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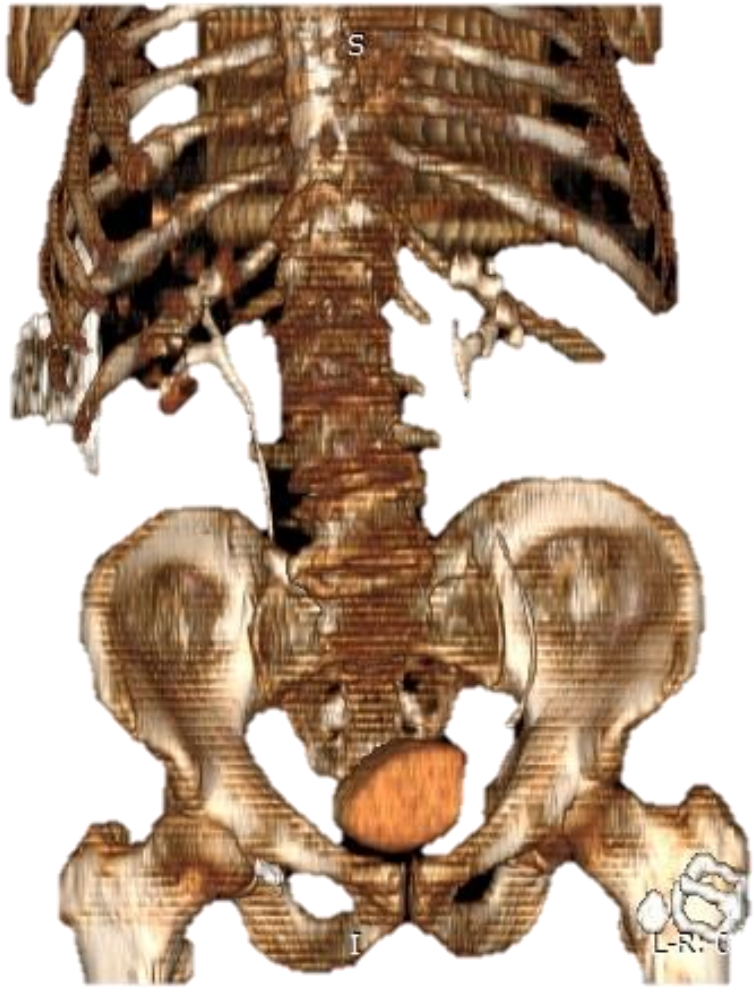

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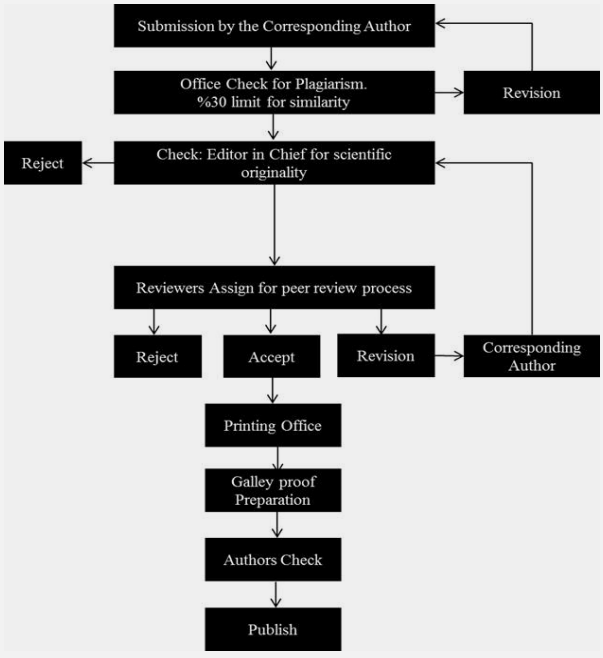

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Recommendations for oncological orthopaedics in the Covid-19 pandemic; Review of the literature and clinical experiences

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Abstract

Objective: The Covid-19 pandemic which arose from Wuhan city in December 2019 led to some changes in the treatment and follow-up of orthopedic patients to protect both the patients and the health workers and their relatives from the contagion. Long-term settings for the sake of patients and health workers have been made to decrease the viral load and the Covid-19 transmission risk. The specialist opinions and the data coming from Italy and Spain where the pandemic affected earlier than most countries facilitated the necessary steps to take in oncologic orthopedics. These steps in general, it should be limited to acute cases such as pathological fractures and malignant tumors. During the acute phase of the pandemic; it requires postponement of all other oncological orthopedic cases and outpatient controls. All surgeries where delaying 3 months will not be a big problem in the long term should be kept waiting.

Keywords: Pandemic, Covid-19, Oncological Orthopaedic

Introduction

In December 31 2019, the health commission in Wuhan city of China reported 27 pneumonia cases to National Health Commission, China Disease Control Center (CDC), and World Health Organization (WHO) (1). In January 7 2020, China CDC discovered a new coronavirus (2019-nCoV) known as "Wuhan Coronavirus" in the local language.

WHO renamed it as SARS-CoV-2 to relate the virus to the disease symptomatology and not to describe the relationship between the virus and any geographical place and nationality. In January 30 2020, WHO declared this viral pneumonia as an emergent situation. Spreading all over the world in 3 months, WHO declared the pandemic on 11 March 2020 (1). By 19 May2020, the coronavirus infected 4,911,839 patients and caused 320,458 deaths (2). Infected cases and casualties have been increasing day by day.

The pandemics of new Coronavirus (COVID-19) known also as SARS-CoV-2 has loaded a great burden on the shoulders of health systems all around the world. Operational disciplines suggested postponing the elective surgeries in the face of this pandemic which obliterated the world health systems. Orthopedists have made decisions on which patients to operate in order to decrease the viral load and to prevent the contagion and they also had to change the way they give health service (3).

