

Outcomes of laparoscopic versus open appendectomy in overweight and obese patients: The impact of surgical approach on clinical results and quality of life

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ABSTRACT

Introduction: Appendectomy stands as the primary curative intervention for acute appendicitis, and the emergence of minimally invasive techniques has propelled interest in laparoscopic procedures. This study aimed to compare the outcomes of open appendectomy (OA) and laparoscopic appendectomy (LA) in overweight and obese patients, shedding light on optimal surgical strategies for this specific patient group.

Materials and Methods: This study scrutinized and compared the outcomes of acute appendicitis treatment using LA and OA methods in overweight and obese patients. Carried out at Bursa Cekirge State Hospital, the study spanned from January 2015 to June 2020. Patient evaluation encompassed demographic characteristics such as age, gender, body mass index (BMI), and American Society of Anesthesiologists (ASA) classification, along with comorbidities, leukocyte count, hemoglobin levels, appendicitis severity, time from symptom onset to surgical intervention, and surgical duration. Surgical outcomes included complications within 30 days, length of hospital stay, pain scores, time to resume work, and complications beyond the initial 30-day post-surgery.

Results: The two groups showed no significant differences in age, gender, BMI, ASA scores, medical history (hypertension, diabetes), leukocyte count, hemoglobin levels, or time to surgery. However, operative time ($p<0.001$), incision length ($p<0.001$), and post-operative pain scores ($p<0.001$) differed significantly. Laparoscopic group had fewer 30-day complications, shorter return to work, and slightly higher satisfaction. Significant differences emerged on the 15th day after surgery. Laparoscopic group had notably better scores in physical function, role, pain, general health ($p=0.005$, $p<0.001$, $p=0.038$, $p=0.002$). At 1-year milestone, laparoscopic group showed advantages in role and pain ($p=0.039$, $p=0.005$).

Conclusion: The benefits of LA for obese and overweight patients include shorter surgery durations, reduced infection rates, and faster recovery. These advantages underscore its preference, enhancing patients' quality of life, and lowering complication risks.

Keywords: Appendectomy, Laparoscopy, Obese, Overweight

Introduction

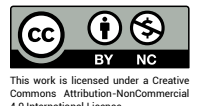
Minimally invasive techniques have revolutionized surgical treatments, and laparoscopic procedures are gaining

popularity for various conditions, including acute appendicitis. Laparoscopic appendectomy (LA) has become the preferred approach due to its advantages over open ap-



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pendectomy (OA).^[1,3] The benefits of laparoscopy include reduced wound infections, faster recovery times, and cost-effectiveness.^[4-6] However, there are considerations regarding increased costs associated with laparoscopy in cases of intra-abdominal abscess.^[7] Individuals with obesity often present challenges in surgery due to their thicker abdominal walls. Laparoscopy effectively addresses these difficulties by providing better access to the surgical area and facilitating wound management. LA is particularly advantageous in treating appendicitis, offering better outcomes compared to OA. While some studies support the safety and effectiveness of LA for both acute and perforated appendicitis, there is still debate, and certain cases may lean toward the open procedure.^[1,8]

The increasing numbers of obese and overweight individuals, along with the continuing trend, have rendered the assessment of the benefits of LA in appendicitis cases critical. Despite the prevalence of obesity being a significant reason for preferring LA over OA, the distinct difference between these two approaches remains elusive. The primary goal of this study was to explore potential disparities between OA and LA procedures, specifically focusing on patients stratified by their body mass index (BMI), particularly those classified as overweight or obese. This article aims to elucidate these disparities within the context of individuals with varying degrees of obesity.

Materials and Methods

A retrospective study is presented, involving a single-center comparison of acute appendicitis treatment through appendectomy in overweight and obese patients. The study covers the period from January 2015 to June 2020 and was conducted at Bursa Cekirge State Hospital. Both laparoscopic and OA procedures were performed on patients diagnosed with acute appendicitis during this timeframe. The study encompasses patients who received contributions from seven different surgeons. Among these surgeons, one consistently performed LA, while the remaining surgeons exclusively opted for the OA method.

