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CONTENTS

Volume: 3 Issue: 2 Year: 2025

ORIGINAL ARTICLES

CASE REPORTS

LETTER TO THE EDITOR

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Original Article

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Recurrent anesthesia applications in pediatric radiotherapy: a retrospective observational study

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ABSTRACT

Aims: Pediatric radiotherapy is used for various indications in childhood malignancies. This descriptive study aims to describe the demographic data, anesthesia method and complications of pediatric radiotherapy patients.

Methods: This study was conducted retrospectively and observationally in a tertiary care center. Patients aged 18 years and younger who received anesthesia for radiotherapy were included. Data were obtained from the hospital information system and anesthesia observation forms. Demographic data, radiotherapy indication, fraction number and dose, anesthesia method, anesthetic drug and dose, patient position, complications and recovery time were analyzed.

Results: 485 patients received radiotherapy and anesthesia was administered to 19 of these patients (3.91%). 3 patients were excluded due to missing data, and 16 patients received anesthesia 417 times. Patients were between the ages of 1-17 years, mean age was 4.9 years. Sedation was used in 92.3% of the procedures and general anesthesia in 7.7%. The most common indication for radiotherapy was glial tumor. The number of radiotherapy fractions ranged between 8-33 sessions, the median number of sessions was 30 and the mean number of sessions was 24.8. Treatment doses were 150-200 Gray. Complication rate was 2.87%. A statistically significant difference was found when the doses of propofol, fentanyl, midazolam used in the first and last fractions and recovery times of the patients were compared ($p<0.01$).

Conclusion: Anesthetic management in pediatric radiotherapy requires multidisciplinary treatment due to the unique requirements of the procedure. Patients should be thoroughly re-evaluated at each session and protected from the potential for addiction.

Keywords: Pediatrics, radiotherapy, radiation oncology, anesthesia, pediatric oncology

INTRODUCTION

Malignancies in childhood are not as common as they are in adulthood, accounting for fewer than 1% of all new pediatric cancer cases.[1] The most common childhood malignancies are acute lymphoblastic leukemia (ALL) (26%), central nervous system tumors (21%), and neuroblastoma (7%).[2] Childhood malignancies require multidisciplinary treatment management, whereby treatment success rates increase accordingly.[3] Radiotherapy (RT) was first applied under general anesthesia by Harrison and Bennet in 1963 and continues to be applied for palliative and therapeutic purposes.[4]

The aim of RT treatment is to protect normal tissues and to deliver an appropriate and effective dose to target cancerous tissue. Although RT is a painless procedure, immobilization is required during treatment.[5] Repeated general anesthesia and sedation applications are required for immobilization, particularly in young children who are unable to cooperate and stand still.[5] Anesthesia applications are required in almost all patients aged 0-3 years and the need for anesthesia during RT increases inversely proportional to age.[6]

Although there is no surgical procedure, such as a large incision or blood loss, in RT treatment, it is uncomfortable for most anesthesiologists due to the necessary special physical conditions.[7] These include the physical distance from the patient during RT, lack of access to the patient during treatment, difficulty in airway access due to a thermoplastic mask, lack of support in emergencies, complex patient positions, and the high number of RT fractions.[7]

In this retrospective study, we aimed to present and discuss 417 recurrent anesthesia experiences due to RT of 16 pediatric patients aged 1-17 years. Our primary objective was to describe the demographic characteristics of the patients in our center and the secondary objective was to report anesthesia-related complications and anesthesia techniques.

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METHODS

This study was conducted retrospectively and observationally in a tertiary-level training and research hospital. Our study was approved by the Ankara Etlik City Hospital Scientific Researches Evaluation and Ethics Committee (Date: 10.07.2024, Decision No: AEŞH-BADEK-2024-580). The study was conducted in accordance with the Declaration of Helsinki. Inclusion criteria were patients aged 18 years and younger who had received anesthesia for RT treatment in our center between October 1, 2022 and June 1, 2024. Patients who had not completed RT treatment, turned 19 years of age during treatment, or had missing data were excluded from the study. Data of the patients were obtained from the hospital information system and anesthesia observation forms. Demographic data, RT indication, RT fraction number and dose, anesthesia method used, anesthetic drug and dose, patient position, complications, and recovery time were analyzed.

Medical records are susceptible to bias and human error, including missing or inaccurate data, particularly concerning the perioperative period and patient or parent perceptions of disease severity. In this study, discrepancies in information and interventions may arise due to underreporting by patients or parents during the pre- and post-anesthetic periods for both inpatient and outpatient cases. Additionally, certain subjective and objective complications may have been underreported among outpatient patients.

Statistical Analysis

For statistical analysis of the research data, Statistical Package for Social Sciences (SPSS), version 22.0 for Windows (SPSS Inc. Chicago, USA) computer package program was used. In the descriptive statistics section, categorical variables were presented as numbers and percentages, and continuous variables were presented as mean±standard deviation or median (minimum-maximum value). Compliance with normal distribution of continuous variables was assessed using visual (histogram and probability graphs) and analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk tests). In the study, paired T test was preferred to compare the anesthesia drug doses and recovery time in the first and last cycles for each patient. Due to the small sample size, nonparametric tests (e.g., Wilcoxon signed-rank test) were evaluated as alternatives. However, since normality tests gave appropriate results, paired T test was preferred. It was examined whether the data were affected by extreme values and outliers that should be excluded from the analysis were determined. In this study, the statistical significance level was accepted as $p<0.05$.

RESULTS

Between October 1, 2022 and June 1, 2024, a total of 485 patients aged 18 years and younger received RT treatment, with 3.91% of these patients (19 patients) undergoing anesthesia. Data of 19 patients were analyzed; three patients were excluded due to missing data and the study was conducted on 16 patients (Figure). The patients included in the study were aged between 1-17 years, with a median age of four years and a mean age of 4.9 years. A total of 62.5% of the patients were female and 37.5% were male. There were no patients with American Society of Anesthesia (ASA) physical status scores of 1 and 4. Of the patients, 19% were classified as ASA2 and 81% as ASA3. There was a preoperative fasting period of 4-8 hours (Table 1).

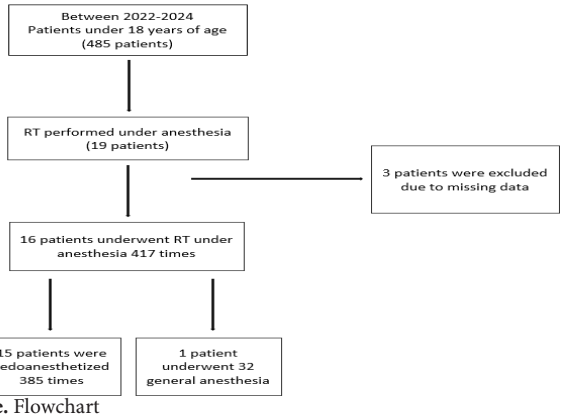

Figure. Flowchart

Table 1. Demographic data of the patients and indications for radiotherapy

	n=16
Age	
Median	4
Mean	4.9
Range	1-17
Gender	
Female	10 (62.5)
Male	6 (37.5)
Weight (kg)	
Median	15.75
Range	10-58
Height (mt)	
Median	0.98
Range	0.71-1.68
ASA score	
1	0
2	3 (19)
3	13 (81)
4	0
Disease	
Brain tumor	8
Chemoterapy	8
VP shunt	1
Nephrectomy	2
Bone marrow transplantation	2
Epilepsy	5
Hypothyroidism	1
Tracheostomy	1
Puberty precocious	1
Fasting period	
4 h	1
6 h	14
8 h	1
RT indication	
Glial tumor	8 (50)
Ependymoma	3 (18 8)
Neuroblastoma	2 (12.5)
Rhabdomyosarcoma	1 (6.3)
Wilms tumor	2 (12.5)

kg: Kilogram, mt: Meter, h: Hours, RT: Radiotherapy

Anesthesia was administered a total of 417 times on 16 patients who needed it during RT. Of the anesthesia applications, 385 (92.3%) were sedation and 32 (7.7%) were general anesthesia. Only one patient-who had a tracheostomy-received general anesthesia. Sevoflurane and midazolam were used for general anesthesia. Propofol, midazolam, ketamine, and fentanyl were the other anesthetic agents used. Ketamine was used in only one patient. Sixteen patients received anesthesia for CT simulation a total of 20 times (Table 2).