However, in oncological orthopedics, it is arguable which case is elective due to the immune-suppressed conditions of most patients. The literature review on various fields such as the in-patient care and the welfare of the doctor is looked at.

It is important that the health workers who serve in the oncological orthopedic area must admit this pandemic as an evolving and progressive entity; Therefore everybody must be prepared to be flexible, ready to transform according to the changing environment. For this reason, health professionals must get informed about the last protocols using resources such as AAOS (American Academy of Orthopaedic Surgeons) web site and Center for Disease Control (CDC) web site.

General Principles

The Covid-19 Pandemic has necessitated significant changes in the current implementation methods. Oncological Orthopaedics professionals must have revised the pre—contagion treatment protocols to decrease the transmission risk. Conservative treatments must be kept at the forefront in the acute phase of the contagion. Emergent operations must be performed under the utter precautions and with personal safety equipments.

The use of telemedicine and online file sharing applications in oncological orthopedics might contribute to the

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protection of the medical staff and patients from the COVID-19 spread (4).

ESMO (EuropeanSociety of MedicalOncology) has also made recommendations for oncology patients without COVID-19 symptoms. Soft tissue sarcomas and malignant bone tumors might continue to be operated. Neoadjuvant chemotherapy, adjuvant chemotherapy and radiotherapy must not be delayed. Tumors with high malignant potential such as Ewing's or osteosarcoma must be treated like the way before the Covid-19 pandemic (5). For the tumors with lower malignant potential such as desmoid fibromatosis, active follow-up must be done and intervention must be considered only if any progression occurs (6).

American Academy of Orthopaedic Surgeons classified the major orthopedic operations according to how long they could be safely delayed considering the studies in the literature.

They have categorized orthopaedic surgeries into 5 categories based on priority: Priority A (emergency surgery within 24 hours), Priority B (urgent surgery within<48 hours), Priority C (Expedited Surgery within 2 weeks), Priority D (Short-Term Delayed<3 months), and Priority E (Long-TermDelayed>3 months). When considering this study in terms of oncological orthopedics, "impending pathological fractures" are inpriority B category. In the same table, "Surgical Spine Tumor with Cord Compression" is in priority A category(4).

Patient Selection for Surgery

All the operations that were thought not to lead important problems in three months, were delayed. The patients who presented with acute pathological fracture and the ones with malignant tumors of which the tumor load could increase have been continued to be operated considering the Covid-19 precautions.

In the pandemic period while the benign soft tissue tumor operations have been delayed; sarcoma operations have continued by council decision. Nonetheless, in borderline aggressive tumors (such as fibromatosis) the decision must be made uniquely for each patient. The decision must be made considering the patient's age, the localization of the tumor, the grade, the type of tumor, and the comorbidities.

While the benign soft tissue tumor operations have been delayed; sarcoma operations have continued. For the benign bone tumors with fracture risk and benign aggressive bone tumors (giant cell tumor, aneurysmal bone cyst), the decision must be made uniquely for each patient.

The decision must be made considering the patient's age, the localization of tumor, the grade, the type of tumor and the comorbidities. Due to the fact that malignancy could not be always clinically and radiologically excluded in benign aggressive tumors, the decision for those patients must be given by discussing in the tumor council. Similarly, for the lesions that are close to the joint cartilage such as giant cell tumor and aneurysmal bone cyst, an operation for sparing the joint might be decided.

Chemotherapy and radiotherapy protocols must go on taking the necessary steps as being neoadjuvant and adjuvant. The patients whose neoadjuvant treatment process is complete are discussed in the tumor council and the decision has been made by a multidisciplinary team (oncological orthopaedist, medical oncologist, radiation oncologist, pathologist and psychologist). The patient's age, comorbidities, cigarette usage, and immune-suppressed condition have been considered.

The decision process for the operation is also a process in which the decision is made together with the patient. Covid-19 symptoms are questioned for all the patients who we decide to operate and the patient is isolated in the Covid-19 service until the screening results are seen and the operation is suspended. Despite all these, from the first day to the day of discharge, all patients are treated as if they are Covid-19 positive. The procedures are performed by taking all the personal cautions. The number of operation room staff is limited to a minimum number.

Protection of Health Staff and the Patients

Health staff has started to work as rotatoryly and the number of visitors in the service is limited. The necessary information and the training about the protective equipment and hand hygiene have been given to the health staff. Lessons have been continuing isolatedly on the computer using the technological facilities. The number of polyclinics is decreased and the polyclinic started to serve only for emergent and indispensable situations.

Fever is measured during entering into and going out the hospital. Mask wearing is made obligatory. During the surgery, protective equipment such as glasses, mask, and visors are used by the entire health team.

The hospital restaurant has been designed according to social distancing rules. The number of staff is decreased to a minimum number for the night shifts. The staff who had close contact with Covid-19 patients and the ones with symptoms are screened immediately and isolated. Moreover, the staff are divided into groups to work in the polyclinic, operation room, and service.

The patients and the next-of-kins are obliged to use masks and to keep the social distancing rules both before and after surgery. They have been informed about how to protect themselves and hand hygiene before the hospitalization. Fever measurements have been made and recorded frequently for all patients. All patients are questioned for suspicious close contacts. The discharges of the patients are planned early postoperative period and the patients are isolated during hospitalization.

Recommendations

Our clinic is experienced in differentiating emergent and elective cases due to its experience with oncologic orthopedics during the last 30 years. However treatment protocols must have been updated for this pandemic which is experienced for the first time. Our clinic has kept being a pioneer for serving by developing rapid algorithms. The aim is to protect the health staff and the patients and to provide the treatment not to cease. The treatment algorithm is summarized below (Table 1).

