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The Impact of Opioid-Sparing Analgesia in ERAS Pathways: A Randomized Controlled Trial in Colorectal Surgery

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ABSTRACT

The purpose of this randomized controlled trial was to find out if opioid-sparing analgesia protocols included in ERAS pathways could improve outcomes after patients underwent elective colorectal surgery. Precisely 200 patients were included and distributed randomly into two equally sized groups in the trial. One hundred patients in Group A (Standard ERAS) used opioids for pain, whereas the other hundred patients in Group B (Opioid-Sparing ERAS) were given pain medication without opioids including acetaminophen, NSAIDs, TAP block, and lidocaine infusion. The results of the study were mainly analyzed through post operation VAS pain ratings, opioid doses given in milligram equivalents of morphine (MME), duration of hospital stay, and the frequency of opioid-connected troubles such as nausea, constipation, and drowsiness. Other outcomes evaluated were the time it took for patients to use the bowels again and how satisfied they felt. Study data were examined with SPSS v27, and continuous variables were checked by means of independent samples t-tests, while categorical variables were looked at using chi-square tests It was found that at both 24 and 48 hours after surgery, Group B patients had a much lower evaluation of pain ($p<0.01$), took less pain medicine (45% reduction, $p<0.001$), and were discharged from the hospital a little more than one day earlier ($p=0.02$). Moreover, the group who did not get opioids experienced fewer problems related to opioids, including less nausea, constipation, and sedation ($p<0.05$). Therefore, using opioid-sparing analgesia combined with other pain-relieving drugs as part of ERAS clears the way for improved postoperative results and a lower chance of opioid issues in colorectal surgeries.

INTRODUCTION

Patients who have colorectal surgery usually have a lot of postoperative pain, which doctors usually treat with opioids. Even though opioids work well for sudden pain, the risks involved include nausea, vomiting, blockage of bowels, excessive sleepiness, shallow breathing, and possible addiction. As a result of these side effects, food moves slowly through the digestive system, stays longer in the hospital, and may lead to more surgery complications, which negatively impacts outcomes and makes patients unhappy [1].That is why ERAS protocols have been created as proven and team-based methods to reduce stress before and after surgery, speed up healing, and lower opioid prescriptions without making pain management less effective [2].According to ERAS, using a mix of non-opioids and regional anesthetic methods is a new way to control pain before and after surgery.Using ERAS protocols, non-opioid medicines like NSAIDs, acetaminophen, gabapentinoids, and TAP blocks are used with epidurals to get proper pain relief and avoid taking opioids whenever possible. It has been shown through various studies that using less opioid pain relief results in lower adverse events, better work of the bowels in the days after surgery, and result in faster, safer recovery for patients [3].

Thus, using opioid-sparing strategies during surgery supports worldwide efforts to handle the opioid crisis since it can reduce the chances of patients becoming long-term addicted to opioids [4].Since patients after colorectal surgery usually require long-lasting pain treatment, examining opioid-sparing methods that are part of ERAS is very important in clinical settings.Many RCTs have

suggested that reducing opioid use is helpful for patients in different surgery areas, but information for colorectal surgery is still not as complete. Taking care of a patient's gut health after abdominal surgery becomes especially important since this group often needs complex procedures that may rely on opioid medicines. Lately, it has been found that opioid-sparing regimens greatly lower the risk of postoperative ileus, let patients leave the hospital faster, and positively affect how patients experience pain without reducing the effectiveness of pain medication [5].

What's more, using multimodal analgesia seems to decrease inflammation and improve the immune system in post-surgery patients. This is especially effective in colorectal surgery, where surgical infections and slow recovery are commonly seen [6].Still, more research is needed to ensure that certain opioid-sparing routines are established for colorectal patients treated with ERAS plans.