Table 2. Anesthesia management and radiotherapy data of the patients

	n=417
Sedation	385 (92.3)
General anesthesia	32 (7.7)
RT fraction time	
Median	30
Range	8-33
RT dose (Gy)	
Median	180
Range	150-200

RT: Radiotherapy

All patients received RT in the supine position and no patients in the prone position. The indications were Glial tumor in 50%, Ependymoma in 18.8%, Neuroblastoma in 12.5%, Wilms tumor in 12.5%, and Rhabdomyosarcoma in 6.3% (Table 1). The most common treatment site was the cranium (69%). The number of RT fractions of the patients ranged between 8-33 sessions; the median number of sessions was 30 and the mean number of sessions was 24.8. Treatment doses were in the range of 150-200 gray (Table 2).

Complications occurred in 12 of the 417 anesthesia procedures with a complication rate of 2.87%. The complications encountered were as follows: mobilization (four times), desaturation (three times), bradycardia (three times), hypo-hypertension (once) and nausea-vomiting (once) (Table 3). Complications were detected with a camera in the RT room. Interventions were made on patients who developed complications and no patient required cardiopulmonary resuscitation. Desaturated patients were treated with mask ventilation and the treatment was completed without any problems. An intervention was made on one patient who became mobile and was about to fall off the treatment table.

Table 3. Complication rates and types of complications encountered in radiotherapy sessions

	First cure	Last cure	p
Propofol (mg/kg)	1.8±0.48	3.2±0.52	<0.001
Fentanyl (mg/kg)	0	0.75±0.62	<0.001
Midozolam (mg/kg)	0.06±0.025	0.09±0.028	<0.001
Recovery time*	19.6±3.68	36.9±7.84	<0.001

*Paired T test, mg: Miligram, kg: Kilogram

Vascular access was provided with port catheters in two patients, central venous catheters in four patients, and peripheral venous cannulas in 10 patients. There were no complications related to central venous access. Peripheral venous cannulas were changed every five days. When the doses of propofol, fentanyl, and midazolam used in the first and last RT fraction anesthesia applications and recovery times of the patients were compared, a statistically significant difference was found (p<0.01) (Table 4).

Table 4. Comparison of the amount of anesthetic drugs used and recovery times in the first and last RT sessions of the patients

	n=417
Number of complications	12 (2.87)
Type of complication	
Mobility	4
Desaturation	3
Bradycardia	3
Hypo/hypertension	1
Nausea-vomiting	1

Recovery time is the time when the modified aldrate score is 9 and above, RT: Radiotherapy

DISCUSSION

The frequency of non-operating room anesthesia (NORA) applications is gradually increasing with the developing technology. One of the NORA applications is RT, which is a multi-purpose treatment method in various malignant diseases. It allows for the treatment of damaged tissues with high and homogeneous doses of ionizing radiation while preserving normal tissues. Immobilization is very important for RT treatment to be effective and successful, and to avoid negative consequences. Anesthesia is used for immobilization in the pediatric population who cannot cooperate, cannot understand the procedure, have bad experiences in their medical history, and feel anxiety and discomfort.[8] In our study, we presented the experience of anesthesia 417 times for RT treatment in 16 pediatric patients who met these criteria.

The need for anesthesia increases inversely proportional to age in RT.[9] In the literature, the incidence of anesthesia for RT in the pediatric population varies and different incidences-such as 11.8%, 12.8%, 25.7% and 45% have been reported.[10-13] We think that this difference in incidences is due to the treatment modalities of the centers, differences in the population, and behavioral modified therapies adopted over the years. In our center, the incidence of anesthesia for pediatric RT is 3.91%. In the literature, the need for anesthesia for RT has been reported in 100% of children younger than three years of age and 10% of children older than 12 years of age.[14] According to the results of our study, 85.5% of the anesthetized children were younger than eight years of age and the mean age was 4.9 years. Only one patient was 17 years old. In a study conducted by Lydia et al.[10] in 2021, no patient aged 16 years or older was reported. Similarly, only one patient in our study was older than 12 years of age. Despite the patient's age, when the need for anesthesia was questioned, it was observed that the patient had undergone poor medical experiences. Studies have also shown that the need for anesthesia decreases with various behavioral modified therapies, especially in children aged 3-12 years and older than 12 years.[15] In line with the literature, there is a playground in the RT unit in our center to reduce the children's anxiety. Parental anxiety should not be neglected, since children may also be affected by their parents' emotions during RT sessions, which is a long and tiring treatment program.[11] Parents and children should participate in modified therapy programs together.[11,16] For this reason, both children and parents are routinely informed

in detail about the process in our clinic. All questions of both children and parents are answered. We think that the lower incidence rate in our center compared to the rates reported in the literature is due to the modified behavioral therapies we apply and the active participation in the therapies of both children and parents.

Anesthetic management is a challenging process due to the anatomical and physiological variations of children, as well as the physical conditions and unique features of RT treatment. The "thermoplastic mask" used particularly in head and neck malignancies limits airway access. In RT, late recognition of potential complications may be caused by the lack of possibility of instant intervention, physical barriers with the patient, complexity of the positions, and the fact that patient follow up can only be performed with a camera.[3] Considering both the difficulty of physical conditions and the effects of RT treatment, patients should be evaluated and followed up in detail at each session to prevent complications.[6] We routinely subject our patients to a complete physical examination and evaluate them in detail in the preoperative period before each anesthesia application. There is a limited number of studies in the literature, most of them retrospective. In the studies, anesthesia-related complication rates differ according to anesthesia management (0.3%-10.57%).[6,10,17,18] While nausea-vomiting and hypotension are common in patients under general anesthesia, respiratory complications are prominent in patients under sedation. According to the results of our study, the anesthesia complication rate in pediatric RT in our clinic is 2.87%. Our complication rates are similar to those in the literature. The complications we encountered are shown in **Table 3**. In addition, none of the patients with complications required cardiopulmonary resuscitation and the procedures were successfully completed. In our clinic, routine Bispectral Index (BIS) monitoring is performed in NORA procedures. We believe that, particularly in patients sedated for RT, it would be beneficial to fix the patient on the RT table with auxiliary equipment and additional monitoring and to monitor the depth of anesthesia with BIS monitoring.

RT can be performed on an outpatient basis in appropriate patients. In long and repetitive anesthesia applications, outpatient treatment increases the tolerability of the process. Therefore, the postoperative period is as important as the intraoperative period. The method of anesthesia (general anesthesia/sedation) and anesthetic drugs used for RT are among the most important parameters affecting the postoperative period.[6] Compared with general anesthesia, sedation is a more feasible method in recurrent daily procedures.[19] Therefore, in our clinic, the sedation rate is 92.3% and the general anesthesia rate is 7.7%. In line with our clinical practice and results, we believe that sedation is more feasible in recurrent anesthesia procedures.

The drugs used, as well as the preferred method of anesthesia, affect the postoperative period.[20] In a study conducted by Sane et al.[18] in 2022, when ketamine and propofol were compared, it was found that ketamine prolonged the return time of cognitive functions and increased secretions. According to the results of our study, ketamine was used in only one patient with tracheostomy, who was followed up on with a mechanical ventilator. The reason for this was that the patient was hypotensive at the beginning of treatment. We preferred ketamine because of its better hemodynamic stabilization in hypotensive patients. In another study, it was emphasized that the use of propofol for RT can be safely used without the need for an airway device, as well as its anti-emetic efficacy and short duration of action.[21] Therefore, we preferred to administer anesthesia with propofol in our routine practice.