Table 1 : Patient Selection for Surgery

Group type	Surgery time	Diseases
Group A	Within the first 24 hours	Oncological cases with the orthopedic emergency (such as vascular-nerve damage
Group B	Within 1 week	1.Malign bone tumors (Osteosarcoma, Ewing sarcoma, chondrosarcoma, fibrosarcoma, multiple myeloma, lymphoma, cordoma) 2. Malignant soft tissue sarcomas (liposarcoma, pleomorphic sarcoma, fibrosarcoma, synovial sarcoma, extra-skeletal sarcoma, rhabdomyosarcoma) 3. Metastaz on; if there is a risk of fracture or cure is intended
Group C	Active monitoring, decide on follow-up	1.Benign aggressive bone tumors (osteoblastoma, chondroblastoma, chondromyxoid fibroma, aneurysmal bone cyst, giant cell tumor, osteo-fibrous dysplasia) 2. Local aggressive soft tissue tumors (fibromatosis, pigmented villonodular synovitis) 3. Metastases; if there is no risk of fracture or cure is not intended
Group D	After pandemic	1.Benign bone tumors (Osteoid osteoma, enchondroma, osteochondroma, non-ossifying fibroma, fibrous dysplasia, eosinophilic granuloma, simple bone cyst) 2.Benign soft tissue tumors (lipoma, hemangioma, neurofibroma, nodular fasciitis)

As a result, soft tissue sarcomas, malignant bone tumors, and benign aggressive borderline tumors can be operated in this process. However, this surgery decision should be made specifically for each patient, and it should be decided together with the patient and tumor council. During the operation, healthcare personnel must comply with the disease control and Prevention Centers (CDC) guidelines and protect themselves and their environment with full protective equipment.

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The effect of paricalcitol on Hepatitis B immunization in hemodialysis patients

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Abstract

Objective: Hepatitis B virus (HBV) infection has high morbidity and mortality. Therefore vaccination for HBV is crucial, especially for risk groups. In this study, we aimed to determine the effect of paricalcitol on HBV immunization in maintenance hemodialysis (HD) patients.

Methods: Forty-two maintenance HD patients enrolled in the study. Group 1 was control who didn't receive paricalcitol treatment (n:28, control group). Group 2 was paricalcitol treatment group for secondary hyperparathyroidism (n:14, paricalcitol group). Anti-HBs titers were measured with a three-month interval for two times.

Results: The mean age of the patients in Group 1 was 58.50(18-80) years, while of the patients in Group 2 was 46.50 (23-81) years. There was no statistically significant difference between the groups in terms of age and gender (p = 0.200, p = 0.508, respectively). Baseline anti-HBs titer in the control group was 190.32 IU/L (20.18-1000), and 187.89 IU/L (38.77-1000) in the paricalcitol treated group. After 3 months of follow-up, anti-HBs titers decreased to 114.72 IU/L (13.68-1000) from 190.32 IU/L (20.18-1000) in the control group and to the 175.27 IU/L (14.25-1000) from 187.89 IU/L (38.77-1000) in the paricalcitol group. The decrease in anti-HBs titers was significant in the control group, whereas it was not significant in the paricalcitol group (P = 0.001, 0.209, respectively).

Conclusion: The protective effect of paricalcitol on hepatitis B seroconversion in HD patients was observed. We think that paricalcitol may be used as an adjuvant for hepatitis B seroconversion.

Keywords: Hemodialysis, Hepatitis B, Vaccination, Paricalcitol, Vitamin D

Introduction

HBV infection is an important health care problem for all of the world as it in developing countries (1). There are 248 million chronic infected individuals estimated to be infected with HBV (2). In the globe, nearly 3.6% of the individuals are positive for the hepatitis B surface antigen (HBsAg) (3). HBV infection has high morbidity and mortality (2). For this reason vaccination for HBV is crucial, especially for risk groups, and has been used safely over 35 years (3).

HBV rate is higher in HD patients than in the general population (4). Also, this specific group is prominently sensitive to hepatitis B transmission. Impaired immunity, frequent blood transfusion, and common use of the equipments markedly increase the risk (5). Therefore, HBV vaccination has been proposed to prevent infection in all HD patients susceptible to HBV (6). But, patients suffering from hemodialysis cannot show the desired response to HBV vaccination compared to healthy individuals due to insufficient immune response (7,8). There are several reasons to explain this situation. Chronic inflammation and malnutrition is one of them and generally result in an impaired immune response, and also seen frequently in maintained hemodialysis patients. The development of an immune response to vaccination is a complex state covering innate and adaptive immune systems both. (9). Several adjuvant strategies have been proposed to accelerate the hepatitis B immunization in hemodialysis patients. Levamisole, GM-CSF, Advax (a polysaccharide adjuvant), Polymethylmethacrylate are such adjuvants used to stimulate the immune response (4). Despite all these efforts, enough response to vaccination has not been acquired. Furthermore, patients tend to lose acquired immune response easily compared to healthy individuals (9).

The 1,25-dihydroxycholecalciferol (1,25(OH)2 D3), an active form of vitamin D, has a significant role in the immune response. 1,25(OH)2 D3 converted from 25-hydroxycholecalciferol (25(OH)2 D3) across the kidney through the action of the 1-hydroxylase enzyme (10).

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The impact of vitamin D administration has been shown to increase antigen-specific antibody generation on animals. Also reduces the expression of inflammatory cytokines (11).

In light of this knowledge, we postulated that paricalcitol might affect HBV immunization. For this purpose, we retrospectively evaluated the Anti-HBs titer of patients receiving paricalcitol treatment for hyperparathyroidism on HD patients and examined the impact of paricalcitol on HBV immunization. We also examined the probable relationship with the blood counts.