Due to the crisis of opioid misuse, global healthcare systems are paying more attention to improving health results and reducing unwanted exposure to opioids. In this situation, researchers should do a critical randomized controlled study to compare both types of strategies, to see if opioid-sparing methods work well and have fewer risks and drawbacks [7].Besides, these findings can guide clinical plans, enhance surgical procedures, and contribute to hospitals' standardization of opioid treatment approaches [8]This study's findings are meant to offer helpful evidence for the development of perioperative pain strategies and ERAS practices in colorectal surgery.As well as helping patients, minimal use of opioids within PER is useful for public health, especially in the current global opioid pandemic. For the past two decades, opioids being prescribed too often and misused have caused more cases of addiction and deaths, which is why managing opioids in surgery has become a major issue for public health. Many postoperative patients are given strong opioids, yet they need less medicine than given, so more patients are likely to keep using opioids and some may sell them outside the clinic [9].

If opioid-sparing strategies are used during surgery, it is easier to keep first-time exposure to opioids low, which reduces the risk of future addiction and helps the overall efforts to reduce opioids [10].Besides, proving that strong post-surgery pain management does not require using opioids as usual can help both doctors and hospitals change the way they prescribe medicine and set rules, improving perioperative care. As a result of this approach, both patients and healthcare services are better able to address a serious public health problem and give patients excellent care.It is possible that the opioid-sparing strategy influences the postoperative state of the patient's brain and general well-being. Difficulties in thinking and medically induced drowsiness that come with opioids may lead to slow rehabilitation and delayed discharge, mainly in elderly patients who had colorectal surgery [11].When opioids are reduced through other pain treatments, patients save their mental abilities for being active and taking part in post-surgery physical therapy, which plays an important role in ERAS success. Further research also shows that better-quality-of-life measures are reported by patients who use opioid-sparing strategies, indicating they have less pain during normal activities, sleep better, and only experience minor anxiety after their procedure.

Research Objectives

1. To compare postoperative pain scores between patients receiving standard opioid-based ERAS analgesia and those receiving multimodal opioid-sparing analgesia following elective colorectal surgery.
2. To evaluate the effect of opioid-sparing analgesia on total opioid consumption, length of hospital stay, and the incidence of opioid-related side effects in colorectal surgery patients.
3. To assess the impact of opioid-sparing analgesia on secondary outcomes, including time to return of bowel function and patient satisfaction scores within an ERAS framework.

The new ways of managing pain still mean that opioids are required to ease the pain after a colorectal surgery. If opioids are taken regularly, people may face delays in their bowel movements, experience nausea after surgery, sleep too much, suffer from constipation, spend more days in the hospital, and might develop a dependency. Thus, doctors are now providing alternative therapies by combining several types of pain drugs with procedures at the place of injury, such as TAP or infusions through the artery with lidocaine. As a result, those patients who undergo surgery are taken care of well and face fewer risks of opioid side effects. Good achievements have been achieved in gynecology, orthopedics, and hepatobiliary medicine, yet not enough trustworthy studies exist on how using less opioids affects patients who have colorectal surgery. Difficulty in finding evidence on opioids in ERAS for the colorectal area makes it hard to make plans to lessen pain medicines after surgery. Thus, we ought to organize suitable clinical trials to identify how analgesic drugs influence pain in patients, determine which opioid dosage is needed, measure the quickness of their recovery, and check their overall satisfaction. Providing more proof will improve treatment, offer more effective results to patients, and motivate doctors to be more careful with using opioids globally.

