomidine infusion (0.3–0.7 µg/kg/hour), and additional rocuronium as required, without the use of intraoperative opioids. Patients in the OBA group received glycopyrrolate and midazolam for premedication, fentanyl (2 µg/kg), propofol (2 mg/kg), and rocuronium (0.6 mg/kg) for induction. Maintenance was achieved with an oxygen-air mixture, sevoflurane, intermittent fentanyl supplementation when required, and additional rocuronium.

Intraoperative Monitoring

Standard ASA monitoring was used throughout the procedure. Heart rate, systolic blood pressure, diastolic

blood pressure, mean arterial pressure, oxygen saturation, and end-tidal carbon dioxide were recorded at baseline, after induction, after intubation, during pneumoperitoneum, every 15 minutes intraoperatively, at extubation, and in the immediate postoperative period.

Postoperative Assessment

Patients were observed in the post-anaesthesia care unit, where postoperative pain was assessed using the Visual Analogue Scale (VAS) at 1, 2, 4, 8, 12, and 24 hours. Rescue analgesia was administered when the VAS score was ≥4. Recovery characteristics, time to extubation, time to first rescue analgesia, total postoperative analgesic consumption, incidence of postoperative nausea and vomiting, patient satisfaction, and adverse events such as hypotension, bradycardia, respiratory depression, shivering, and dizziness were also recorded.

Outcome Measures

The primary outcome was intraoperative hemodynamic stability. Secondary outcomes included postoperative pain scores, time to first rescue analgesia, total analgesic requirement during the first 24 hours, recovery profile, incidence of postoperative nausea and vomiting, patient satisfaction, and perioperative adverse events.

Ethical Considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee of CSI Redfern Memorial Hospital, Hassan. Written informed consent was obtained from all participants before enrollment, and the study was carried out in accordance with accepted ethical principles and the Declaration of Helsinki.

Statistical Analysis

Statistical analysis was performed using SPSS version 26.0. Continuous variables were expressed as mean ± standard deviation and compared using the independent Student's t-test. Categorical variables were analysed using the Chi-square test or Fisher's exact test. A p-value <0.05 was considered statistically significant.

RESULTS AND OBSERVATIONS

A total of 74 patients undergoing elective laparoscopic cholecystectomy under general anaesthesia were enrolled in the study. The patients were randomly allocated into two equal groups: Group OFA (Opioid-Free Anaesthesia, n=37) and Group OBA (Opioid-Based Anaesthesia, n=37). Both groups were comparable with respect to demographic characteristics, baseline clinical parameters, and laboratory investigations. The intraoperative hemodynamic profile, recovery characteristics, postoperative pain scores, analgesic requirements, postoperative nausea and vomiting, patient satisfaction, and adverse events were compared between the two groups.

Table 1. Demographic Characteristics of the Study Population

Parameter	Group OFA (n=37)	Group OBA (n=37)	p-value
Age (years)	42.8 ± 10.2	43.5 ± 9.8	0.76
Male	15 (40.5%)	16 (43.2%)	0.81
Female	22 (59.5%)	21 (56.8%)	
Weight (kg)	64.5 ± 8.7	65.2 ± 9.1	0.73
BMI (kg/m ²)	24.3 ± 2.8	24.6 ± 2.9	0.65

Observation: There was no statistically significant difference between the two groups regarding age, gender distribution, body weight, or body mass index (p>0.05).

Table 2. Baseline Laboratory Investigations

Parameter	Group OFA (n=37)	Group OBA (n=37)	p-value
Haemoglobin (g/dL)	13.0 ± 1.2	13.2 ± 1.1	0.47
Total Leukocyte Count (×10 ³ /μL)	7.3 ± 1.4	7.5 ± 1.5	0.58
Platelet Count (×10 ⁵ /μL)	2.62 ± 0.39	2.58 ± 0.42	0.69
Random Blood Sugar (mg/dL)	103.5 ± 15.1	104.8 ± 14.6	0.71
Blood Urea (mg/dL)	25.1 ± 5.6	25.8 ± 6.2	0.64
Serum Creatinine (mg/dL)	0.83 ± 0.15	0.84 ± 0.16	0.82
AST (U/L)	29.1 ± 7.4	29.8 ± 7.2	0.68
ALT (U/L)	31.6 ± 8.5	32.4 ± 8.1	0.67
Serum Sodium (mmol/L)	139.3 ± 2.6	138.8 ± 2.9	0.45
Serum Potassium (mmol/L)	4.08 ± 0.36	4.05 ± 0.34	0.73