Materials and methods

Study Design

The study was performed retrospectively at Fırat University Hemodialysis Unit. Ethical approval was taken from the local ethical committee (Date:28.03.2019, Decision no: 33). A total of 90 maintenance hemodialysis patients, 42 subjects who meet the criteria were included in the study. All of the participant's anti-HBs titers were above >10 mIU/mL that was accepted to seroprotective. Anti-HBs titers were measured with a three-month interval for two times and titer slopes examined between groups. Patients who have to vaccinate or rappel were not included in the study either between the two intervals or within 1 month of the first Anti-HBs titers measurement because of confounding factors.

Patients Selection and Data Collection

Patients were devided into two groups. Group 1 consisted of controls who didn't receive either paricalcitol or vitamin D treatment (n:28, control group). Group 2 was comprised of patients who received paricalcitol treatment for secondary hyperparathyroidism (n:14, paricalcitol group). Patients who are ongoing on a vaccination schedule or non-sensitive to the vaccine that was defined as anti-HBs concentration <10 mIU/mL have been excluded from the study. All of the participants were older than 18 years. Patients who have a malignancy or thought to have been malnutrition by clinical or laboratory excluded from the study. Testing blood counts, biochemical parameters such as urea, creatinine, PTH, calcium, phosphorus, CRP, and Anti-HBsAg was examined at 0. and 3.mounts, retrospectively.

Demographic and laboratory data were obtained from the records. The biochemical data used in the study was measured by the ADVIA 2400 device (manufactured by SIEMENS). ARCHITECT Anti-HBsAg method (ABBOTT Laboratories) was used to measure anti-HBs titer which is the so-called chemiluminescence microparticle immunoassay (CMIA).

Statistical analysis

All analyses performed in this study were obtained using the SPSS software program (Version 20.0). Continuous variables were given as mean ± standard deviation or median values and intervals, and categorical variables were given as absolute numbers. Wilcoxon test was used to evaluate the anti-HBs titer changes in each group. Differences between the groups were evaluated by Mann-Whitney U or Chi-square test. Values less than $p < 0.05$ were considered statistically significant.

Results

A total of 42 patients (24 female, 18 male) were included in the study. In Group 1, there were 28 patients, 13 of whom were women and 15 of them were men. Group 2 consisted of 14 patients, 5 of whom were women and 9 men. The mean age of the patients in Group 1 was 58.50 ± 18-80 years, while the mean age of the patients in Group 2 was 46.50 ± 23-81 years. There was no statistically significant difference between the groups in terms of age and gender ($p = 0.200$, $p = 0.508$, respectively). White blood cell, neutrophil, and platelet counts were significantly lower in the paricalcitol group compared to the control group ($P = 0.048$, 0.020, 0.009, respectively), but there were no significant differences in terms of lymphocyte, hemoglobin, and MPV (Mean Platelet Volume) values between the two groups. ($P = 0.800$, 0.650, 0.186, respectively). There were no significant differences between the groups in terms of biochemical parameters. The comparison of demographic and blood parameters of the groups is summarized in Table 1. The mean paricalcitol dose given to the paricalcitol group was 14.14 ± 10.29 mcg/ week . PTH levels were significantly higher in both the first and the 3. month measurement in the paricalcitol group than the control ($p < 0.001$, 0.048, respectively) (Table 2) .

The median anti-HBs titer measured at baseline in the control group was 190.32 IU/L (20.18-1000), and also the Anti-HBs titer measured initially in the paricalcitol group was 187.89 IU/L (38.77-1000). After 3 months of follow-up measured anti-HBs titers decreased to 114.72 IU/L (13.68-1000) from 190.32 IU/L (20.18-1000) in the control group and the 175.27 IU/L (14.25-1000) from 187.89 IU/L (38.77-1000) in the paricalcitol group. Although this decrease in anti-HBs titers was significant in the control group, it was not significant in the paricalcitol group. ($P = 0.001$, 0.209, respectively). The changes in anti-HBs titers in groups is summarized in Table 3.

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Table 1. Demographic and blood parameters of groups (*p<0.05)

	Group 1 (Control Group) (median/min-max)	Group 2 (Paricalcitol Group) (median/min-max)	P Value
Gender (F/ M)	13/15	5/9	0.742
Age (year)	58.50 (18-80)	46.50 (23-81)	0.200
CRP (mg/L)	5.86 (3.13-21.20)	5.01 (3.13-60.00)	0.755
White blood cells (mm^3/mL)	7.01(3.76-12.90)	6.24 (2.99-9.86)	0.048*
Neutrophils (mm^3/mL)	4.45 (1.83-7.91)	3.76 (1.79-6.00)	0.020*
Lymphocyte (mm^3/mL)	1.56(0.43-4.95)	1.70(0.74-2.74)	0.800
Hemoglobin (g/dL)	11.45(7.20-13.80)	11.05 (8.50-14.00)	0.650
Platelets	224.5(132.00-594.00)	171.50 (96.00-327)	0.009*
MPV (fL)	8.70(7.50-11.40)	9.10 (7.20-12.00)	0.186
Urea (mg/dl)	121.50(50-232)	141.00 (66.00-245.00)	0.839
Creatinine (mg/dl)	6.92(4.39-14.70)	8.11 (5.15-16.00)	0.157
Calcium (mg/dl)	8.990(6.05-10.43)	9.08 (8.24-11.55)	0.196
Phosphor (mg/dl)	4.00 (1.40-7.90)	5.25 (3.70-7.30)	0.106
Albumin (g/dl)	4.20 (2.80-5.0)	4.20 (7.70-7.30)	0.494
Uric acid (mg/dl)	5.40 (3.80-8.40)	6.10 (4.40-8.50)	0.112
Bicarbonate (mmol/L)	20.10 (13.80-27.40)	19.90 (15.30-24.50)	0.612

CRP, C-reactive protein; MPV, Mean Platelet Volume

Table 2. Comparison of PTH values of groups (*p<0.05)