In the Lap group, LA was carried out, while in the Open group, OA was performed. Patient details such as age, gender, comorbidities, previous abdominal surgical procedures, BMI, American Society of Anesthesiologists (ASA) classification, total leukocyte count ($10^3/\mu\text{L}$), hemoglobin levels (g/dL), severity of appendicitis, time from symptom onset to surgery (in hours), and duration of the surgical procedure (in minutes) were recorded for

analysis. Post-operative outcomes were assessed based on various parameters. Complications occurring within the initial 30 days after the surgery were documented, with specific types including pelvic abscess, post-operative ileus, wound infection, wound seroma, and dehiscence. The length of hospital stay was measured in hours. Pain scores using the Visual Analog Scale (VAS) were documented at the 6-h mark post-surgery, as well as during the discharge period. The period needed for the patient's return to work was noted in days. Late post-operative complications, occurring beyond the 30-day timeframe, were examined. These complications encompassed specific issues such as intestinal obstruction and incisional hernia.

Furthermore, patients were surveyed about their post-surgery satisfaction using a question that presented three response options. This inquiry took place 1 week following the procedure, with patients given the choice between the following responses: "Very satisfied," "Satisfied," or "Dissatisfied." On the 15th day post-operatively, an evaluation was carried out the 36-Short Form Health Survey (SF-36) scales. Similarly, a comparable assessment was conducted at the 1-year milestone, utilizing the same SF-36 scales.^[9]

The clinical diagnostic criteria were defined as follows: Acute abdominal pain (with pain on to the right iliac fossa, tenderness during palpation and decompression), presence of leukocytosis, and/or identification of free fluid and/or an enlarged cecal appendix through abdominal ultrasound. In instances where ultrasound results were uncertain and inconclusive, confirmation was achieved using abdominal computed tomography.

Inclusion Criteria

The study encompassed individuals aged 18 years and above, possessing a BMI exceeding 24.9 kg/m^2 . The inclusion criteria involved patients attending clinical monitoring, who duly accomplished VAS assessments and SF-36 questionnaires. Moreover, participation in the study was contingent on the patient's voluntary consent to engage with the provided forms.

Exclusion Criteria

Patients under the age of 18, those with a BMI $\leq 24.9 \text{ kg/m}^2$, individuals with clinically or ultrasonographically detected masses, patients who underwent midline laparotomy, those who did not complete their follow-up, individ-

uals with incomplete VAS scores or SF-36 forms, patients who missed their follow-up appointments, and those who declined to participate were excluded from the study.

Statistical Analysis

The initial clinical data underwent thorough statistical analysis. Continuous data were evaluated using t-tests and Mann–Whitney U-tests, while categorical data were analyzed using Fisher's exact test or the Chi-square test. SPSS version 22.0 software was used a significance level of $p < 0.05$.

Surgical Techniques

All appendectomy procedures were conducted under general anesthesia. Each patient was administered a single intravenous dose of metronidazole (500 mg) and ceftriaxone (2 g IV for < 120 kg, 3 g IV for ≥ 120 kg) perioperatively. In LA, an initial 10-mm trocar was inserted through an umbilical incision to establish pneumoperitoneum with carbon dioxide, maintaining 10–12 mmHg pressure. Another 10-mm trocar was inserted above the pubic bone for appendix manipulation and specimen extraction, while a third 5-mm trocar was placed in the left iliac fossa. OA involved a McBurney incision followed by appendectomy, saline irrigation of the abdominal cavity, and closure of the abdomen.

Results

Between January 2015 and June 2020, a total of 113 overweight and obese patients who underwent appendectomy were evaluated. After excluding specific cases, a total of 87 patients were enrolled in the study, with 33 patients in the laparoscopic group and 54 patients in the open group.

In terms of age, the laparoscopic group had a mean age of 30.48 ± 10.53 years (range: 18–67), while the open group had a mean age of 30.50 ± 9.84 years (range: 18–58). The difference in mean age between the two groups was not statistically significant ($p = 0.995$). Regarding gender distribution, 69.7% of the laparoscopic group were male, and 30.3% were female. In the open group, 64.8% were male, and 35.2% were female. No statistically significant gender-based difference was observed ($p = 0.410$). In terms of BMI distribution, in the laparoscopic group, 39.4% were classified as overweight, 51.5% as obese class I, 6.1% as obese class II, and 3% as obese class III. In the open group, these percentages were 51.9%, 35.2%, 7.4%,