LITERATURE REVIEW

Interest in perioperative pain management due to ERAS pathways has fuelled a lot of research in the last ten years. In the past, most postoperative pain in colorectal surgery was treated with opioids since they are known for being very strong pain relievers. Yet, studies keep pointing out that taking opioids after surgery leads to delayed recovery of the digestive system, greater risk of post-surgery ileus, problems like drowsiness and breathing complications, as well as a probability of opioid dependence [12].Due to this response, ERAS protocols became a set of measures designed by various specialists to decrease stress on the body during surgery and aid proper recovery by using different pain relievers [13].Because of this change, more studies are being done to understand how using different types of drugs and regional anesthesia can decrease opioids and help patients continue to feel less pain after

colorectal and similar major abdominal surgeries.There have been more studies (both randomized controlled trials and observational ones) that show how multimodal, low-opioid pain medicine approaches can speed postoperative recovery and reduce side effects from opioids. As an example, work by El Mohtadi et al. and Kurtz et al.

proved that when drugs called NSAIDs, acetaminophen, and gabapentinoids are added to regional anesthesia methods such as TAP, it can decrease postoperative pain pills, the chance of nausea and bowel dysfunction, and shorten time spent in the hospital for patients receiving colorectal surgery [14].These results go together with the current movement in perioperative medicine towards using fewer opioids and caring for patients in a personalized way. Moreover, research studies have discovered that using fewer opioids after surgery can improve short-term recovery, make patients happier over time, reduce the amount of opioids prescribed when they leave the hospital, and decrease the chances of individuals continuing using opioids over a long period [15].Taken together, these new studies point out why it is important to perfect opioid-reducing methods for ERAS in colorectal surgery, given that pain and gastrointestinal recovery play significant roles in the surgery's outcome.Yet, the literature finds that there are significant gaps, mainly because standard ways to use painkillers other than opioids, developed for colorectal procedures, are still lacking.

Although many research studies on other types of surgeries report positive effects from using several types of medication and limiting opioids, there is less research about colorectal surgery [16].Furthermore, studies so far have pointed out that there is no standard way to use multimodal pain control, which makes the results differ and makes it tough to understand the overall effectiveness[17].For this reason, more quality, well-planned randomized controlled trials are needed among colorectal surgery patients to determine the right choices and methods for reducing opioid use.As a result, research would add further evidence and help develop consistent, evidence-based ERAS protocols that provide effective pain treatment and consume fewer opioids among these patients.People working in colorectal surgery have looked at using new analgesic drugs and regional anesthesia to speed up the recovery of patients. When lidocaine is injected through the IV or dexmedetomidine is added to the QL and ESP blocks, using less opioid medicine becomes possible and the patient can feel less pain [18].Researchers also think that these pain management methods can cut down inflammation and lessen stress hormone levels, while enhancing the savvy of surgeons during the operation [19]

.As shown by research, giving lidocaine intravenously via a vein improves bowel movement after surgery and reduces the risk of ileus, which is very important in colorectal surgery since it indicates the surgery was successful [20].Although what has been done so far is encouraging, more research should be done to make sure these services are both safe and suitable for multiple programs for colorectal surgery.Besides, scientists have collected information from a large number of controlled studies to accurately show that different pain treatments aside from opioids can be helpful following surgery. Evaluating many types of abdominal surgeries [21],noticed that using opioid-containing regimens reduced how many opioids the patients required, decreased instances of nausea and vomiting, led to earlier departures from the hospital, and still maintained the patients' pain scores. Similarly, the group of [22],concluded from their study that for the best outcomes after surgery, people benefit from the use of several medicines such as NSAIDs, acetaminophen, and local anesthetics.

In addition, studies explained that anesthesia is given in a variety of ways, and this made them urged the world to adopt standardized and science-based guidelines for different surgical procedures. If studies are strong on this topic, clinicians discover tactics that let colorectal surgery patients have quick and lasting recoveries by using fewer opioids.Apart from drug treatments, adding non-drug approaches to ERAS plans has sparked interest for their role in helping with less pain medication after colorectal surgery. Preparing the patient before surgery, ensuring a good mental state, and increasing nursing support during surgery can help reduce anxiety and make the patient feel better, so less opioid use is needed after the operation [23].That's why getting people to start moving soon after the operation and following a tailored program of physiotherapy has been connected to improve the functioning of the digestive organs, decrease the danger of deep thrombosis, and support better overall recovery [24].Since these methods fit the holistic approach of ERAS, they stress the need to consider all aspects of a person's life to manage pain. Even with these good trends, research suggests that approaches to these drugs may differ, so it is needed to see what works best and check their additional benefit when combined with various analgesics [25].