	Group 1 (Control Group)	Group 2 (Paricalcitol Group)	P Value
PTH (First Value) (pg/mL)	262.0 (2-482)	650.5 (324-1890)	0.001*
PTH (3.Month Value) (pg/mL)	309.5 (2.5-1443)	630.5 (148-1071)	0.048*

Table 3. Anti-HBs titers of groups (*p<0.05)

	Group 1 (Control Group)	Group 2 (Paricalcitol Group)
Anti-HBs (First titers) (IU/L)	190.32 (20.18-1000)	187.89 (38.77-1000)
Anti-HBs (3.Month titers) (IU/L)	114.72 (13.68-1000)	175.27 (14.25-1000)
P Value	P=0.001*	P=0.209

Discussion

Recent advances in vitamin D biology have increased the interest of researchers and clinicians in this field. Vitamin D has not only the effect on the skeletal system but also has an impact on skeletal muscle, immune system cells, adipocytes, pancreas glands, and non-skeletal tissues been shown (12). 1.25 (OH)2 D3 directly affects the function of B and T lymphocytes by modulating the effect of the immune system, and also have an impact on antigen-presenting cells and dendritic cells through a change both the phenotype and function of the cells. The immunomodulatory effect of 1,25 (OH)2 D3 is generated by either direct action on nuclear transcription factors such as NF-AT and NF-B, or by VDR in promoter regions of cytokine genes (13). Zitt et al. (14), in their retrospective studies, found that patients with vitamin D levels below <10 ng / mL had worse hepatitis B seroconversion levels in patients with chronic kidney disease than those with higher vitamin D levels. Similar to previous study results, Grzegorzewska et al. (11) reported that 25 (OH)2 D3 levels were lower in patients who did not respond to the Hepatitis B vaccine compared to responders, but the differences between in groups were not statistically significant.

In the present study, the paricalcitol group was found to have a better seroconversion response than that the control group.

Uremic environment in chronic kidney disease is associated with increased incidence of malignancy, poor immunization response, and increased frequency of infections. It is widely accepted that uremic patients are immunosuppressive. The reason for this situation is unclear and probably multifactorial (15). Sharon et al. studied the effect of paricalcitol on the immune system cytokines such as IL-6, TNF-a, IL-2, and IFN-y and did not identify any effect on cytokines with used paricalcitol dose (1 mcg of paricalcitol). They also examined the hepatitis B seroconversion (defined as 10 U / mL titer increase) response rate to Hepatitis B booster dose and did not detect any differences in terms of response to booster dose (6 of 13 patients in paricalcitol; 9 of 13 patients in placebo). In this study, the dose of paricalcitol was kept low, due to the high risk of side effects (10). In our study, there was a significant difference in terms of Hepatitis B seroconversion between both groups. The relevant explain

of this differences may be that we had used too much more dose than used by Sharon et al.

It is known that immunological response to hepatitis B vaccine (HBVax) is decreased in patients with chronic kidney disease. A study, which examined the effect of the hepatitis B vaccine on subtypes of regulatory T (Treg) cells in hemodialysis patients and healthy volunteers were performed. Treg levels were measured immediately before vaccination and on days 3, 7, 10, and 14 after vaccination. Accordingly, the study results showed that a significant difference was not found between the two groups. The authors explain this situation by that the IL-10 levels, which have a Treg suppressor feature, were higher in HD patients than the other group (16). In contrast, Gonzalez-Mateo et al. found that the number of CD4 and CD8 T cells was higher in paricalcitol-treated mice than those not-treated. In the same study peritoneal fibrosis was regressed by paricalcitol treatment (17).

Unlike many other infections, vaccination in HBV infection plays an important role as a protective strategy (4). A study in HD patients, the seroconversion rate of HBV was detected at 84 %. The cause of the high seroconversion rate was explained by that a higher dose was used (40 mcg) instead of the traditional hepatitis B vaccine dose (20 mcg) (5). Various methods have been proposed to enhance the response to HBV immunization in chronic kidney patients. These substances used to increase the effectiveness of the vaccine are called adjuvant. For example, high thymopentin doses and Levamisole are such adjuvants used in clinical practice (4). In their meta-analysis, Fabrizi et al. (18) found that the vaccine response may be enhanced in hemodialysis patients when added GM-CSF as an adjuvant to the HBV vaccine. Similarly to these results, we think that paricalcitol may contribute positively to the hepatitis B vaccine response at the clinically used doses. It is clear that, prospective studies are needed to evaluate the paricalcitol to validity as an adjuvant.

Koeffler et al. (19) treated their 12 patients, who have the myelodysplastic syndrome, with high dose paricalcitol and examined patients for changes in blood counts. At the end of 4.5 months, neutrophil and platelet counts were not significantly different in 11 of 12 patients, but there was a significant increase in platelets in only 1 patient. However, the patient had also simultaneous mucormycosis infection which made it difficult to associate with paricalcitol. On the other hand, In the present study, peripheral blood cells such as white blood cell, neutrophil and platelet counts were observed to be significantly lower in the paricalcitol group compared to the control group. The main difference between the two studies was that ın the other study very high doses of the paricalcitol was used compared to the present study.

It is known that parathyroidectomy reverses the immunological disorders of patients with high PTH levels. Those patients are sensitive to infections due to immune dysfunction of a variety of reasons. PTH plays a role in the development of dysfunction in various cells of the immune system (20). High PTH levels may play a role in the pathogenesis of impaired immune response in dialysis patients. Yasunaga et al. revealed the positive effect of parathyroidectomy on the humoral immune system in patients with secondary hyperparathyroidism (21). As PTH levels were high in the paricalcitol group than control in our study this effect does not seem likely.