and 5.6%, respectively. The comparison of BMI categories yielded a $p = 0.506$. The distribution of ASA scores showed that 87.9% of the laparoscopic group had an ASA score of I, 9.1% had an ASA score of II, and 3% had an ASA score of III. In the open group, 90.7% had an ASA score of I, 9.3% had an ASA score of II, and there were no cases with an ASA score of III. No statistically significant difference in ASA scores was observed ($p = 0.437$). Regarding medical history, 15.2% of the laparoscopic group had hypertension, compared to 13% in the open group ($p = 0.505$). Similarly, 15.2% of the laparoscopic group had diabetes mellitus, compared to 13% in the open group ($p = 0.505$). The prevalence of previous abdominal surgical procedures varied among participants. Laparoscopic cholecystectomy was previously performed in 2 (6.1%) of the laparoscopic group and 3 (5.6%) of the open group ($p = 0.632$). Cesarean section was observed in 4 (12.1%) of the laparoscopic group and 5 (9.3%) of the open group ($p = 0.466$). Open inguinal hernia surgery was performed in 3 (9.1%) of the laparoscopic group and 6 (11.1%) of the open group ($p = 0.534$). Total leukocyte count ($10^3/\mu\text{L}$) was 13.43 ± 2.85 in the laparoscopic group and 13.51 ± 3.09 in the open group, with a $p = 0.904$. Hemoglobin levels (g/dL) were 13.03 ± 1.35 in the laparoscopic group and 13.02 ± 1.22 in the open group, showing no statistically significant difference ($p = 0.955$). The degree of appendicitis distribution revealed that in the laparoscopic group, 9.1% had normal appendices, 78.8% had non-complicated appendicitis, 12.1% had perforated appendicitis, and none had gangrenous appendicitis. In the open group, these percentages were 7.4%, 85.2%, 5.6%, and 1.9%, respectively, yielding a $p = 0.597$. The time from symptom onset to surgical intervention was 32.12 ± 12.60 h (range: 8–60) in the laparoscopic group and 33.70 ± 10.82 h (range: 12–60) in the open group, with a $p = 0.536$ (Table 1).

Operative duration (minutes) revealed a significant difference, with a mean of 33.12 ± 8.45 min in the laparoscopic group and 41.40 ± 9.74 min in the open group ($p < 0.001$). Total incision length (mm) also exhibited a substantial contrast, with a mean of 22.42 ± 1.54 mm in the laparoscopic group and 93.33 ± 23.67 mm in the open group ($p < 0.001$). For complications occurring within < 30 days, the laparoscopic group had no cases of pelvic abscess or post-operative ileus, 1 case (3%) of wound infection, and 2 cases (6.1%) of wound seroma. In comparison, the open group had 2 cases (3.7%) of pelvic abscess, 3 cases (5.6%) of post-operative ileus, 11 cases (20.4%) of wound infection, 19 cases (35.2%) of wound seroma,

Table 1. Comparison of baseline patient characteristics between the laparoscopic and open surgery groups

Variables	Lap. group (n=33)	Open Group (n=54)	p
Age (years)			
Mean±SD	30.48±10.53	30.50±9.84	0.995
Range	(18–67)	(18–58)	
Gender, n (%)			
Male	23 (69.7%)	35 (64.8%)	0.410
Female	10 (30.3%)	19 (35.2%)	
BMI, n (%)			
Overweight (25–29.9 kg/m ²)	13 (39.4)	28 (51.9)	0.506
Obese class I (30–34.9 kg/m ²)	17 (51.5)	19 (35.2)	
Obese class II (35–39.9 kg/m ²)	2 (6.1)	4 (7.4)	
Obese class III (≥40 kg/m ²)	1 (3)	3 (5.6)	
ASA score, n (%)			
I	29 (87.9)	49 (90.7)	0.437
II	3 (9.1)	5 (9.3)	
III	1 (3)	0	
Hypertension, n (%)	5 (15.2)	7 (13)	0.505
Diabetes Mellitus, n (%)	5 (15.2)	7 (13)	0.505
Previous abdominal surgical procedures, n (%)			
Laparoscopic cholecystectomy	2 (6.1)	3 (5.6)	0.632
Cesarean section	4 (12.1)	5 (9.3)	0.466
Open inguinal hernia surgery	3 (9.1)	6 (11.1)	0.534
Total leukocyte count (10 ³ /μL), Mean±SD	13.43±2.85	13.51±3.09	0.904
Hemoglobin (g/dL) Mean±SD	13.03±1.35	13.02±1.22	0.955
The degree of appendicitis			
Normal	3 (9.1)	4 (7.4)	0.597
Non-complicated	26 (78.8)	46 (85.2)	
Perforated	4 (12.1)	3 (5.6)	
Gangrenous	0	1 (1.9)	
The time from symptom onset to surgical intervention (hours) mean±SD	32.12±12.60	33.70±10.82	0.536
Range	(8–60)	(12–60)	