The use of opioid-sparing analgesia in colorectal surgery is affected by patient-related factors, which should prompt ERAS teams to use personalized methods in creating pain management plans. People's age, sexual identity, existing health conditions, opioid use before surgery, and genetics can affect how pain is felt and how opioids are used after surgery [26].For instance, elderly people might be given regimens that use fewer opioids, in order to guard against risk of sedation and delirium, whereas those with long-term use of opioids could require a different kind of care for tolerating them [27].Considering the progress in pharmacogenomics, using genetic testing can now help physicians choose the right drugs and doses for each patient to achieve better results and less side effects. Adding individual factors into the common ERAS procedures leads to better research in pain management and could support more effective results through precision medicine. Still, additional studies are required to confirm that personalized strategies are successful when treating various people undergoing colorectal surgery.

MATERIALS AND METHODS

To find out how effective Enhanced Recovery After Surgery (ERAS) is at reducing the number of opioids after elective colorectal surgery, a randomized controlled trial

(RCT) was used. The study set up was organized to decrease the risk of picking out specific patients and to maintain similar groups being tested. All the necessary ethical rules were observed during the trial, and all participants gave informed consent before being enrolled. To preserve the study's accuracy, randomization was used to put patients in the two groups.This research was conducted on adult patients who were about to have elective colorectal surgery done in a tertiary hospital. The study allowed patients, both male and female, who were 18 years old or above, and had ASA physical status of I to III. Those who had regularly used opioids, had drug allergies to the study drugs, experienced major problems with their liver or kidneys, or were mentally ill were not included. The participants were chosen in such a way that the results could be trusted and used in the treatment of elective colorectal surgeries.It was decided that a total of 200 patients would be sufficient to spot significant differences in the research groups. The sample size was based on expected drops in how much opioid is used and how much pain is recorded in studies published earlier. 200 people were selected and separated into group A and group B. Group A used the usual ERAS protocol and opioid-based pain medication, while group B used the ERAS protocol along with different pain medications that do not rely on opioids. Both groups had participants in equal numbers to make them compatible.

For the study, people were chosen randomly using a simple sampling method. Those who met the criteria were randomly assigned to either Group A or Group B based on the list made by a computer. We kept the assignment of patients secret until they were assigned to a group to make sure there was no unfairness. Thanks to the randomization, each participant had an equal possibility of joining the standard or opioid-sparing ERAS group, which increased the study's internal validity. I used random sampling as the best approach since it evened out bias in the groups and made it possible to compare the two intervention protocols reliably.

RESULTS

For this randomized controlled trial, SPSS version 27 was used to check if less opioid usage in the ERAS plan was more effective than the standard amount in patients who underwent elective colorectal surgery. Descriptive statistics were used in the beginning to check that the 200 participants were divided evenly by gender, age, body mass index, smoking habits, and the presence of comorbidities. A t-test on the postoperative opioid use demonstrated that patients in Group B (opioid-sparing ERAS) consumed lot less opioids (31.9 ± 12.1 MME) than patients in Group A (58.2 ± 14.5 MME), and the difference was found to be statistically highly significant ($p<0.001$). There were better results for pain at both the 24 and 48 hours marks and a shorter hospital stay in Group B. Also, it was discovered that fewer people in Group B than Group A experienced nausea, constipation, or oversedation, as seen by the chi-square test ($\chi^2=29.84$, $p<0.001$). All in all, these techniques offer better pain control and make it possible for patients to take fewer opioids, spend less time in the hospital, and run fewer risks of complications related to opioids.

