Effect of Neuromuscular Blockade Reversal on Postoperative Gastrointestinal Motility after Laparoscopic Cholecystectomy: Neostigmine / Atropine *versus* Sugammadex

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ABSTRACT

Objective: To compare sugammadex with neostigmine / atropine combination for reversal of neuromuscular blocker agents in terms of postoperative gastrointestinal motility in patients who underwent laparoscopic cholecystectomy.

Study Design: Experimental study.

Place and Duration of the Study: University of Health Sciences, Izmir Bozyaka Training and Research Hospital, Izmir, Turkiye, between December 2020 and June 2021.

Methodology: Seventy-two patients undergoing laparoscopic cholecystectomy were included. At the end of the surgery, patients were antagonised for neuromuscular blockers either by atropine / neostigmine or sugammadex by an anaesthesiologist who was not involved in the study. Total anaesthesia time, pneumoperitoneum time, surgery time, number of postoperative opioid dose requirements and total opioid dose administered, number of medication requirements for postoperative nausea and vomiting, postoperative hospital stay, and first gas and stool output time of all the cases were evaluated by the researcher who was unaware of the medicines used for antagonisation.

Results: There were no statistically significant differences between the two groups in terms of their effects on postoperative gastrointestinal motility (first gas and stool output time), duration of anaesthesia, duration of surgery, duration of pneumoperitoneum, the number of postoperative opioid dose requirements, the number of drug requirements for postoperative nausea / vomiting, and the postoperative hospitalisation duration of the cases.

Conclusion: Effects of reversal agents on postoperative gastrointestinal motility are still debated. Studies on this subject in the literature are both limited in number and have been conducted with different medicine combinations in a wide variety of patient populations. The authors thought that further prospective randomised studies are needed to interpret this effect more clearly.

Key Words: *Sugammadex, Neostigmine / atropine, Gastrointestinal motility, Laparoscopic cholecystectomy.*

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INTRODUCTION

Laparoscopic cholecystectomy (LC) is the gold standard procedure for cholecystitis.[1,2] The most preferred anaesthesia method for LC is general anaesthesia.[2]

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Although regional blocks such as low thoracic epidural, spinal, and combined spinal-epidural blocks have been used for LC, these methods are restricted to patients with lung disease who are at high risk during general anaesthesia.[3] LC under general anaesthesia eliminates the discomfort caused by pneumoperitoneum and changes in the patient's position on the operating table during surgery,[4] but often requires tracheal intubation to prevent aspiration and respiratory complications secondary to pneumoperitoneum induction.[3] Therefore, neuromuscular blockers which belong to non-depolarising neuromuscular blockers (NDMBs) are applied concomitantly with intravenous anaesthetic agents during the induction of anaesthesia to facilitate tracheal intubation,[5] to achieve muscle relaxation during surgery,[5,6] and to reduce the rate of postoperative adverse events.[6]

To combat the postoperative residual neuromuscular blockade, acetylcholinesterase inhibitors [5,7-9] or sugammadex have been used.[5,7,9]

Acetylcholinesterase inhibitors such as neostigmine and pyridostigmine, often cause muscarinic side effects (salivation, lacrimation, diarrhoea, bradycardia, etc.).[7-10] So to prevent these side effects, anticholinergic agents such as atropine and glycopyrrolate were applied before a cetylcholinesterase inhibitor was applied.[6-10] Sugammadex is a newly introduced γ-cyclodextrin derivative[6-8,11,12] which creates a water-soluble complex by encapsulation with steroid Neuromuscular Blockade (NMB) agents and creates a reverse effect.[6,9] Since it does not have a muscarinic effect, there is no need for concomitant administration of anticholinergic agents.[8-11,13] Its clinical use is becoming increasingly common as it provides fast and reliable reverse from any depth of neuromuscular block.[11,14]

Factors that affect postoperative bowel dysfunction are secondary bowel dysfunction from operative trauma, surgical stress response and opioid analgaesics.[9]

One of the factors that affect bowel motility after surgical applications is the reversal agents used for the antagonisation of NMB agents.[7-9,13,14] While acetylcholinesterase inhibitors increase mobility, anticholinergic agents reduce it.[8,9,13] Less is known about the effect of sugammadex on bowel motility after surgery.[7]

The aim of this study was to compare sugammadex with a neostigmine / atropine combination for the reversal of NMB agents in terms of postoperative gastrointestinal motility in patients who underwent laparoscopic cholecystectomy. The primary outcome was the time between the first flatulence and defaecation after antagonisation of neuromuscular blockers. The secondary outcome was adverse effects such as nausea, vomiting, etc.