In our center, the number of sedation for anesthesia method was higher compared to general anesthesia (92.3%/7.7%). This may be due to the higher number of outpatients in our clinic, and the preference for sedation for rapid postoperative recovery in frequently recurrent anesthesia applications. The combined use of the agents used in the ideal sedation method has gained a place in anesthesia practice as a general opinion. For this reason, no single agent is used alone in our clinic and a balanced anesthetic regimen is applied. In addition, when the anesthetic agents used in the first RT session were examined, a combination of midazolam and propofol was mostly used. In repeated sessions, it was determined that the patients' need for anesthetic increased. In the following sessions, the dose requirement for midazolam and propofol increased and fentanyl was added. When the doses of propofol (1.8±0.48/3.2±0.52), midazolam (0.06±0.025/0.09±0.028), and fentanyl (0/0.75±0.62) used in the first and last fractions of the patients were compared, a statistically significant difference was found between the first and last fraction ($p<0.001$). We surmise that this statistical difference is due to the development of tolerance to anesthetic drugs because of frequent and repeated anesthesia applications.[22] When the recovery times of the patients in the first and last sessions were compared, there was a statistically significant difference, which we surmise that this was due to the increase in the amount of anesthetic drugs used in the increased number of sessions ($p<0.01$) (19.6±3.68/36.9±7.84).

Limitations

The implementation of pediatric RT anesthesia in our center within the protocol and sharing the results of patients treated according to this protocol may be a guide for other centers. Although our study is a single-center study, it may be a guide for future multicenter studies with participation from different regions of the world in terms of long-term anesthesia management and clinical practices. For this purpose, we determined the incidence of anesthesia in pediatric patients who received RT in our hospital for the first time and created a step for future studies. Of course, there were some limitations to our study. These limitations are; the retrospective design of the study, reflecting single-center results, exclusion of 3 patients who received anesthesia due to incomplete data, inability to include patients with incomplete data in the study, and especially the subjective nature of the reports of outpatients.

CONCLUSION

In conclusion, anesthesia management in pediatric RT is a special procedure that requires multidisciplinary management due to its unique requirements. Because of inadequate sedation doses based on anesthesiologists feeling themselves outside the safe zone, mobilization and repetition of the procedure may occur. In order to prevent undesirable results, patients should be re-evaluated in detail at each session of repeated anesthesia applications, all necessary equipment should be prepared in advance, and close monitoring should be conducted on the depth of anesthesia. We recommend the use of behavioral modified therapies in certain age groups to

avoid the potential for addiction due to frequent and repetitive anesthesia. Most studies on this subject are retrospective reviews and we believe that further controlled clinical studies are required.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was carried out with the permission of the Ankara Etlik City Hospital Scientific Researches Evaluation and Ethics Committee (Date: 10.07.2024, Decision No: AEŞH-BADEK-2024-580).

Informed Consent

Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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Original Article

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The effect of ligasure use on serum parathormone and calcium levels in thyroidectomy surgery

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ABSTRACT

Aims: The use of the modern bipolar closure system enabling a more rapid dissection and hemostasis has increased in thyroidectomy. A significant complication encountered following thyroidectomy is hypocalcemia. This study evaluated the effect of LigaSure™ (LS) use only on postoperative parathormone and calcium levels during total thyroidectomy.

Methods: Patients who underwent total thyroidectomy between June 2018 and January 2022 participated in the research. The patients on whom LS was used without any ligature during thyroidectomy were categorized as group 1; those on whom the ligature was used were categorized as group 2. Both groups were compared in terms of demographic features, postoperative hypocalcemia, and other complications.

Results: In total, 84 patients meeting the criteria were included in the study. Group 1 consisted of 36 patients and group 2 of 48 patients. The postoperative 1st-day hypocalcemia rate was observed to be higher in the LS group (47.2% for group 1 and 22.9% for group 2; p=0.019). However, on the postoperative 30th day, both groups were observed to be evened out in terms of hypocalcemia, and the difference between the two groups lost its statistical significance (2.8% for group 1 and 2.1% for group 2; p=0.836). On the postoperative 30th day, no statistically significant differences were observed in either group in terms of hypoparathyroidism, permanent hypocalcemia, and other complications.

Conclusion: Although the use of LS increases temporary hypocalcemia in total thyroidectomy, it does not increase the risk of permanent hypocalcemia.

Keywords: Ligasure, thyroidectomy, serum parathormone, calcium levels, surgical impact

INTRODUCTION

Total thyroidectomy is one of the most commonly used treatment options in surgical practice. Postoperative hypocalcemia (PH), a surgery-related complication encountered in patients, can lead to serious symptoms and an increase in hospitalization duration. In cases where PH is permanent, using calcium and Vitamin D supplements for long periods can increase medical expenditure and adversely affect the patient's life quality.[1] Although there is no definite consensus on the definition of hypocalcemia, it can be identified as a total serum calcium level lower than 8.5 m/g.[1] PH is defined as temporary when it goes away after six months and permanent if it continues after six months. Postoperative temporary hypocalcemia incidents in the literature vary but are listed as being between 0.3% and 49%; for permanent hypocalcemia, the incident rate is between 0% and 13%.[1] The most common reason for PH is parathyroid gland (PG) ischemia.[2] Therefore, it is of the utmost importance to maintain PG health to decrease PH levels.[3,4]

The use of modern bipolar closure systems, enabling a more rapid dissection and hemostasis has increased in thyroidectomy, like in many other fields. These devices are shown to have positive effects on the duration of surgery, blood loss, analgesic need, incision cosmetic, and hospitalization period.[5] However, the advantages and disadvantages of these devices on the protection of PG functions during thyroidectomy are still unclear. In addition to the limited research on this topic in the literature, several studies have proposed contradictory conclusions.[6,7] The present study aims to compare the PH levels of patients to whom conventional ligature was applied and the PH levels of those to whom only LigaSure™ (LS) was applied without ligature for bleeding control during total thyroidectomy.

METHODS

This study was conducted with the approval of the Hatay Mustafa Kemal University Non-interventional Clinical Researches Ethics Committee (Date: 23.12.2021, Decision No: 05). All patients provided informed consent in accordance with the institutional review board guidelines and in compliance with the Declaration of Helsinki. The research was retrospectively carried out in the General Surgery Clinic of Ankara Etlik City Hospital by examining the files and data

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of patients in the hospital's electronic database on whom total thyroidectomy was performed by the same surgical team between June 2018 and January 2021. Patients who had a previous thyroidectomy, those whose thyroidectomy was not totally performed, and those who underwent cervical lymphoma nodule dissection at the same time were excluded from the research. Additionally, patients with a calcium metabolism disorder before surgery, those who required intramuscular stitching due to excision of intraoperative parathyroid tissue, and those whose parathyroid tissue was identified during the pathological examination were also excluded. Furthermore, patients with incomplete data, those we could not contact, and those under the age of 18 were not included in the study. Patients who met the research criteria were included in the research after the collection of their informed consent forms. The patients on whom LS was used without any ligature during thyroidectomy were categorized as group 1; those on whom the conventional ligature was used were categorized as group 2. In group 1, an LS small jaw instrument and Valleylab™ LS10 generator (Valleylab, Boulder, CO, USA) were used, and 3/0 polyglactin was used for the ligation process in group 2. A Hemovac drain was placed in every patient. On the postoperative 1st day, the calcium levels were checked, and on the 30th day, both the calcium and parathormone values were examined. Patients whose blood calcium values were under 8.5 mg/dl (2 mmol/L) were accepted as hypocalcemic. Intravenous calcium was applied to patients who had clinically hypocalcemic symptoms. In addition, the patients whose hypocalcemia continued on the postoperative 30th day were contacted after six months, and they were asked whether or not they still needed calcium replacement. Statistical analysis was conducted after examining the demographic information, radiological results, the diameter of the biggest nodule, retrosternal extension, tracheal pressure, surgery indications, findings of the fine-needle aspiration biopsy, pathological results, postoperative blood calcium levels, parathormone levels, and all related complications (bleeding, laryngeal nerve injury, permanent hypocalcemia) of the patients.