Observation: Baseline laboratory investigations were comparable between the two groups, with no statistically significant differences (p>0.05).

Table 3. Baseline Clinical Parameters

Parameter	Group OFA (n=37)	Group OBA (n=37)	p-value
Heart Rate (beats/min)	78.5 ± 8.3	79.2 ± 8.6	0.71
Systolic Blood Pressure (mmHg)	124.2 ± 10.6	123.6 ± 11.1	0.81
Diastolic Blood Pressure (mmHg)	78.4 ± 7.2	79.1 ± 7.0	0.68
Mean Arterial Pressure (mmHg)	93.8 ± 6.8	94.1 ± 7.0	0.84
Oxygen Saturation (SpO ₂ , %)	98.8 ± 0.7	98.7 ± 0.6	0.52

Observation: Baseline hemodynamic parameters were similar in both groups with no statistically significant difference.

Table 4. Intraoperative Hemodynamic Parameters

Time Point	HR (OFA)	HR (OBA)	MAP (OFA)	MAP (OBA)
Baseline	78.5 ± 8.3	79.2 ± 8.6	93.8 ± 6.8	94.1 ± 7.0
After induction	73.2 ± 7.4	76.8 ± 8.2	88.9 ± 6.1	92.7 ± 6.9
After intubation	80.1 ± 7.6	91.4 ± 8.3	95.2 ± 6.5	103.6 ± 7.5
Pneumoperitoneum	81.7 ± 7.9	92.6 ± 8.6	96.5 ± 6.8	104.1 ± 7.9
15 min	80.6 ± 7.5	90.5 ± 8.4	95.3 ± 6.7	102.2 ± 7.6
30 min	79.4 ± 7.3	88.8 ± 8.2	94.7 ± 6.5	101.4 ± 7.2
Extubation	82.3 ± 7.7	94.2 ± 8.8	97.1 ± 6.9	105.2 ± 7.8

p-value: <0.001 for heart rate and MAP after intubation, pneumoperitoneum, 15 minutes, 30 minutes, and extubation.
Observation: Patients receiving opioid-free anaesthesia maintained significantly better intraoperative hemodynamic stability compared with the opioid-based anaesthesia group.

Table 5. Recovery Profile

Parameter	Group OFFA	Group OBA	p-value
Time to Extubation (min)	8.4 ± 2.1	10.7 ± 2.6	<0.001
Time to Orientation (min)	11.3 ± 2.9	14.5 ± 3.4	<0.001

Observation: Recovery was significantly faster in the OFA group.

Table 6. Postoperative Pain Scores (VAS)

Time	Group OFA	Group OBA	p-value
1 hour	2.9 ± 0.8	4.2 ± 0.9	<0.001
2 hours	3.1 ± 0.9	4.4 ± 1.0	<0.001
4 hours	3.3 ± 0.8	4.5 ± 0.9	<0.001
8 hours	2.8 ± 0.7	3.8 ± 0.8	<0.001
12 hours	2.2 ± 0.6	3.0 ± 0.7	<0.001
24 hours	1.6 ± 0.5	2.2 ± 0.6	<0.001

Observation: The OFA group had significantly lower postoperative pain scores at all observation periods.

Table 7. Postoperative Analgesic Requirement

Parameter	Group OFA	Group OBA	p-value
Time to First Rescue Analgesia (hours)	8.9 ± 1.8	5.4 ± 1.5	<0.001
Total Rescue Analgesic Doses (24 h)	1.1 ± 0.5	2.0 ± 0.7	<0.001

Observation: Patients in the OFA group required significantly less postoperative analgesia.