Conclusion

In conclusion, we have revealed the effect of paricalcitol on hepatitis B seroconversion in maintenance of HD patients. At hemodialysis, paricalcitol is a commonly used drug in the treatment of secondary hyperparathyroidism. However, side effects such as hypercalcemia and adynamic bone disease are the most encountered side effects limiting the ıts widely clinical use. To be able to use paricalcitol as an adjuvant for hepatitis B seroconversion, we think that both in vivo and in vitro molecular studies are needed to produce paricalcitol biosimilars that only interact in the immune system.

Conflict of Interest: The authors have no conflicts of interest to declare.

Ethical Approval: Ethical approval was taken from the local ethical committee (Date:28.03.2019, Decision no: 33).

Informed Consent: Informed consent was obtained from all patients

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Author's contributions: MD, Gİ, BY, AD; Study design, Data Collection and analyses **MD;** Revisions

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Comparison of the effects of sagittal versus transvers 25-gauge quincke needle insertion on post-dural puncture headache development

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Abstract

Objective: Post-dural puncture headache (PDPH) is one of the most important complications after spinal anesthesia. This study aimed to investigate the effect of the sagittal or transverse application of 25-gauge Quincke spinal needle on PDPH development in patients undergoing cesarean section.

Material and Methods: A total of 295 patients with a planned cesarean section between the ages of 18-40 years with an American Society of Anesthesiologists score of 1 or 2 were included in the study. For the spinal intervention, 25-gauge Quincke spinal needle was used in all patients. Patients were included in one of two groups according to the spinal needle cutting direction of the dura mater fibers as sagittal (parallel to dura mater fibers, Group S; n=145) or transverse group (perpendicular to dura mater fibers, Group T; n=150).

Results: PDPH developed in 27 (9.2%) patients. Patients in Group T had significant higher ratio of PDPH compared to patients in Group S (16% vs. 2.1%, p<0.001). Additionally, patients with PDPH had a significantly higher frequency of ⩾2 spinal puncture attempts compared to patients without PDPH (22.2% vs. 4.5%, p=0.003). Multivariate logistic regression analysis demonstrated that transverse needle direction (OR: 11.40, 95% CI: 2.73-34.71; p<0.001) and ⩾2 spinal puncture attempts (OR: 9.73, 95% CI: 3.13-41.55; p<0.001) and were independent predictors for PDPH development.

Conclusion: Transverse insertion of the 25-gauge Quincke needle into spinal cord fibers and repeated interventions are independently associated with the development of PDPH in cesarean section patients undergoing spinal anesthesia.

Key words: Spinal anesthesia, cesarean section, post-dural puncture headache, Quincke needle, cutting direction

Introduction

Spinal block is a frequently used regional anesthesia method in cesarean deliveries. The local anesthetic solution is administered to the subarachnoid space and sensory and motor block is created within the surgical field in this anesthesia method (1). The spinal needles used for this procedure are of different thicknesses and pointcuts. Post-dural puncture headache (PDPH) is one of the most important complications after spinal anesthesia, which is a discomforting complication for the physician and the patient (2). It is defined as a headache developing within 5 days of dural puncture, which cannot be explained by any other reason. Its incidence varies between 2%-40%, depending on the needle thickness, needle type, and patient population (3-5). Several mechanisms related to PDPH formation have been proposed. All of these theories implicate the basic pathology as cerebrospinal fluid (CSF) leakage after rupture of the dura mater due to the spinal intervention. As high CSF leakage occurs, intracranial pressure decreases, resulting in the dilation of the intracerebral arteries and veins. Also, CSF loss causes tension in intracranial pain-sensitive structures, leading to PDPH (2,6,7).

Previous studies demonstrated that different spinal needle thicknesses and tips (e.g. pencil point) affect PDPH development (8-12). Dura mater penetration with the spinal needle at different angles (sagittal or transverse) might also have effects on PDPH development (13,14). However, to the best of our knowledge, there is no study evaluating the effect of dura penetration angle of the 25-gauge Quincke spinal needle on the development of PDPH in patients undergoing cesarean section. The primary aim of our study was to investigate the effect of sagittal or transverse insertion of 25-gauge Quincke spinal needle on PDPH formation in patients undergoing cesarean section.

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Besides, the secondary aim of our study was to determine the effect of sagittal or transverse insertion of 25-gauge Quincke spinal needle on hemodynamic parameters including mean arterial pressure (MAP), heart rate (HR) and peripheral oxygen saturation (SpO2).

Material and Methods

Patient Selection

This randomized prospective study was initiated after the approval of the local ethics committee. The study protocol is also registered in a clinical trial registry (www.anzctr.org.au number, ACTRN12619000553178). Three-hundred patients with a planned cesarean section in Sanliurfa Research and Training Hospital between the ages of 18-40 years, with an American Society of Anesthesiologists (ASA) score of 1 or 2 were enrolled in the study. Emergency cases and patients with contraindications for spinal anesthesia (non-compliance with the intervention or refusal to consent, infection at the intervention site, hematological abnormalities, hemodynamically unstable patients, preeclampsia, and patients with a diagnosis of increased intracranial pressure or with similar symptomatology) were excluded. Patients were informed about the study procedures and their written informed consent was obtained. Five patients developed perioperative agitation requiring deep sedation, resulting in the exclusion of these patients from the study groups. Consequently, 295 patients were assessed in the study. The sealed envelope method was used for randomization.