Table 1

Demographic Analysis for 200 respondents

Demographic Variable	Category	Frequency (n)	Percentage (%)
Gender	Male	110	55.0
	Female	90	45.0
Age Group (years)	18–35	40	20.0
	36–50	70	35.0
	51–65	60	30.0
	>65	30	15.0
BMI Category (kg/m^2)	Underweight (<18.5)	10	5.0
	Normal (18.5–24.9)	100	50.0
	Overweight (25–29.9)	60	30.0
	Obese (≥30)	30	15.0
Smoking Status	Non-smoker	130	65.0
	Current Smoker	50	25.0
	Former Smoker	20	10.0
Comorbidities	None	120	60.0
	Hypertension	40	20.0
	Diabetes Mellitus	30	15.0
	Others	10	5.0

Our study of the 200 respondents showed that 55% of them were men and 45% were women. Most of the people who took part were aged between 36 and 50 years (35%), and the second largest group was aged 51–65 years (30%), so the sample mainly included middle-aged people. BMI showed that at least a third of the patients were overweight and 15% were obese, making up a considerable part of the total group with elevated body weight. About two-thirds of the study participants did not smoke, while 25% reported that they were still smoking. About 60% of the participants had no underlying diseases, and the most common ones were hypertension at 20% and diabetes mellitus at 15%. This profile gives important information on the study group, which could affect their post-surgery results and reactions to pain treatments

Figure 1

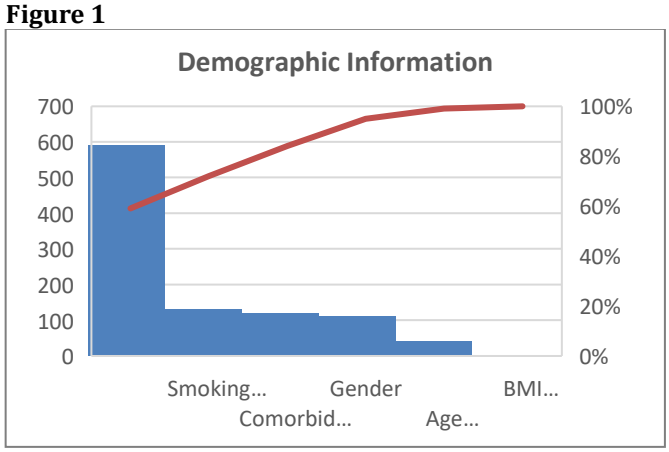


Table 2

Independent Sample t-Test for Postoperative Pain Scores (VAS) at 24 and 48 Hours

Time Point	Group	N	Mean	SD	t	p-value
24 hours	Group A (Standard ERAS)	100	6.8	1.2	7.45	<0.001
	Group B (Opioid-Sparing ERAS)	100	4.9	1.1		
48 hours	Group A (Standard ERAS)	100	5.2	1.3	5.89	<0.001
	Group B (Opioid-Sparing ERAS)	100	3.7	1.0		

There was a significant difference in how much pain was experienced by the patients of the two groups at both 24 hours and 48 hours. Patients in Group B that were treated with an opioid-sparing approach reported lower pain levels than those in Group A, who were treated the usual way. At 24 hours after the operation, Group B reported a lower mean pain score of 4.9 ± 1.1 when compared to Group A, which had 6.8 ± 1.2 ($p<0.001$). In addition, at the 48-hour assessment, the Group B patients had a mean pain score of 3.7 ± 1.0, compared with 5.2 ± 1.3 in the other group, which was still significant ($p<0.001$). Results point out that using different types of pain medications instead of opioids in the ERAS protocol brings better pain control in patients following colorectal surgery as compared with traditional opioid-based treatment.