Table 8. Postoperative Nausea and Vomiting (PONV)

Finding	Group OFA	Group OBA	p-value
Present	3 (8.1%)	11 (29.7%)	0.02
Absent	34 (91.9%)	26 (70.3%)	

Observation: The incidence of postoperative nausea and vomiting was significantly lower in the OFA group.

Table 9. Adverse Events

Group OFA	Adverse Event	Group OBA	p-value
4 (10.8%)	Bradycardia	1 (2.7%)	0.16
3 (8.1%)	Hypotension	2 (5.4%)	0.64
0	Respiratory Depression	3 (8.1%)	0.07
2 (5.4%)	Shivering	6 (16.2%)	0.14
1 (2.7%)	Dizziness	4 (10.8%)	0.17

Observation: Both anaesthetic techniques were safe. Mild bradycardia occurred more frequently in the OFA group, whereas respiratory depression and dizziness were observed more often in the opioid-based anaesthesia group.

Table 10. Patient Satisfaction

Satisfaction	Group OFA	Group OBA	p-value
Excellent	24 (64.9%)	15 (40.5%)	
Good	11 (29.7%)	16 (43.2%)	
Fair	2 (5.4%)	6 (16.2%)	0.04

Observation: Patient satisfaction was significantly higher in the opioid-free anaesthesia group than in the opioid-based anaesthesia group. Overall, opioid-free anaesthesia provided better perioperative hemodynamic stability, superior postoperative analgesia, faster recovery, reduced incidence of postoperative nausea and vomiting, and higher patient satisfaction while maintaining a favourable safety profile.

DISCUSSION

The present prospective randomized controlled study compared opioid-free anaesthesia with conventional opioid-based anaesthesia in patients undergoing elective laparoscopic cholecystectomy. Both study groups were comparable with respect to demographic characteristics, baseline clinical parameters, and laboratory investigations, thereby minimizing potential confounding factors and ensuring that the observed differences in perioperative outcomes were attributable to the anaesthetic technique.

A major finding of the present study was the significantly better intraoperative hemodynamic stability observed in the opioid-free anaesthesia group. Heart rate and mean arterial pressure remained significantly lower following intubation, during

pneumoperitoneum, and at extubation compared with the opioid-based group. These findings are consistent with the sympatholytic action of dexmedetomidine, which suppresses catecholamine release and effectively attenuates cardiovascular responses to surgical stress. Similar observations have been reported by Bakan et al. and Mulier, who demonstrated superior hemodynamic control with dexmedetomidine-based opioid-free anaesthesia during laparoscopic surgery [5,9].

Recovery following anaesthesia was significantly faster in the opioid-free group. Patients experienced earlier extubation and regained orientation more rapidly than those receiving conventional opioid-based anaesthesia. The absence of opioid-induced sedation and respiratory depression likely contributed to this

enhanced recovery profile. These findings support the principles of Enhanced Recovery After Surgery (ERAS), which advocate minimizing perioperative opioid exposure to facilitate rapid postoperative recovery and early discharge [8].

Postoperative pain scores were consistently lower in patients receiving opioid-free anaesthesia at all measured time intervals during the first 24 hours after surgery. Furthermore, the duration before first rescue analgesia was significantly prolonged, and total postoperative analgesic consumption was markedly reduced. These findings indicate that dexmedetomidine combined with intravenous lidocaine provides effective multimodal analgesia. Similar reductions in postoperative pain and opioid requirements have been reported in previous randomized clinical trials evaluating opioid-free anaesthesia [7,9–11].

Postoperative nausea and vomiting remain among the most common complications following laparoscopic surgery and are strongly associated with perioperative opioid administration. In the present study, the incidence of PONV was significantly lower in patients receiving opioid-free anaesthesia than in those receiving conventional opioid-based anaesthesia. Elimination of intraoperative opioids likely reduced stimulation of the chemoreceptor trigger zone and improved postoperative gastrointestinal function. Comparable findings have been reported in previous studies evaluating opioid-free anaesthesia protocols [10].