Statistical Analysis

Constant variables were expressed as mean±standard deviation and median (min-max); categorical data were expressed with numbers and percentages. An independent T test was applied for the analysis of the constant variables between the two groups that complied with normal distribution; the Mann-Whitney U test was used for those that did not comply. Pre-post comparisons within the groups were carried out with the Wilcoxon signed-ranks test. In the comparisons between the discrete/categorical data, the Chi-square test (Fisher's exact test) was applied. The analyses were made with IBM's SPSS Package Program version 26.0 (IBM Corporation, Armonk, NY, USA). The statistical significance level was deemed as $p<0.05$.

RESULTS

The total number of patients who underwent thyroidectomy was 116. Eighty-four patients who met the research criteria were included in the study. Group 1 consisted of 36 patients, 32 of whom were female and 4 male. The mean age for group 1 was 45.5±13.3. Group 2 consisted of 48 patients, 42 of whom were female and 6 male. The mean average for this group was 41.2±11.1. While there were no significant differences between the groups in terms of age, sex, hospitalization duration, indication, and pathology, the monitoring period and the diameter of the maximum nodule being ≥4cm were significantly statistically identified as higher in group 1 ($p<0.001$). In the results of the FNAB carried out after surgery, malignity and the significance of undetermined atypia were significantly determined as higher ($p<0.001$) (Table 1).

Table 1. Comparison of the groups according to their sociodemographic characteristics and clinical parameters

	LigaSure™ (n=36)	LIGATURE (n=48)	p
Age (year) (mean±SD)	45.5±13.3	41.2±11.1	0.113*
Hospitalization period (days) [median (min-max)]	2 (1-5)	2 (2-3)	0.670**
Monitoring period (days) [median (min-max)]	1192.5 (68-1610)	528 (50-990)	<0.001**
Gender, n (%)			
Female	32 (88.9)	42 (87.5)	0.846***
Male	4 (11.1)	6 (12.5)	
Pathology (post-op) , n (%)			
Nodular hyperplasia	23 (63.9)	36 (75.0)	0.629***
Papillary carcinoma	10 (27.8)	9 (18.8)	
Follicular adenoma	2 (5.6)	1 (2.1)	
Follicular carcinoma	1 (2.8)	1 (2.1)	
Graves	0 (0.0)	1 (2.1)	
Maximum nodule diameter (cm), n (%)			
<4 cm	12 (33.3)	39 (81.3)	<0.001***
≥4 cm	24 (66.7)	9 (18.8)	
Retrosternal goiter, n (%)			
Yes	5 (13.9)	7 (14.6)	0.928***
No	31 (86.1)	41 (85.4)	
Ultrasound, n (%)			
Multinodular	36 (100.0)	45 (93.8)	0.256***
Solitary nodule	0 (0.0)	3 (6.3)	
Computed tomography, n (%)			
No	28 (77.8)	42 (87.5)	0.197***
Retrosternal goiter	3 (8.3)	5 (10.4)	
Trachea pressure	3 (8.3)	1 (2.1)	
Magnetic resonance, n (%)			
No	35 (97.2)	48 (100.0)	0.429***
Trachea pressure	1 (2.8)	0 (0.0)	
Scintigraphy, n (%)			
Yes	0 (0.0)	2 (4.2)	0.504***[a]
No	36 (100.0)	46 (95.8)	
Fine-needle aspiration biopsy, n (%)			
Benign	22 (61.1)	27 (56.3)	<0.001***
Malign	0 (0.0)	5 (10.4)	
Significance undetermined atypia	0 (0.0)	16 (33.3)	
Non-diagnostic	3 (8.3)	0 (0.0)	
Malignant suspect	1 (2.8)	0 (0.0)	
Without biopsy	10 (27.8)	0 (0.0)	

*Independent samples T test, **Mann–Whitney U test, ***Chi-square test ([a]Fisher's exact test), SD: Standard deviation, min: Minimum, Max: Maximum

The hypocalcemia encounter rate on the postoperative 1st day was observed to be statistically significantly higher in group

1 (47.2% in group 1 and 22.9% in group 2; p=0.019). On the postoperative 30th day, however, the hypocalcemia in both groups was observed to have evened out, and the difference between the groups lost its statistical significance (2.8% and 2.1%, respectively; p=0.836). When both groups were internally compared from the postoperative 1st day until the 30th day in terms of the difference in hypocalcemia rates, the hypocalcemia rates in both groups were determined to have significantly decreased (p<0.001 and p=0.002, respectively) (Table 2). It was determined that there were no statistically significant differences between the two groups in terms of hyperparathyroidism on the postoperative 30th day, permanent hypocalcemia after 6 months, and other complications (Table 3).

Table 2. Comparison of hypocalcemia rates

	LigaSure™ (n=36)	LIGATURE (n=48)	p
1st day of hypocalcemia			
No	19 (52.8%)	37 (77.1%)	0.019*
Yes	17 (47.2%)	11 (22.9%)	
30th day of hypocalcemia			
No	35 (97.2%)	47 (97.9%)	0.836*
Yes	1 (2.8%)	1 (2.1%)	
Total	36 (100%)	48 (100%)	
	p<0.001**	p=0.002**	

*Chi-square test, **McNemar's test

Table 3. Complications and comparison of hypoparathyroidism and permanent hypocalcemia rates on the post-operative 30th day

	LigaSure™ (n=36)	LIGATURE (n=48)	p
30th day of hypoparathyroidism			
No	35 (97.2%)	47 (97.9%)	0.836*
Yes	1 (2.8%)	1 (2.1%)	
Complications (except for temporary PH)			
No	35 (97.2%)	47 (97.9%)	0.836*
Yes	1 (2.8%)	1 (2.1%)	
Permanent hypocalcemia			
No	35 (97.2%)	47 (97.9%)	0.836*
Yes	1 (2.8%)	1 (2.1%)	
Total	36 (100%)	48 (100%)	

*Chi-square test, PH: Postoperative hypocalcemia

DISCUSSION

The most common cause of hypocalcaemia after thyroidectomy is hypoparathyroidism.[3,4] The fact that the PGs are situated in a localization close to the thyroid capsule and recurrent laryngeal nerve and sometimes localized in the thyroid gland leads to an increase in PG damage.[8] Often, as the blood circulation of the PG is disrupted, hypoparathyroidism can develop, and this happens due to ischemia, direct injury, or the excision of the PG.[9] The PGs of the patients who participated in our research were regularly intraoperatively checked in terms of their sensitive anatomy and vitality. Cases where the researchers were sure that only the four PGs were intact and those that did not have a PG in the pathology results were included in the research; thus, factors that might have inadvertently affected the research results were avoided.

Although the use of modern bipolar closure tools such as LS has made a positive impact on surgery duration and hemostasis, injuries related to lateral thermal expansion still pose a risk. Opinions about the safest distance required to avoid thermal injury differ between 1-3 mm.[10-13] Studies comparing the use of LS (LigaSure™) and ligature in terms of pH levels and postoperative hypoparathyroidism have yielded various, often differing, results.[7,14-16] We believe that the difference in the results may arise from the extent of the thyroidectomy (total, subtotal, with neck dissection), whether the postoperative calcium aid was applied regularly or not, or because the surgeries in these particular studies were carried out by different surgeons.[17-22] As the surgical experience increases, so does the identification of PG and recurrent laryngeal nerves, and, as a result, complications are expected to decrease.[23,24] Therefore, the fact that the same surgeons performed the operations and the presence of patients that were only going through total thyroidectomy are key factors in the current research. No calcium replacement was applied to the patients with PH as long as they did not have clinical symptoms. This way, our research was kept homogenous in terms of clinical methods, and, therefore, we attained more objective results.