METHODOLOGY

The Ethics Committee of the University of Health Sciences, Izmir Bozyaka Training and Research Hospital approved this prospective, observational study that was carried out from December 2020 to June 2021.

Seventy-two patients undergoing laparoscopic cholecystectomy with four trochar techniques were eligible for inclusion in the study. Patients were included if they were ≥20 and ≤70 years, American Society of Anaesthesiologists (ASA) physical status I or II, and patients who gave consent to participate in the study. Exclusion criteria included emergency surgery, ASA physical status score ≥III, preoperative history of diabetes, ulcerative colitis, or Crohn's disease, renal failure or renal dysfunction, previous abdominal surgery, patients having drugs that can affect gastrointestinal motility, and patients who did not give consent to participate in the study.

No premedication was applied before the induction of anaesthesia. In the operating theatre, after routine monitorisation (non-invasive blood pressure, electrocardiogram, end-tidal carbon-dioxide, and pulse-oximeter), and Train of Four (TOF) monitoring, anaesthesia was induced with propofol (2mg/kg), remifentanil infusion (0.2 - 0.5 µg kg - 1 min - 1) and rocuronium (0.5mg/kg) to facilitate the tracheal intubation while TOF monitoring was in progress. Anaesthesia was maintained with desflurane 6% concentration in a gas mixture consisting of 45% oxygen in the air. Perioperative insufflation was performed with a maximum pneumoperitoneum pressure of 12 mmHg. After removal of the gallbladder, 1 gm paracetamol and 0.3 mg/kg tramadol were administered intravenously for postoperative analgaesia.

At the end of the surgery, when TOF score ≥2 was achieved, either sugammadex or neostigmine / atropine combination was administered intravenously for antagonisation of muscle relaxation by an anaesthesiologist who was not involved in the study. The patients were extubated when the patients' TOF ratio was ≥ 90% and then they were transferred to the postanaesthesia care unit (PACU).

Patients' demographic characteristics, surgery time, anaesthesia time, pneumoperitoneum time, total remifentanil dose administered intraoperatively, number of analgaesic demands for postoperative analgaesia, number of patients who developed nausea and vomiting, and postoperative hospital stay duration of the patients were noticed. Postoperative first flatulence (first flatulence) and defaecation time were also recorded to evaluate the improvement of patients' bowel movement by the researcher who was unaware of the medicines used for neuromuscular block antagonisation.

The time between the first flatulence and defaecation after antagonisation of neuromuscular blockers was noted and accepted as the primary outcome of the study. The adverse effects such as nausea, vomiting, and dry mouth were also noted and evaluated as the secondary outcome of the research.

The 11-point numeric rating scale was used to assess the pain scores on arrival and every 30 minutes for the first two hours in PACU and on 4th, 6th, 12th, and 24th hours on the ward. All scores were noted.

All these parameters were summarised as the patients were categorised as below.

Group Sugammadex (Group S): Patients who received sugammadex after surgery for reversal of neuromuscular block.

Group Neostigmine / Atropine (Group N): Patients who received atropine / neostigmine after surgery for reversal of neuromuscular block.

Package for the Social Sciences IBM® SPSS® 22 (SPSS Inc., Chicago, IL, ABD) was used for statistical analysis. Kolmogorov-Smirnov / Shapiro-Wilk's tests were used for the conformity of the variables to the normal distribution. Descriptive analyses were reported as mean ± standard deviation. Descriptive analyses, mean ± SD for continuous data. Deviation was given as count (n) and percentage (%) for categorical variables. To compare paired groups, t-test was used for normally distributed independent groups. Pearson's Chi-Square or Fisher's Exact Chi-Square tests were used to compare categorical variables. A value of $p < 0.05$ was considered statistically significant.

Table I: Patient characteristics.

		Group S	Group N	p-value
Age (year)		49.69 ± 13.44	45.11 ± 14.97	0.176
BMI (Kg/m^2)		30.47 ± 9.46	28.67 ± 5.16	0.318
ASA (n)	I	7 (19.4%)	7 (19.4%)	0.99
	II	29 (80.6%)	29 (80.6%)	
Comobidity (n)	Yes	16 (44.4%)	25 (69.4%)	0.032
	No	20 (55.6%)	11 (30.6%)	

Descriptive analyses used for continuous data (Chi-square test) and t-test was used to compare paired groups. Values are presented as mean ± SD or as number and percentages. ASA: American Society of Anaesthesiologists physical status classification.

Table II: Perioperative data and comparison of outcomes.