Patient satisfaction was significantly higher in the opioid-free anaesthesia group. Improved postoperative analgesia, reduced nausea and vomiting, faster recovery, and fewer opioid-related adverse effects collectively contributed to greater patient comfort and satisfaction. These findings are in agreement with current ERAS recommendations emphasizing patient-centered perioperative care and enhanced recovery [8]. With regard to safety, both anaesthetic techniques demonstrated acceptable safety profiles. Although mild bradycardia occurred more frequently in the opioid-free group, the episodes were transient and responded well to routine treatment. Respiratory depression was observed only in the opioid-based group, reflecting the respiratory-sparing properties of dexmedetomidine. Similar safety outcomes have been documented in previous clinical studies evaluating dexmedetomidine-based opioid-free anaesthesia [6,9].

The present study possesses several strengths, including its prospective randomised design, standardised anaesthetic protocol, and comprehensive assessment of both intraoperative and postoperative outcomes. Nevertheless, certain limitations should be acknowledged. The study was conducted at a single institution with a relatively small sample size, limiting the generalizability of the findings. Additionally, long-term outcomes such as chronic postoperative pain, persistent opioid consumption, quality of life, and cost-

effectiveness were not evaluated. Future multicenter studies with larger sample sizes and longer follow-up periods are warranted to validate these findings.

Overall, the results of the present study demonstrate that opioid-free anaesthesia is an effective and safe alternative to conventional opioid-based anaesthesia for elective laparoscopic cholecystectomy. Opioid-free anaesthesia provided superior intraoperative hemodynamic stability, better postoperative analgesia, reduced analgesic requirements, lower incidence of postoperative nausea and vomiting, faster recovery, and higher patient satisfaction while maintaining an acceptable safety profile. These findings support the increasing adoption of opioid-free anaesthesia as part of modern multimodal perioperative care.

Future multicentre randomized trials with larger sample sizes are recommended to evaluate long-term outcomes, cost-effectiveness, chronic postoperative pain, and quality of recovery.

Strengths of the Study

Strengths of the present study include its prospective randomized design, standardized anaesthetic protocol, and comprehensive perioperative assessment.

CONCLUSION

Opioid-free anaesthesia was found to be an effective and safe alternative to conventional opioid-based anaesthesia in elective laparoscopic cholecystectomy. It provided better hemodynamic stability, improved postoperative analgesia, faster recovery, reduced postoperative nausea and vomiting, and higher patient satisfaction with an acceptable safety profile.

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Nil.

Conflict of Interest

None declared.

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Data Availability Statement

The datasets generated and analysed during the current study are available from the corresponding author upon reasonable request.

Author Contributions

Dr. Divyashri C.N: Conceptualization, study design, patient recruitment, data collection, supervision, and manuscript drafting.

Dr. Bharath M.S: Study design, perioperative patient management, data collection, data interpretation, and critical revision of the manuscript.

Dr. Shruthi Jayaram: Statistical analysis, data interpretation, manuscript preparation, literature review, and critical revision of the manuscript.

All authors read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Abbreviations

OFA – Opioid-Free Anaesthesia

OBA – Opioid-Based Anaesthesia

ASA – American Society of Anesthesiologists

VAS – Visual Analogue Scale

PONV – Postoperative Nausea and Vomiting

ERAS – Enhanced Recovery After Surgery

MAP – Mean Arterial Pressure

HR – Heart Rate

SBP – Systolic Blood Pressure

DBP – Diastolic Blood Pressure

SpO₂ – Peripheral Oxygen Saturation

EtCO₂ – End-Tidal Carbon Dioxide

ECG – Electrocardiogram

CBC – Complete Blood Count

RBS – Random Blood Sugar

LFT – Liver Function Tests

RFT – Renal Function Tests

BMI – Body Mass Index

IEC – Institutional Ethics Committee

RCT – Randomized Controlled Trial

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