Some studies indicate that PH levels might be lower due to the side thermal effect of LS.[15,17] Nonetheless, Petrakis et al.[7] stated that the use of LS reduces the PH damage. It was seen in our research that on the 1st postoperative day, while the hypocalcemia rate in the LS group was statistically higher, on the 30th day, hypocalcemia and hypoparathyroidism rates statistically significantly evened out in both groups; furthermore, the significance of the statistical difference between the groups disappeared. We also think that the high frequency of PH in the LS group on the 1st day might be related to the necessity of opening a bigger pocket in the tissue to place the LS mouth, which, relatively, has a broader distance compared to the clamp; also, it might be related to side heat expansion. In addition, considering the frequent encounter of the presence of a ≥4 cm thyroid nodule in the LS group, we believe that a possible surgical dissection difficulty might lead to this. The statistical similarity between the hypocalcemia and hypoparathyroidism rates and permanent hypocalcemia on the postoperative 30th day leads us to think that LS creates an impact on PG on a level that cannot distract the revascularization process; therefore, the level of PH on the 1st day is acceptable. Despite this, we believe that in thyroidectomy with LS, the use of ligature instead of LS in PG localization might eliminate the issue.

Although it was stated in several studies in which the ligature and LS are compared that recurrent laryngeal nerve injury is seen less in LS, other reports indicate that the injury risk is similar.[7,14,25-27] However, in this study, we did not encounter any recurrent laryngeal nerve injury or aphonia. Although this leads us to think that there might be no changes in recurrent laryngeal nerve injury risk in LS, we believe the results might differ in research that is conducted with larger numbers of patients.

Limitations

Our study has a few limitations. The retrospective design and the limited number of cases are prominent among them.

Nevertheless, we believe that analyzing surgeries performed by a single surgeon within the same timeframe provides reliable results for comparing ligature and LS.

CONCLUSION

Compared to a ligature, LS use in total thyroidectomy leads to higher rates of permanent hypocalcemia. However, it does not increase the risk of permanent hypocalcemia. Using ligature in PG localization in thyroidectomy with LS can eliminate this issue.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was carried out with the permission of the Hatay Mustafa Kemal University Non-interventional Clinical Researches Ethics Committee (Date: 23.12.2021, Decision No: 05).

Informed Consent

Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

Declarations

This manuscript was prepared without the use of artificial intelligence or assisted technologies in the production of text and figures. The authors are fully responsible for the content and originality of the manuscript, and confirm the absence of plagiarism.

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Transanal minimally invasive surgery (TAMIS) for malign or benign rectal lesions: a series of 19 cases

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ABSTRACT

Aims: Colorectal cancer (CRC) is the second leading cause of death and the third leading cause of incidence worldwide. Thanks to colorectal cancer screening programs, early-stage colorectal cancers are detected more frequently. The aim of this study is to evaluate the short-term results of 19 TAMIS cases performed in our clinic.

Methods: Data of 19 patients aged ≥18 years who underwent TAMIS procedure due to rectal nonneoplastic and neoplastic polyps/T1N0 cancers at Ankara Bilkent City Hospital between September 2020 and December 2022 were analyzed retrospectively. Preoperative and postoperative findings were reviewed.

Results: Among the 19 patients, 7 (33.3%) were female, and 12 (66.7%) were male, with a mean age of 56.9 years. All patients underwent TAMIS without postoperative complications. Pathological results showed that 9 (47.4%) had neoplastic polyps (7 tubulovillous adenomas, 1 serrated adenoma, 1 adenocarcinoma), while 10 (52.6%) had non-neoplastic polyps. The patient with adenocarcinoma showed mucosal and submucosal invasion with a tumor base 1 mm from the margin. At the 3-month follow-up, rectoscopy revealed no pathological findings, only fibrosis.

Conclusion: TAMIS is an effective method for selected cases of early-stage rectal cancer that are well-staged preoperatively, offering a low-morbidity alternative to more invasive surgical approaches. Since our cases do not have long-term follow-ups, a clearer judgment can be reached with the results of long-term follow-ups.

Keywords: TAMIS, polyp, rectal cancer, minimally invasive surgery, effectiveness

INTRODUCTION

Transanal minimally invasive surgery (TAMIS) has attracted attention in recent years as one of the important innovations in colorectal surgery. First described by Atallah et al.[1] in 2010, this technique offers a safe and effective method for the removal of both benign and early-stage rectal lesions.[2,3] Compared to transanal endoscopic microsurgery (TEM), TAMIS offers a less invasive option, stands out with its lower costs and less complex device infrastructure.[1] With these features, it has rapidly gained popularity among colorectal surgeons and has become an important alternative in the field of minimally invasive surgery.[4]

TAMIS is suitable for benign and early-stage malignant lesions confined to the submucosal layer, as identified by preoperative magnetic resonance imaging (MRI) or endoscopic ultrasonography (EUS). For patients with early-stage cancer and poor histologic features (lymphatic/vascular/perineural invasion, poor differentiation, tumor budding) or deeper invasion (submucosal levels: sm2 or sm3), TAMIS is not recommended, and they should be managed as T2 lesions.[5] Also the European Society for Medical Oncology (ESMO) and the American Society of Colon and Rectal Surgeons (ASCRS) advise proctectomy with whole mesorectal excision for cT1 rectal cancers that are sm2 or sm3, but local excision for those that are sm1.[6,7] In patients with indeterminate lesions (T1 vs T2), TAMIS can be used for definitive tumor staging, but further radical surgery may be needed if poor features or deeper invasion are present.[5]

While The gold standard for treating locally advanced or node-positive rectal tumors is complete mesorectal excision (CME).[8] Furthermore, positive results have also been observed in the treatment of locally advanced malignancies in conjunction with neoadjuvant chemoradiotherapy, although comprehensive evaluation of the role of TAMIS in non-early rectal cancer still requires randomized controlled trials with long-term follow-up and standard procedures.[9] Other indications for TAMIS include anastomotic dehiscence, rectal stenosis, re-excision for R1 resections, and cases where endoscopic removal is not possible due to tumor size, location, or morphology. According to the NCCN guidelines, localized trans anal excision is recommended for movable, non-fixed

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rectal tumors, small tumors (<3 cm), or tumors affecting less than one-third of the rectal wall circumference.[5]

While prospective data are lacking, TAMIS offers comparable results with TEM in terms of oncologic outcomes, 5-year disease-free survival, peritoneal violation and postoperative morbidity[10]. TEM and TAMIS offer similar outcomes for rectal neoplasms, but TEM has longer operative times. TAMIS is preferred for its cost, time efficiency, and ease for less experienced surgeons. With advancements, TEM has become obsolete, and TAMIS has enabled faster adoption of TaTME.[11]

In this study, the clinical outcomes of patients who underwent TAMIS in our clinic and its place in the current literature will be examined and the potential benefits of this minimally invasive procedure in colorectal surgery will be discussed.

METHODS

We retrospectively analyzed the data of 19 patients who underwent TAMIS for rectal nonneoplastic and neoplastic polyps/ T1N0 cancers at Ankara Bilkent City Hospital between September 2020 and December 2022. The study included patients aged 18 years and older with T1 tumors of the middle and upper rectum without lymph node involvement on preoperative pelvic MRI. Patients with poor prognostic criteria (lymphatic/vascular/perineural invasion, poor differentiation, tumor budding) as a result of preoperative biopsy, patients with positive lymph nodes, and patients with T2 and more advanced tumor invasion were excluded. The study was carried out with the permission of Ankara Bilkent City Hospital No: 2 Clinical Researches Ethics Committee (Date: 27.111.2024, Decision No: TABED2-24-679). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki. Preoperative and postoperative rectoscopy/colonoscopy and radiological findings were reviewed. Patients whose data could not be accessed were excluded from the study. Age was obtained as mean (min-max). Numerical data were expressed as percentage (%).