BMI: Body mass index; ASA: American Society of Anesthesiologists physical status classification.

and 5 cases (9.3%) of wound dehiscence. The P-values for these complications ranged from 0.020 to 0.383. Hospital stay (hours) showed no significant difference between the groups, with a mean of 16.42±7.34 h in the laparoscopic group and 16.38±9.20 h in the open group (p=0.985). Pain scores (VAS) 6 h after surgery exhibited similar mean scores, with 2.57±0.79 in the laparoscopic group and 2.74±0.97 in the open group (p=0.414). However, pain scores (VAS) during discharge displayed a substantial difference, with a mean of 1.78±0.59 in the

laparoscopic group and 3.05±0.85 in the open group (p<0.001). Return to work time (days) was shorter in the laparoscopic group, with a mean of 7.24±1.76 days compared to 9.70±2.07 days in the open group (p<0.001). Late post-operative complications (>30 days) were minimal, with 1 case (3%) of intestinal obstruction in the laparoscopic group and 1 case (3%) of intestinal obstruction and 12 cases (22.2%) of incisional hernia in the open group. The P-values for these complications were 0.617 and 0.020, respectively (Table 2).

Table 2. Comparison of laparoscopic and open surgery groups: Operative duration, <30-day and >30-day complications, pain scores, and return to work

Variables	Group Lap (n=33)	Group Open (n=54)	p
Surgical time (min.) mean±SD, range	33.12±8.45 (22–55)	41.40±9.74 (21–68)	<0.001
Total incision length (mm) mean±SD	22.42±1.54 (20 – 25)	93.33±23.67 (45 – 160)	<0.001
Complications within <30 days, n (%)			
Pelvic Abscess	0	2 (3.7)	0.383
Post-operative ileus	0	3 (5.6)	0.234
Wound Infection	1 (3)	11 (20.4)	0.020
Wound Seroma	2 (6.1)	19 (35.2)	0.001
Dehiscence	0	5 (9.3)	0.086
Hospital stay (hours) mean±SD, range	16.42±7.34 (8–40)	16.38±9.20 (10–60)	0.985
Pain scores (VAS) 6 h after surgery, mean±SD, range	2.57±0.79 (2–5)	2.74±0.97 (2–5)	
Pain scores (VAS) during discharge, mean±SD, range	1.78±0.59 (1–3)	3.05±0.85 (1–5)	<0.001
Return to work time (days)	7.24±1.76 (5–14)	9.70±2.07(7–17)	<0.001
Late post-operative complications (>30 days), (%)			
Intestinal obstruction	1 (3)	1 (3)	0.617
Incisional hernia	0	12 (22.2)	0.020

VAS: Visual Analog Scale.

Regarding patient satisfaction, the majority of participants in the laparoscopic group (87.9%) reported being very satisfied with their surgical outcomes. In contrast, 74.1% of participants in the open surgery group expressed similar high levels of satisfaction. While a trend of slightly higher satisfaction was observed in the laparoscopic group, the difference did not reach statistical significance ($p=0.071$).

Analysis of the SF-36 scale scores on the 15th day after surgery highlighted important differences between the two groups in various dimensions. The laparoscopic group exhibited significantly better scores in physical function (93.93 ± 7.04 vs. 87.59 ± 11.39 , $p=0.005$) and physical role (96.21 ± 9.10 vs. 81.94 ± 16.40 , $p<0.001$) compared to the open surgery group. However, no significant differences were observed between the two groups in the dimensions of emotional role, vitality, mental health, and social function ($p=0.929$, 0.871 , 0.556 , and 0.573 , respectively). The laparoscopic group reported slightly higher pain scores on the 15th day (95.60 ± 5.23 vs. 91.94 ± 9.06 , $p=0.038$) and better

general health scores (95.15 ± 7.55 vs. 88.32 ± 10.69 , $p=0.002$).