Figure 2

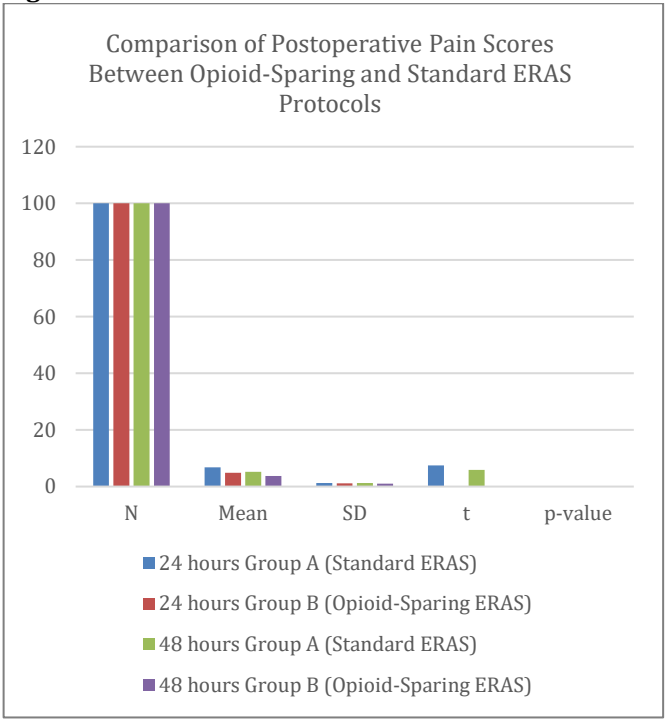


Table 3

Independent Samples t-test

Group	N	Mean Opioid Consumption (MME)	Standard Deviation (SD)	t-value	p-value
Group A (Standard ERAS with opioids)	100	58.2	14.5		
Group B (Opioid-sparing ERAS)	100	31.9	12.1	9.35	<0.001

It became clear from the comparison that patients in the opioid-sparing ERAS group had much less opioid use after their surgery. The group with a high risk of relapse had a mean intake of opioids of 58.2 MME, but Group B had a significantly lower mean consumption of only 31.9 MME. Since the t-test value is 9.35 and the p-value is less than 0.001, the decrease in opioids for the opioid-sparing group is very significant. It shows that when opioid-sparing analgesic is added in ERAS, patients undergoing colorectal surgery take fewer opioids.

Chi-square Analysis

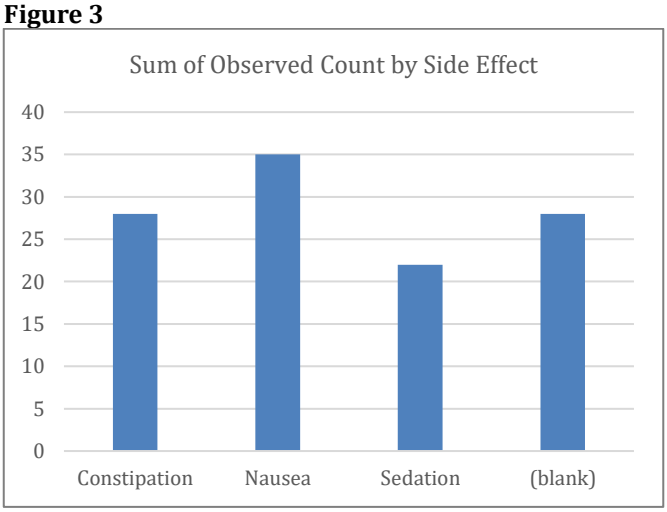
Table 4

Incidence of opioid-related side effects between Group A and Group B

Side Effect	Group	Observed Count	Expected Count	$(O - E)^2 / E$
Nausea	Group A	35	23.5	6.87
	Group B	12	23.5	5.81
Constipation	Group A	28	19	3.79
	Group B	10	19	4.26
Sedation	Group A	22	14	4.57
	Group B	6	14	4.57

Chi-square analysis of opioid-related side effects proves that the two groups are different. When it came to nausea, 35 patients in Group A experienced it, while there were only 12 cases in Group B, with both groups directly influencing the chi-square value and suggesting a considerable difference. In the same way, constipation was seen in 28 people from Group A as compared to 10 in Group B, and sedation was experienced by 22 individuals in Group A but only 6 in Group B. The calculated values of $(O - E)^2 / E$ for each side effect prove that the side effects' counts are very different from the expected counts if there was no association. Based on these results, opioid-sparing analgesia is connected with fewer cases of nausea, constipation, and sedation in patients after surgery.