RESULTS

Of the 19 patients included, 7 (33.3%) were female, and 12 (66.7%) were male, with a mean age of 56.9 (range: 30-82 years). All patients underwent the TAMIS procedure, and no postoperative complications were observed. Pathological results revealed that 9 patients (47.4%) had neoplastic polyps, and 10 patients (52.6%) had non-neoplastic polyps. Among the neoplastic polyps, 7 were tubulovillous adenomas, 1 was a serrated adenoma, and 1 was adenocarcinoma. Preoperative MRI for the patient with serrated adenoma showed a clear circumferential resection margin (CRM) with no involvement of the sphincter or extramesorectal lymph nodes. Postoperative colonoscopy revealed no mucosal pathology. The patient with adenocarcinoma had a preoperative imaging report indicating a soft tissue mass measuring 3.2x3.9x2.5 cm located 7 cm proximal to the anal verge on the right lateral wall of the mid-rectum. Pathology showed mucosal and submucosal invasion, no perineural or lymphovascular invasion, and a tumor base 1 mm from the surgical margin. At the 3-month postoperative follow-up, rectoscopy showed no pathological findings, and only fibrosis was observed at the surgical site. No colonoscopic findings of polyp recurrence were found in the follow-up of other neoplastic cases. Demographic and pathological examination results of the patients are given in Table.

Table. Demographic and clinical data of patients

Variables	n, (%), mean (min-max)
Patient number, n	19
Sex	
Female	7 (33.3)
Male	12 (66.7)
Mean age (min-max)	56.9 (30-82)
Polyps, n (%)	
Neoplastic	9 (47.4)
Non-neoplastic	10 (52.6)
Neoplastic polyps, n	
Tubulovillous adenoma	7
Serrated adenoma	1
Adenocarcinoma	1

Min: Minimum, Max: Maximum

DISCUSSION

Conventional transanal excision (TAE), colonoscopic resection, TEM, and TAMIS are the surgical platforms used for local excision or rectal tumors.[12] The management of early-stage rectal cancer has evolved significantly in recent years with the advancement of minimally invasive surgical techniques.[13] When compared to traditional TAE, transanal endoscopic microsurgery (TEM), which was initially described in 1984, offers better resection quality, higher negative microscopic margins, and lower recurrence rates. Its high initial cost and steep learning curve, however, have delayed its adoption in standard practice. These restrictions prompted the creation of TAMIS, which reduces expenses and permits 360° exposure of the rectal lumen using standard laparoscopic tools and a single incision port. TAMIS, which was first introduced in 2010, is a viable substitute for TEM that provides comparable advantages without the need for specialized equipment and at a significantly lower cost.[12] With advancements in technology and the adoption of TAMIS, the use of TEM has become obsolete, and TAMIS has facilitated the rapid implementation of the TaTME technique with a shorter learning curve.[11]

Transanal minimally invasive surgery (TAMIS) represents a major innovation in this field.[14] In our study, the outcomes of 19 patients who underwent TAMIS for rectal polyp or mass excision were evaluated, demonstrating the safety and efficacy of this technique in early-stage rectal cancer and large colorectal polyps.

Literature has established TAMIS as an effective treatment option for T1N0M0 rectal cancers with low-risk pathological features.[12] According to several studies, TAMIS allows for a minimally invasive approach that reduces perioperative morbidity while maintaining acceptable oncological outcomes, especially for well-selected patients.[12,15,16] The technique has been shown to be effective and safe, with low morbidity and with good quality of life (QOL) postoperatively for patients with early rectal cancer and adenomas of the mid and distal rectum.[17] Our findings are consistent with these reports, as none of the patients in our study experienced postoperative complications, and short-term follow-up revealed no recurrence of malignancy.

In our series of 19 cases including 9 neoplastic polyps, the only notable case was the one that was diagnosed as adenocarcinoma as a result of pathological examination. In this case's colonoscopy performed at the 3rd month postoperatively, there were no pathological findings, only fibrosis was detected in the excision area. No colonoscopic findings of polyp recurrence were found in the follow-up of other neoplastic cases. This result suggests that TAMIS can achieve adequate oncological outcomes when preoperative staging is accurate and the case selection is appropriate. However, the close proximity of the tumor margin to the surgical resection line (1 mm) in this case raises concerns about the potential for recurrence. Resection margin has been previously discussed in the literature regarding margin safety and the risk of local recurrence.[15,18] This highlights the importance of vigilant follow-up in such cases to ensure long-term disease control.

TAMIS offers a substantial advantage in preserving the surrounding anatomical structures while achieving sufficient oncological resection, particularly in early-stage tumors.[10] However, its limitations must also be considered. TAMIS may not be sufficient for tumors with a higher risk of lymph node metastasis or those at more advanced stages of the disease.[18] In such cases, more extensive surgery, such as total mesorectal excision (TME), may be warranted.[12]

Limitations

The limitations of this study include its retrospective nature, small sample size, and the lack of long-term follow-up data. Larger, prospective studies with longer follow-up are necessary to further validate the oncological safety and effectiveness of TAMIS.

CONCLUSION

In conclusion, TAMIS provides a minimally invasive and low-morbidity option for the treatment of early-stage rectal cancer in selected patients. Although our number of cases is low and our follow-up period is short, our findings may suggest that TAMIS is an effective and safe option for well-selected patients with early-stage rectal cancers or large benign polyps. This technique offers the potential for favorable oncological outcomes without the need for more aggressive surgical interventions, making it an attractive option in appropriate clinical scenarios.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was carried out with the permission of Ankara Bilkent City Hospital No: 2 Clinical Researches Ethics Committee (Date: 27.111.2024, Decision No: TABED2-24-679).

Informed Consent

Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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Journal of Comprehensive Surgery

Case Report

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Black seed oil induced acute liver failure: a case report and literature review

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ABSTRACT

Acute liver failure (ALF) is a clinical condition that develops suddenly in individuals with no history of liver disease due to various factors and has a high morbidity and mortality rate. Drugs, chemicals, and herbal products are the leading causes of ALF. Black seed is widely used among the population due to its diuretic, antihypertensive, antidiabetic, anticancer, antimicrobial, anti-inflammatory, gastroprotective, hepatoprotective, kidney-protective, and antioxidant properties. In this report, an 82-year-old female patient with a history of diabetes, hypertension, and chronic kidney disease who received hemodialysis treatment twice a week was examined for ALF due to black seed oil use. The patient, who applied to the emergency room with confusion, had increased liver function tests in laboratory findings. In addition, no pathology was detected in the patient's computed tomography angiography and ultrasonography other than grade 1 steatosis and increased linear echogenicity in the liver. The patient, who was diagnosed with ALF, started treatment in the intensive care unit. The patient, who had a poor prognosis in the intensive care unit, died on the 9th day of her hospitalization. Considering the studies in the literature and the patient we examined, although it is thought to be harmless among the public, herbal products should not be used with medications and in patients receiving renal replacement therapy without the advice of a physician or pharmacist due to their possible toxic effects.