Management of Anesthesia

A peripheral intravenous (iv) line was placed with a 20-gauge iv cannula and used for the preoperative administration of 10 ml/kg Ringer's lactate solution to all patients. No pharmacological premedication was used. Patients were monitored NIBP, ECG, and SpO2 in the operating theater. Spinal needle insertion (intervention) was performed in the sitting position according to the routine spinal anesthesia protocol. For the spinal intervention, a 25-gauge Quincke spinal needle was used in all patients. Patients were divided into two groups as sagittal insertion (parallel to the fibers of dura mater; Group S, n=145) or transverse insertion (perpendicular to dural fibers; Group T, n=150) regarding the dural cutting direction of the spinal needle. After the free flow of CSF was observed, two ml of 0.5% hyperbaric bupivacaine was administered intrathecally to both patient groups. After the intervention, the patients were placed in supine position and supported from the back and hip regions with 15 degrees left lateralization. Sensory block was determined with pinprick test and surgery was initiated when the block reached T4-T6 spinal level. Hypotension was defined as a $\geqslant$20% decrease in baseline mean arterial pressure (MAP) and 5 to 10 mg iv ephedrine was administered when detected, whereas bradycardia was defined as a heart rate (HR) below 45 beats per minute and iv atropine was administered at a dose of 0.015 mg/kg for HR correction.

Data Collection

Age, weight, height, body mass index (BMI), and preoperative hemoglobin levels along with previous spinal anesthesia and PDPH history of the patients were recorded. MAP, HR, and SpO2 values were obtained preoperatively and at 1 minute, 5 minutes, 10 minutes, and at 5-minute intervals thereafter following the intervention. Spinal intervention level (L3-4 or L4-5), the dural cutting direction of the spinal needle (sagittal or transverse), and the number of intervention attempts were recorded. Patients were contacted by the study investigators via telephone to determine the headache complaints one week following the cesarean section. The followed questions were used to diagnose the PDPH: the onset time, localization, and positional dependence of the headache. Patients with PDPH were evaluated and severity of headache was recorded according to the visual analog scale (VAS).

Statistical Analysis

Statistical analysis was performed with Statistical Package for Social Sciences (SPSS, version 23 for Windows; SPSS Inc. an IBM Company, Chicago, USA). Kolmogorov-Smirnov test was used to examine the normality of continuous variables. Continuous variables with a normal distribution were expressed as mean ± standard deviation (SD) and compared with Student's t-test. Categorical variables were expressed in numbers and percentages and compared by chi-squared test. Variables with a p-value of <0.1 were defined as variables possibly related with PDPH in univariate analysis. Multivariate logistic regression analysis was performed to determine the independent predictors of PDPH (presented as odds ratio [OR] with 95% confidence interval [CI]). A p-value of <0.05 was considered as statistically significant.

Results

A total of 295 pregnant women were included in this randomized prospective trial. The baseline characteristics of the study groups are presented in Table 1. There was no significant difference between the groups in terms of baseline characteristics. MAP, HR, and SpO2 values at each point of time during the procedure are listed in Table 2. They were also comparable in both groups.

The number of spinal puncture attempts is demonstrated in Table 3. Two or more spinal puncture attempts were performed in 18 patients (6.1%). The mean number of the spinal puncture attempts (1.1 $\pm$ 0.4 vs. 1.1 $\pm$ 0.3, p = 0.351) and patients with $\geqslant$2 spinal puncture attempts (6.9% vs. 5.3%, p = 0.575) were similar between Group S and Group T, respectively.

PDPH developed in 27 patients (9.2%): three patients (2.1%) in Group S and 24 patients (16%) in Group T. It was found that the incidence of PDPH was significantly lower in Group S compared to Group T (p < 0.001). There was no difference between the two groups in terms of VAS scores for headache and day of the PDPH onset (Table 4). The baseline and procedural characteristics of the patients according to the development of PDPH are shown in Table 5. Patients who developed PDPH had statistically significant higher frequency of $\geqslant$2 spinal puncture attempts compared to patients who did not develop PDPH

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(22.2% vs. 4.5%, p = 0.003). In addition to PDPH, the frequency of transverse needle direction was significantly higher in patients who developed PDPH (88.9% vs. 47.0%, p < 0.001). In univariate analysis, ⩾2 spinal puncture attempts and transverse needle direction were found to be associated with increased risk of PDPH development. Multivariate logistic regression analysis demonstrated that ⩾2 spinal puncture attempts (OR:9.73, 95% CI:3.13-41.55, p<0.001) and transverse needle direction (OR:11.40, 95% CI:2.73-34.71, p<0.001) were the independent predictors of the PDPH development (Table 6).

Table 1. Comparison of baseline characteristics of the study groups

	Group S (n = 145)	Group T (n = 150)	p value
Age, years	28.2 ± 5.8	28.6 ± 5.8	0.469
Body mass index, kg/m^2	30.2 ± 3.4	30.1 ± 2.8	0.796
ASA status, n (%)			0.656
I	97 (66.9)	105 (70.0)	
II	48 (33.1)	45 (30.0)	
Hemoglobin, g/dL	11.6 ± 1.5	12.7 ± 8.5	0.119

ASA: American Society of Anesthesiologists, S: sagittal, T: transvers

Table2. Comparison of mean arterial pressure, heart rate and peripheral oxygen saturation of the study groups

Time	Group S (n = 145)			Group T (n = 150)					
	MAP (mmHg)	HR (bpm)	SpO_2 (%)	MAP (mmHg)	HR (bpm)	SpO_2 (%)	p value for MAP	p value for HR	p value for SpO_2
0 min.	95 ± 13	104 ± 19	99 ± 1	93 ± 11	106 ± 18	99 ± 3	0.114	0.452	0.518
1 min.	87 ± 14	106 ± 21	99 ± 1	85 ± 13	106 ± 15	99 ± 2	0.176	0.860	0.184
5 min.	79 ± 15	105 ± 19	99 ± 1	76 ± 11	106 ± 19	98 ± 4	0.116	0.719	0.597
10 min.	75 ± 13	104 ± 18	99 ± 1	77 ± 20	107 ± 18	99 ± 1	0.415	0.088	0.118
15 min.	78 ± 13	103 ± 16	99 ± 1	79 ± 10	104 ± 14	99 ± 1	0.436	0.539	0.118
20 min.	79 ± 11	101 ± 16	99 ± 1	81 ± 10	99 ± 12	99 ± 1	0.065	0.269	0.130
25 min.	80 ± 11	104 ± 13	99 ± 1	80 ± 11	99 ± 15	99 ± 1	0.828	0.082	0.353