In terms of the post-operative 1-year SF-36 scale results, Physical Function, Group Lap demonstrated an average score of 97.57 ± 3.97 (range: 90–100), while Group Open had a mean score of 96.48 ± 6.03 (range: 75–100), yielding a non-significant $p=0.358$. Similarly, for Physical Role, Group Lap scored 98.48 ± 6.05 (range: 75–100), and Group Open scored 93.05 ± 14.08 (range: 50–100), with a $p=0.039$. Concerning Emotional Role, both groups achieved a perfect score of 100 (range: 100), resulting in a $p=0.172$. For Vitality, the mean score of Group Lap was 85 ± 7.07 (range: 70–100), while Group Open scored 83.42 ± 8.73 (range: 65–100), resulting in a $p=0.384$. Group Lap had a Mental Health score of 84.96 ± 9.43 (range: 68–100), and Group Open scored 81.11 ± 9.14 (range: 64–100), yielding a $p=0.063$. In terms of Social Function, Group Lap scored 93.93 ± 8.90 (range: 75–100), and Group Open scored 94.21 ± 9.31 (range: 75–100), resulting in a $p=0.893$. Pain scores were 96.89 ± 4.80 (range: 87.5–100) for Group Lap and 91.94 ± 9.06 (range: 67.5–100) for Group Open,

yielding a $p=0.005$. Finally, for General Health, Group Lap achieved a score of 97.12 ± 6.25 (range: 80–100), while Group Open scored 95 ± 7.89 (range: 80–100), resulting in a $p=0.193$ (Table 3).

Discussion

The obtained results reveal significant differences in the comparison of LA and OA methods among overweight and obese patients. The outcomes of this study underscore the critical importance of selecting the appropriate method in surgical interventions related to overweight and obesity.

Prior research has indicated an association of the laparoscopic approach with longer surgical durations.^[10,11] However, contrasting findings from two separate studies have indicated that LA has shorter average surgical durations.^[12,13] In our study, we observed a significantly shorter operation time in the laparoscopic group when compared to the open group. This outcome suggests that the thicker abdominal wall in overweight and obese individuals could potentially make visualization of the surgical field more challenging, possibly extending the surgical duration.

Nevertheless, it is important to consider that differences in reported average operation times across the literature might stem from varying skill levels of surgical teams at different health-care centers and their diverse experiences with laparoscopic surgical techniques. Similarly, the laparoscopic surgical group exhibited notably lower values in total incision length compared to the open surgical group. This finding suggests the potential for achieving more aesthetically pleasing outcomes and enhancing post-operative comfort for patients. The utilization of smaller incisions may also play a role in reducing the operation time, lowering the risk of infections, and mitigating post-operative complications among patients.

Mohamed et al. reported an infection rate of 8.3% in the LA group, compared to 24.4% in the OA group.^[10] Similarly, Lin et al. demonstrated that the infection rates were significantly lower in the LA group (15.2%) compared to the OA group (30.7%).^[11] When we examined early-term complications in our study, we noticed that the laparoscopic surgical group had fewer complications within the initial 30 days. Notably, the decreased occurrence of issues like

Table 3. Summary of results of satisfaction and SF-36 scales in both groups

	Group Lap (n=33)	Group Open (n=54)	p
Satisfaction Status, n (%)			
Very satisfied	29 (87.9%)	40 (74.1%)	0.071
Satisfied	4 (12.2%)	10 (18.5%)	
Dissatisfied	0	4 (7.4%)	
Post-operative 15 th -day SF-36 scales			
Physical function, mean±SD, range	93.93±7.04 (80–100)	87.59±11.39 (55–100)	0.005
Physical role, mean±SD, range	96.21±9.10 (75–100)	81.94±16.40 (50–100)	<0.001
Emotional role, mean±SD, range	95.93±11.10 (66.5–100)	95.67±14.55 (33–100)	0.929
Vitality, mean±SD, range	78.48±8.96 (55–100)	78.88±12.34 (40–100)	0.871
Mental health, mean±SD, range	82.30±8.60 (68–100)	81.11±9.43 (64–100)	0.556
Social function, mean±SD, range	91.28±10.11 (75–100)	92.82±13.43 (37.5–100)	0.573
Pain, mean±SD, range	95.60±5.23 (87.5–100)	91.94±9.06 (67.5–100)	0.038
General health, mean±SD, range	95.15±7.55 (80–100)	88.32±10.69 (60–100)	0.002
Post-operative 1-year SF-36 scales			
Physical function, mean±SD, range	97.57±3.97 (90–100)	96.48±6.03 (75–100)	0.358
Physical role, mean±SD, range	98.48±6.05 (75–100)	93.05±14.08 (50–100)	0.039
Emotional role, mean±SD, range	100 (100)	98.14±7.73 (66.5–100)	0.172
Vitality, mean±SD, range	85±7.07 (70–100)	83.42±8.73 (65–100)	0.384
Mental health, mean±SD, range	84.96±9.43 (68–100)	81.11±9.14 (64–100)	0.063
Social function, mean±SD, range	93.93±8.90 (75–100)	94.21±9.31 (75–100)	0.893
Pain, mean±SD, range	96.89±4.80 (87.5–100)	91.94±9.06 (67.5–100)	0.005
General health, mean±SD, range	97.12±6.25 (80–100)	95±7.89 (80–100)	0.193