	Group S	Group N	p-value
Anaesthesia time (min)	74.44 ± 28.01	84.58 ± 24.97	0.143
Operation time (min)	9.72 ± 26.10	69.64 ± 27.52	0.121
Pneumoperitoneum time (min)	49.97 ± 25.78	56.17 ± 23.27	0.288
Intraoperative remifentanil dose (mcg)	212.5 ± 90.34	253.33 ± 104.43	0.080*
Gas-out time (hour)	14.03 ± 8.77	11.67 ± 9.91	0.288
Defaecation time (hour)	34.75 ± 13.80	39.25 ± 21.29	0.291

t-test was used to compare unpaired groups. Values are presented as mean ± SD.

Table III: Neostigmine and atropine combinations as injection BP applied for reversal of neuromuscular block.

2 Neostigmine + 1 Atropine	1 (1.4%)
3 Neostigmine + 1 Atropine	27 (37.5%)
4 Neostigmine + 1 Atropine	3 (4.2%)
3 Neostigmine + 2 Atropine	3 (4.2%)

Descriptive analyses used for continuous data (Chi-square test). Values are presented as number and percentages.

Table IV: Number of cases evaluated in terms of number of analgaesic demand for postoperative analgaesia.

Number of analgaesic demand for postoperative analgaesia	Group S	Group N	p-value
Number of patients who did not require	8 (66.7%)	4 (33.3%)	0.293
Number of patients who needed twice	19 (44.2%)	24 (55.8%)	0.455
Number of patients who needed 3 times	6 (66.7%)	3 (33.3%)	0.370
Number of patients who needed 4 times	2 (28.6%)	5 (71.4%)	0.335
Number of patients who needed 6 times	1 (10%)	0 (0%)	0.821

Descriptive analyses used for continuous data (Chi-square test). Values are presented as number and percentages.

RESULTS

Seventy-two patients were enrolled in this prospective observational study. There were 10 (14%) male, 26 (36%) female in Group S and 11 (15%) male and 25 (35%) female cases in Group N. Patient characteristics are reported in Table I. Perioperative data and comparison of outcomes were summarised in Table II. The amount of remifentanil administered intraoperatively was higher in Group N than in Group S. This difference was statistically significant. Group S took less time for defaecation; however, the Group N took less time for first gas-out. Nevertheless, the time elapsed for these was not statistically significant between the groups.

Postoperative hospital stay was similar in both groups. In order to reach the targeted extubation criteria, 200 and 300 mcg of sugammadex were applied to 34 and 2 cases in the sugammadex group, respectively. The injection BP of the neostigmine (1 BP = 0.5 mg/mL) and atropine (1 BP = 0.5 mg/mL) are summarised in Table III.

When the number of cases evaluated in terms of a number of analgaesic demand for postoperative analgaesia requirement, there was no statistically significant difference between the two groups (Table IV). The number of the patients, who developed adverse effects such as nausea and vomiting, was not statistically significant between the groups.

DISCUSSION

Return of bowel motility after surgery is an important parameter that determines the discharge of the cases.[7] Prevention of postoperative ileus is particularly emphasised in ERAS (enhanced recovery after surgery) protocols.[8] Gastrointestinal tract dysfunctions cause discomfort in patients and continue to be a major problem, although many perioperative precautions are taken.[13]

In a retrospective cohort analysis, authors have evaluated the first bowel movement following the laparoscopic colorectal surgery. Patients received either sugammadex or a combination of neostigmine and glycopyrrolate for NMB reversal at the end of the surgery. They demonstrated a faster return of bowel movement with sugammadex when compared with a combination of neostigmine and glycopyrrolate.[7]

In a prospective randomised controlled clinical trial, authors compared the effects of neostigmine / glycopyrrolate and sugammadex on bowel motility recovery and the occurrence

of digestive system complications after the colorectal surgery. They demonstrated that the time to first flatus was significantly shorter in the sugammadex but the time to first defaecation was not significantly different between the sugammadex and neostigmine groups.[11]

In another retrospective cohort study,[13] authors determined that different groups of neuromuscular blockade reversal agents affect the first postoperative bowel movement after intraperitoneal surgery. They reported that the first postoperative bowel movement was earlier with sugammadex according to neostigmine / glycopyrrolate. However, they stated that they do not have a clear mechanistic explanation for their observation.

A meta-analysis evaluated that the postoperative effects of neuromuscular blockade reversal with sugammadex compared with acetylcholinesterase inhibitors in colorectal surgery, supported the beneficial impact of sugammadex on gastrointestinal motility after colorectal surgery.[6] However, they did not show significant superiority on the preventation of surgical complications and length of hospital stay.