Keywords: Acute liver failure, herbal products, black seed

INTRODUCTION

Acute liver failure (ALF) is a rare, life-threatening condition that occurs in patients with no preexisting liver disease and is characterized by liver injury (abnormal liver tests), coagulopathy [international normalized ratio (INR) >1.5], and hepatic encephalopathy (HE). ALF shows a poor prognosis. Since morbidity and mortality rate of patients are high, timely recognition and management of patients is crucial. Viral hepatitis and drug-induced hepatitis are most common cause of ALF. Other causes include hypoxia and hypoperfusion, veno-occlusive disease, Wilson disease, autoimmune hepatitis, hemolysis, elevated liver enzymes, low platelet (HELLP) syndrome, mushroom toxicity, some herbal products and malignant conditions.[1]

Drug-induced acute liver injury is a common clinical condition that can range from mild elevations in liver enzymes to death. Herbal products are among the important causes of drug-induced acute liver damage. It is estimated that the incidence of herbal product-induced acute liver injury reaches up to 20%.[2]

Black seed (*Nigella sativa* L.) is widely used in the treatment of various diseases among the public due to its antioxidant and anti-inflammatory effects. It is a member of the Ranunculaceae family and is widely used to prevent and treat various diseases. The active ingredient responsible for the therapeutic effect of black cumin is thymoquinone. Studies have reported that *Nigella sativa* has diuretic, antihypertensive, antidiabetic, anticancer, immunomodulatory, analgesic, antimicrobial, anthelmintic, analgesic, anti-inflammatory, spasmolytic, bronchodilator, gastroprotective, hepatoprotective, kidney-protective and antioxidant properties.[3-6] In this letter, acute liver damage in a patient who used black seed oil to improve kidney functions was examined.

CASE

An 82-year-old female patient presented to the emergency department due to confusion. The patient had a medical history of diabetes, hypertension, and chronic kidney disease. Before admission to the intensive care unit, the patient used linagliptin, perindopril/indapamide, paroxetine, clopidogrel, cilostazol, aspirin, and sodium hydrogen phosphate. One month ago, the nephrology department enrolled her in a routine hemodialysis program, and she has been undergoing hemodialysis twice a week. Laboratory tests revealed elevated levels of lactate, transaminase, and bilirubin. Additionally, other liver function tests were abnormal (Table). Acute liver

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failure was considered in the patient who was admitted to the intensive care unit.

Table. Laboratory findings of the patient on the first day of intensive care admission

Parameter	Patients' value	Reference range
ALT	565 U/L	<35 U/L
AST	471 U/L	<35 U/L
Albumin	26.3 g/dl	3.5-5.5 g/dl
Total bilirubin	2.33 mg/dl	0.3-1 mg/dl
Direct bilirubin	1.49 mg/dl	0.1-0.3 mg/dl
INR	2.65	0.9-1.2
Lactate	3.5 mmol/L	0.5-1 mmol/L

ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, INR: International normalized ratio

A full abdominal computed tomography angiography and ultrasonography were performed to patient and showing no signs of ischemia or thrombus. In addition, findings included grade 1 steatosis and increased linear echogenicity in the liver. The family stated that they had been giving the patient black seed oil capsules for the last month for the treatment of renal failure.

Despite the intermittent dialysis and other treatments applied to the patient during the intensive care treatment, the patient's liver functions did not improve her hemodynamics deteriorated, and she died on the 9th day of her admission to the intensive care unit.

RESULTS

Herbal products are used to prevent and treat many diseases with the idea that they are "safe" among the population. Although numerous studies have been conducted on the role of herbal products in treatment, only a limited number have demonstrated well-documented pharmacological, toxicological, and clinical effects. Therefore, herbal products should not be used as primary treatments for diseases but rather as complementary therapies, and only under the guidance of a qualified healthcare professional, such as a physician or pharmacist. Herbal products used unconsciously can cause harmful effects on patients and can interact with other medications of patients, resulting in treatment failure and drug toxicity. Various complications such as hepatotoxicity, nephrotoxicity, electrolyte disorders, hypertension, cardiac arrhythmia, seizures, coagulation problems, and death may occur in patients due to the use of herbal products.[7-9] In vivo studies on black seed have reported low toxicity, and reported toxicity symptoms to include respiratory distress, leukopenia, thrombocytopenia, kidney, liver, and heart toxicity.[10,11] It has been reported that allergic contact dermatitis has developed in patients due to the external use of cosmetic preparations containing black seed.[12,13] The number of clinical studies investigating the effects of black seed is limited. In the clinical study conducted with healthy volunteers investigating the effects of black seed on memory, attention, and cognition, no toxic effects were reported in patients due to the use of black seed.[14] In a placebo-controlled clinical study evaluating the antiepileptic effects of thymoquinone, no toxicity was observed. However, the incidence of nausea and vomiting was reported to be higher among patients receiving thymoquinone compared to placebo group.[15] In a case report published by Sener et al.,[16] it was reported that a patient developed rhabdomyolysis and acute kidney injury due to the use of black seed oil.

CONCLUSION

Although studies in the literature inicate that the use of products containing black seed is safe, the interactions of drugs used with black seed and the possible effects on the prognosis of diseases in various patient populations have not been sufficiently studied. Therefore, herbal products containing black seed should be used with caution in patients with chronic diseases and those taking medications. As with other herbal supplements, herbal products containing black cumin should only be used with the advice of a physician or pharmacist.

ETHICAL DECLARATIONS

Informed Consent

The patient signed and free and informed consent form.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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Journal of Comprehensive Surgery

Case Report

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Unexpected motor weakness after ultrasound-guided retrolaminar block: a case report

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ABSTRACT

Retrolaminar block (RLB) is a new and simple approach of paravertebral block with laminar technique. Retrolaminar block is used for pain management of breast surgery, rib fractures and lumbar trauma. However there is not any complication of RLB in the literature. In the present manuscript, we report a case of unexpected motor weakness after ultrasound-guided Retrolaminar block of patient who underwent lumbar disc surgery. After the uneventful general anesthesia, the patient had hypoesthesia as well as loss of muscle strength. The imaging methods were evaluated as normal. The patient was followed up at 4 hour intervals. The motor weakness of the patient completely resolved at the postoperative 28th hour. To our knowledge this is the first report of motor weakness related to the RLB. Retrolaminar block may cause transient muscle weakness. A careful physical examination and follow-up will provide clear information like in this clinical situation.

Keywords: Retrolaminar block, motor weakness, ultrasound

INTRODUCTION

Paravertebral blocks are usually performed for postoperative analgesia. Retrolaminar block (RLB) is a new and simple approach of paravertebral block with laminar technique.[1] When the needle tip contacted to the lamina, local anesthetic is injectated over the vertebral lamina deep to the paraspinous muscles.[1] Local anesthetic spreads paravertebral space, neural foramina and intercostal space and so the spinal nerves are blocked.[1] RLB is used for pain management of breast surgery, rib fractures and lumbar trauma.[2,3] However there is not any complication of RLB in the literature. We performed this truncal block for postoperative analgesia for patient undergoing lumbar spinal surgery. And we report a case of unanticipated motor weakness after ultrasound-guided RLB. To our knowledge this is the first report of motor weakness related to the RLB.

CASE

A 63 years old man was scheduled for lumbar disc surgery due to the lumbar disc herniation. The patient was an ASA class II with regulated hypertension. In our patient nerve block room, oxygen saturation (SPO_2), noninvasive blood pressure, ECG monitoring were performed. After taken written inform form, the single-shot retrolaminar block was performed at the level of L3 lamina. The skin sterilized, then the level of the lamina was located by ultrasound-guided approach from lateral to medial in supine position with 7-12 MHz convex probe at the preoperative waiting area. The needle was inserted in plane technique, contacted to the lamina and 20 ml 0.25% bupivacaine was injectated between the lamina and the deep paraspinous muscles (**Figure A**). The spread of local anesthetic was seen (**Figure B**). Then the patient was taken to the operation theatre. Bispectral Index (BIS) monitoring was performed in addition to standard monitoring. During induction, patient received 2 mg/kg propofol, 1 μg/kg fentanyl and 0.6 mg/kg rocuronium for muscle relaxation. After intubation sevoflurane 2-3% in 50% O_2-air mixture was given for maintenance of anesthesia. The patient was extubated after an uneventful surgery. The patient received 1000 mg intravenous acetaminophen for addition of postoperative analgesia. When adequate spontaneous breathing is achieved, the patient was extubated and transferred to the ward. The evaluating of the pain at determined intervals with Visual Analogue Scale (VAS) scores of resting/dynamic was made. The VAS scores of the patient was below 4/10 at all postoperative time intervals. However, when the patient was examined for pain at the 4th postoperative hour, patients' right hip flexion was 2/5 and right knee extension was 4/5 according to the manual muscle testing. And the patient had hypoesthesia as well as loss of muscle strength. Upon detection of motor deficits, computed tomography was performed for rulling out primary neurologic etiologies. The imaging methods were evaluated as normal. The patient was followed up at 4-hour intervals. Examination findings remained the same until postoperative 16th hour and the patient failed the straight leg lifting test. At the postoperative 20th hour, the patient's motor sensation began to recur, raising the leg slightly in the leg lift test. The motor weakness of the patient completely recovered

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at the postoperative 28th hour. The patient was discharged at postoperative 3rd day without any compliant.