wound infection and seroma in the laparoscopic surgical group points to a safer surgical procedure for patients. This highlights the potential of laparoscopic surgery to lower the risks associated with complications.

One main reason for this is that LA involves minimal manual and instrumental manipulation of the intestines by the surgeon, unlike OA. In addition, in LA, the appendix is visualized within its natural position, avoiding direct contact with the incision site in the layers of the anterior abdominal wall. Moreover, the need for longer incisions in open surgery, particularly for obese and overweight patients, may contribute to a heightened risk of infection. These combined factors underscore the potential of laparoscopic surgery as a promising approach for mitigating the likelihood of early-stage complications.

While there was not a statistically significant distinction in terms of hospital stay duration between the groups, the laparoscopic surgical cohort demonstrated reduced pain scores upon post-operative discharge and quicker return-to-work timelines. This finding aligns with previous studies. In a conducted meta-analysis, it was reported that post-operative pain and return to work times were significantly reduced in patients who underwent laparoscopic surgery.^[7] Furthermore, another study conducted also found that laparoscopic surgery resulted in significantly less pain compared to open surgery.^[14]

In a study conducted on obese patients in the year 2022, no significant difference was found in terms of intestinal obstruction and incisional hernia in the comparisons made 30-day post-operatively. However, this study did not provide clear information about how long the patients were followed up in the long term after the surgery.^[15] On the contrary, in this study, through 1-year long-term follow-up, a higher incidence of incisional hernia development was observed in the open surgery group. This observation suggests the potential of laparoscopic surgery to yield more favorable outcomes in the long term. Moreover, considering patients' long-term health and recovery perspectives, laparoscopic surgery could be deemed a preferable option in the extended horizon. One of the contributing factors to these differing outcomes could be the tendency of patients to seek another surgeon's assistance when late-term complications arise.

The study conducted by Kaplan et al. has demonstrated that laparoscopic surgery positively impacts the quality of life during the post-operative period.^[16] These findings

have been similarly observed in other studies within the field of laparoscopic and open abdominal surgery.^[15,17] When examining the measurements on the 15th-day post-surgery, it was observed that the laparoscopic surgical group obtained higher scores in satisfaction status and quality of life parameters, including physical function, physical role, and pain. This observation supports the idea that LA could positively impact the quality of life parameters during the post-operative period. Furthermore, when analyzing measurements at the 1-year post-operative mark, the laparoscopic surgical group was found to have higher scores in physical function, physical role, and pain areas. As a possible explanation for the divergent results in our study, we speculate that the higher incidence of late-onset incisional hernias in overweight and obese patients might have contributed to this outcome.

However, it is important to note that the results of this study are constrained by its single-center setup and absence of extended follow-up. It would be valuable to conduct future inquiries with larger participant pools and longer observation periods to confirm and strengthen these conclusions.

Conclusion

Among the factors supporting the preference for LA in obese and overweight patients, there are shorter surgical durations, lower infection rates, and the potential for faster recovery. These results underscore the benefits of choosing LA for obese and overweight patients, accentuating the potential to enhance patients' quality of life and diminish the likelihood of complications.

Disclosures

Ethics Committee Approval: The study was carried out with the permission of Bakircay University Clinical Research Ethics Committee.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

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