In a retrospective observational study,[10] authors compared traditional reversal agents with sugammadex for first flatus and oral intake tolerance following open pancreaticoduodenectomy. They reported that sugammadex use was significantly associated with a decrease in time to first flatus and oral intake tolerance.

Contrary to the studies above, there was no statistically significant difference in bowel motility in the present study. However, it is difficult to make a clear interpretation of the effect on gastrointestinal motility since both the patient population and the agents used for reverse were different.

Another group of researchers investigated the effect of sugammadex or neostigmine / atropine on postoperative bowel motility who underwent total thyroidectomy.[9,15] Sen *et al.* reported the first defaecation time as 32 and 26 hours in the sugammadex group and in the neostigmine groups respectively.[15] Although this difference was not statistically significant, it was evaluated significantly by the researchers. Lee *et al.* stated that the use of sugammadex did not affect the delayed recovery of postoperative bowel motility after robotic thyroidectomy.[9] Although postoperative bowel motility, based on the first gas emission time, was comparable, the number of patients with a first gas emission time within 24 hours was significantly higher in the sugammadex group than in the neostigmine group.

According to another prospective randomised study, the authors reported that sugammadex applied for NMB reverse after laparoscopic cholecystectomy had more positive effects on gastrointestinal motility than pyridostigmine / glycopyrrolate administration.[8] Although investigate the reversal of NMBs in the same patient population as utilised in this study, the reasons why the present study's results did not match with this study are: 1. Use of different inhalation agents (desflurane in the present study, sevoflurane in the other study) 2. While the authors applied neostigmine / atropine combination for antagonisation in the present study, the preferred method in the other study was to apply the pyridostigmine / glycopyrrolate combination.

According to this study's results, although it was not statistically significant, the dose of remifentanil admitted perioperatively was higher in the group that was reversed with neostigmine / atropine. While it was thought that bowel motility would be delayed due to the high perioperative opioid dose, no difference was found compared to the sugamadex group. This result showed that there are many factors that affect bowel motility.

The authors evaluated the quality of recovery (PACU stay, postoperative pain scores, rescue analgaesics and antiemetics, urinary retention, and length of hospital stay) after laparoscopic cholecystectomy following neuromuscular blockade reversal with neostigmine / glycopyrrolate or sugammadex. They reported that there was no statistically significant difference in the quality of recovery except urinary retention. The incidence of postoperative urinary retention was lower in the sugammadex group.[16] Contrary to this study, another group of researchers reported that the quality of recovery score was higher in the early postoperative period with sugammadex.[17]

Another study stated that sugammadex has no benefit over neostigmine when used as a primary neuromuscular blocking reversal agent following laparoscopic cholecystectomy.[5]

Moss *et al.* reported that the favourable pharmacodynamic profile of sugammadex may improve perioperative efficiency with offset higher cost in their research.[18] Another study demonstrated sugammadex seems to be effective in decreasing the incidence and severity of postoperative nausea and vomiting after laparoscopic cholecystectomy.[19] A search on neuromuscular blockade reversal with sugammadex after abdominal surgery demonstrated an excellent recovery profile and decreased the risk of pneumonia although it did not affect the length of postoperative hospital stay.[20]

In a meta-analysis of randomised controlled trials, the authors investigated the efficacy and safety of sugammadex compared to neostigmine for reversal of neuromuscular blockade. They suggested that sugammadex is superior to neostigmine, as it is able to reverse neuromuscular blockage faster and more reliably with a lower risk of adverse events.[12]

The variation in the combination and/or dose of the reverse agents in the studies causes differences in the results of the studies.[14] That leads to difficulty commenting on the results

of the studies in the literature. In addition, the different anaesthesia management selected in terms of perioperative anaesthesia management may be effective in obtaining different results on GIS motility. On the other hand, the subjective evaluation of gastrointestinal motility is another limitation of this study.

CONCLUSION

Sugammadex *versus* traditional reverse agents did not have a significant effect on postoperative gastrointestinal motility. However, studies on this subject in the literature are both limited in number and have been conducted with different combinations of medicines in a wide variety of patient populations. The authors thought that further prospective randomised studies are needed to interpret this effect more clearly.

ETHICAL APPROVAL:
Ethical approval of this study was obtained from the University of Health Sciences Izmir Bozyaka Training and Research Hospital, prior to initiation of the research work dated on 11 November 2020.

PATIENTS' CONSENT:
Informed consent was obtained from patients to publish the data concerning this study.

COMPETING INTEREST:
The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:
MB, FYB: Conception and design of work, analysis and interpretation of data, and drafting and revision of work.
SY: Conception of work and drafting of the work.
KB: Design of work and critical revision of the manuscript.
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