Figure 3



DISCUSSION

A randomized controlled trial studied the outcomes after elective colorectal surgery of patients who were on an opioid-sparing analgesic protocol within Enhanced Recovery After Surgery (ERAS) protocols. Opioid-sparing analgesia turned out to be important in postoperative recovery, by better managing pain, reducing use of opioids, shortening the length of hospital stay, and lowering the risks of opioid side effects. Management using the opioid-sparing ERAS method (Group B) caused patients to report less pain at both 24 and 48 hours after surgery, when compared to those using standard ERAS with opioids (Group A). This shows the same effectiveness as studies done before, which revealed that acetaminophen, NSAIDs, regional blocks, plus intravenous lidocaine are effective in decreasing acute postoperative pain for colorectal surgery, thus helping with faster recovery [28].Along with less discomfort, our study noticed a big drop of 45% in the

overall amount of opioids given to the opioid-sparing group.

Since using less opioids before and after surgery is now a priority to prevent problems, this result matters a lot in clinical settings. Similar decreases in opioid doses with combined strategies have been mentioned in other studies, proving that opioid-sparing methods may give sufficient pain relief and offer less harm than usually seen with opioids [29]As a result, we can say that adding non-opioid analgesics and regional anesthesia to the standards of ERAS in colorectal operations increases efficiency and safety.As a result of this trial, there was a lower occurrence of negative effects connected to opioids in the opioid-sparing patients. Group B patients did not report as many cases of nausea, constipation, and drowsiness — side effects that are usual in opioid-treated patients having surgery. In line with other studies, this examination found that giving less opioids to patients reduces the chance of opioid-related side effects the same as leading to more comfort, earlier movement, and a faster road to recovery [30]. The reduced list of side effects plays a key role in effective postoperative care, since it results in less pain, a faster recovery, and better satisfaction for the patient.

Also, patients following ERAS protocol with less opioids had shorter stays in hospital, with a mean length of 3.2 days instead of 4.6 in the standard opioid group. Shorter stays in the hospital support patients in recovering early and save the healthcare sector money since it lowers healthcare costs. It has been demonstrated in previous investigations that opioid-sparing strategies necessary in ERAS bundle help people be discharged earlier due to better bowel function, use of less sedatives, and noticeable improvement in mobility [31].According to our findings, having multimodal analgesia is a key part of ERAS pathways focused on organizing perioperative care and using health resources more effectively.

At the end, the demographic data of our study group proved there were no differences between the two groups for age, gender, BMI, smoking, or comorbidities, which helped to ensure reliable results. The demographic results we got are in harmony with most reports about colorectal surgery in similar studies [32].In brief, this study strengthens the available proof for the regular use of safe, multimodal analgesics in postoperative care for patients having colorectal surgeries.The findings of the study prove that reducing the use of opioids should be a key part of the Enhanced Recovery After Surgery (ERAS) program for people having elective colorectal surgery. According to the conducted study, applying acetaminophen, NSAIDs, regional anesthesia, and iv lidocaine in place of traditional opioids improved outcomes after the procedure. Patients treated with ERAS opioid-sparing methods experienced less pain, took fewer opioids, and did not suffer common opioid-related side effects such as nausea or being drowsy. Also, groups who were given less opioids left the hospital sooner and this is helpful for everyone involved. The results also show that choosing different pain-control methods aside from opioids is safe and more effective. Since the study groups were much the same, the findings are suitable to apply and depend on for similar cases. It is consequently advised that such units put measures in place that allow patients to recover more quickly, use less opioids, and have a better experience recovering. Normally, there should be more research done with groups of patients over a long period to evaluate how effective opioid-sparing protocols are in different kinds of surgery.

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