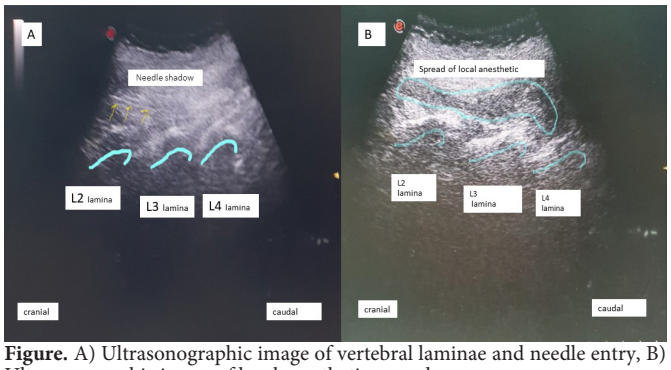

Figure. A) Ultrasonographic image of vertebral laminae and needle entry, B) Ultrasonographic image of local anesthetic spread

DISCUSSION

Providing good analgesia in the postoperative period in patients who have undergone lumbar spine surgery reduces the morbidity of the patients, provides early mobilization and early discharge.[4] In recent years, regional techniques have been frequently used to provide analgesia, especially to avoid adverse effects such as respiratory depression, nausea, vomiting, constipation and addiction due to opioids.[4] Retrolaminar block is a facial plane block used for postoperative analgesia in lumbar spine surgery.[5] We did not find any report related to the motor weakness, muscle weakness or reflex disorder due to RLB. The present case is the first in the literature. In our case the physical examination of weakness of muscles confirmed the spinal nerve infiltration of local anesthetic through the neuraxial space and lumbosacral plexus. So, we thouht that the cause of the motor weakness of the present patient is due to the RLB. The computarized tomography of the patient after the weakness complaint was normal. It was seen that his complaint was reversible (His complaints improved over time at intervals of examining the motor weakness). The spread of local anesthetic through the paravertebral space and blockage of the spinal nerves is the primary wanted effect of the retrolaminar block. However, the anatomic approach of the RLB was the more nearer to the neural foramina than the other paraspinal blocks. So, the spread of the local anesthetic was much more to the neural foramina than intercostal spread. This thought us, the local anesthetic distribution was not only paravertebral space but also epidural space. According to the physical examination of the patient (motor weakness during the straight leg lift testing and the hypoestesia of the internal space of the right leg), the distribution of the local anesthetic was to the epidural space of the L2 vertebrae.

In the literature, we see similar muscle strength loss in the lower extremity only in the erector spinae plane block, which is a block similar to the retrolaminar block (paravertebral area block). In patients who underwent ESP block, conditions such as motor muscle weakness and joint reflex disorders were encountered in the literature, especially in patients who underwent continuous block.[6-8] One of them was knee and ankle reflex weakness that developed in a young patient who had undergone cesarean section and underwent bilateral thoracic ESP.[7] The authors concluded without excluding a possible epidural extension, the weakness of reflexes was due to lumbosacral extension of the local anesthetic. Unlike the authors who applied a single injection, unilateral motor weakness was observed in another patient who underwent ESP by inserting a catheter.[8] These authors, on the other hand, thought that it was due to the neuraxial spread of the local anesthetic because of the motor weakness.

CONCLUSION

Motor weakness seen after a RLB application for post-operative analgesia, especially after spinal surgery, is a condition that can irritate both the doctor and the patient. However, a careful physical examination and follow-up with imaging methods will provide clear information about the current clinical situation.

ETHICAL DECLARATIONS

Informed Consent

The patient signed and free and informed consent form.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

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Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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Journal of Comprehensive Surgery

Letter to the Editor

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The role of nerve stimulation in regional anesthesia practice

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Keywords: Regional anesthesia, nerve stimulation, nerve injury

Dear Editor,

Electrical stimulation of nerves became widely used in the 1970s to more precisely locate nerves and plexuses.[1] However, developing ultrasonography (USG) devices and probes have gradually reduced the interest in nerve stimulation in regional anesthesia.[2]

In the literature, studies on the efficacy and safety of USG alone and nerve stimulation alone methods resulted in increased block success rate, decreased block procedure time, decreased risk of vascular puncture, faster block onset, and longer block duration in the USG group.[1] However, studies comparing USG alone with the addition of nerve stimulation to USG guidance have shown different results for different nerve blocks.[1] For nerve targets that can be easily visualized with USG (e.g., femoral nerve block, interscalene brachial plexus block, infraclavicular brachial plexus block, and popliteal/sciatic nerve block), nerve stimulation added to USG has no significant effect on block success and pain scores. For deep or difficult-to-visualize nerves (e.g., obturator, parasacral sciatic, subgluteal sciatic, and posterior lumbar plexus blocks), nerve stimulation may be beneficial.[1] However, these studies generally focused on block success and vascular puncture as a complication, and the nerve injury that may occur after nerve blocks was not evaluated.

The American Society of Regional Anesthesia and Pain Medicine has reported the incidence of nerve injury within 3 months after nerve blocks as 1-2.2%.[3] These rates are at a level that may cause serious concerns in clinical practice.

Even in skilled hands, the needle tip may not always be visible on USG. One study reported that the success rate of expert anesthesiologists in correctly interpreting needle positions (intraneural and extraneural) during USG-guided sciatic nerve blockade was less than 80%.[4] The simultaneous use of nerve stimulation with ultrasound serves more as a warning against needle-nerve contact that would not be recognized by ultrasound than as a means of finding nerves.[1] Animal and human studies suggest that if a muscle contraction is achieved at or below a threshold of 0.2 mA, the needle tip is likely to have contacted a nerve or is intraneural.[1] Although 0.2 mA appears to be the threshold value that most accurately distinguishes needle-nerve contact from extraneural needle position, many anesthesiologists prefer to set the current intensity higher (e.g., 0.5 mA or more) to provide earlier warning of impending needle-nerve contact.[1] In this method, if the needle under USG guidance can be placed next to the nerve, avoiding contact, and there is no muscle contraction, the stimulator is turned off and the injection is performed.[1] This method is referred to as "double guide" among anesthesiologists.[1]

The advantages of double guidance are evident in certain situations. For example, in adductor canal block, the nerve to the vastus medialis lies lateral to the saphenous nerve and may be difficult to identify on ultrasound. Double guidance allows reliable identification even when the nerve cannot be visualized.[5] Similarly, in retroclavicular block, safety can be ensured by monitoring muscle contraction while advancing the needle due to the risk of damaging the suprascapular nerve.[6] The biggest obstacle to the adoption of double guides by clinicians appears to be the increase in block procedure time.[1] However, if clinicians adopt this method and include it in routine practice, its advantages may become apparent by gradually reducing its disadvantages in terms of time.

Nowadays, nerve block needles are manufactured to be compatible with stimulation. In this context, it should be kept in mind that nerve stimulation, which can be performed with USG guidance without creating additional costs, can increase block success and reduce the risk of postoperative nerve injury.

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Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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