Bpm: beat per minute, Min: minute, MAP: mean arterial pressure, HR: heart rate, SpO2: peripheral oxygen saturation, S: sagittal, T: transvers

Table 3. Comparison of the number of the dural puncture attempts of the study groups

	Group S (n = 145)	Group T (n = 150)	p value
Mean number of the dural puncture attempts	1.1 ± 0.4	1.1 ± 0.3	0.351
Number of attempts, n (%)			
1 attempt	135 (93.1)	142 (94.7)	0.575
≥ 2 attempts	10 (6.9)	8 (5.3)	

S: sagittal, T: transvers

Table 4. Comparison of the incidence and severity of postdural puncture headache of the study groups

	Group S	Group T	p value
PDPH, n (%)	3 (2.1)	24 (16)	< 0.001
VAS	6.7 ± 1.5	7.2 ± 1.0	0.431
Day of PDPH onset			
1	2	14	
2	1	8	0.680
3	0	2	

PDPH: postdural puncture headache, VAS: visual analog scale

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Table 5. Comparison of baseline and procedural characteristics of the study groups according to the presence of postdural puncture headache

	PDPH [+] (n = 27)	PDPH [-] (n = 268)	p value
Age, years	29.9 ± 6.4	28.3 ± 5.7	0.151
Body mass index, kg/m^2	30.4 ± 2.8	30.1 ± 3.1	0.796
ASA status, n (%)			
I	19 (70.4)	183 (68.3)	0.824
II	8 (29.6)	85 (31.7)	
Mean number of puncture attempts	1.3 ± 0.5	1.1 ± 0.3	0.063
Number of attempts, n (%)			
1	21 (77.8)	256 (95.5)	0.003
≥ 2	6 (22.2)	12 (4.5)	
Spinal anesthesia interval, n (%)			
L_3-L_4	17 (63)	179 (66.8)	0.688
L_4-L_5	10 (37)	89 (33.2)	
Previous history of spinal anesthesia, n (%)	18 (66.7)	179 (66.8)	0.990
Previous history of PDPH, n (%)	4 (14.8)	33 (12.3)	0.759
Quincke needle direction, n (%)			
Sagittal	3 (11.1)	142 (53)	<0.001
Transverse	24 (88.9)	126 (47)	

ASA: American Society of Anesthesiologists, PDPH : postdural puncture headache

Discussion

In this study, we investigated the effects of the transverse or sagittal use of 25-gauge Quincke spinal needle insertion on PDPH development in patients undergoing cesarean section. The main finding of the study was that the 25-gauge Quincke spinal needle caused a lower rate of PDPH with the sagittal approach when compared to the transverse approach.

Spinal block is a commonly preferred anesthesia method in cesarean operations due to its fast and effective pain relief feature (16). Although this anesthesia method has many advantages, PDPH stands an important complication (2). PDPH incidence varies between 2% to 40% in relation to needle thickness, needle type, and patient group (3-5). Similar to these findings, PDPH developed in 27 patients (9.2%) in our study.

Several studies were conducted to determine the factors that may affect PDPH development with findings implicating that changes in needle technology have a major effect on PDPH development. In particular, thinner spinal needles and needles with a pencil-point tip have proven to be associated with lower PDPH development (8-12). However, Quincke needles are relatively cheaper and therefore more commonly used in spinal anesthesia. It causes a larger hole formation in dura mater due to their design, leading to more CSF leakage and more frequent PDPH formation (17). To eliminate this disadvantage of Quincke needles, sagittal applications of the needle are emphasized and it is stated that PDPH development risk may be alleviated with sagittal insertion (13,14).

Flaatten et al. (13) examined the effect of sagittal and transverse applications of 27-gauge Quincke spinal needle on PDPH formation in 212 patients undergoing minor non-obstetric surgery.

The frequency of PDPH development with transverse insertion was significantly higher (22.6%) than that of sagittal insertion (3.8%). Salik et al. (18) examined the effect of sagittal versus transverse application of 26-gauge Quincke spinal needle on PDPH formation in 100 patients undergoing obstetric surgery. They found a trend for a higher incidence of PDPH development with transverse administration (14%) when compared with sagittal administration (8%). This finding of a statistically insignificant trend may be explained by the small number of patients included in the study of Salik et al (18). Although the relationship between the insertion directions of 27- and 26-gauge Quincke spinal needles and PDPH development has been investigated, to our knowledge, there is no study examining the relationship between the 25-gauge Quincke spinal needle direction and the frequency of PDPH development in patients undergoing obstetric surgery.

In our study, the effect of the sagittal and transverse application of 25-gauge Quincke needle on the formation of PDPH in patients undergoing cesarean section was investigated. Supporting the findings of Flaatten et al., the incidence of PDPH following transverse administration of the 25-gauge Quincke spinal needle was significantly higher in our study. While Flaatten et al. did not perform a regression analysis to determine whether the needle direction was an independent factor for PDPH development, we performed a multivariate logistic regression analysis to determine whether there was an independent relationship between spinal needle direction and PDPH development. Indeed, transverse needle direction was an independently associated factor, increasing the risk for PDPH development by 11.4 times. The possible mechanism between transverse needle direction and increased risk of PDPH can be explained with a higher

number of dural fiber cut, leading to increased CSF leak and higher chance for PDPH formation. Supporting this theory, in vitro experiments with 22-gauge Quincke needle found increased CSF leakage with transverse placement when compared with parallel needle placement (15.5 mL/min vs. 11.9 mL/min) (19). When all these findings are evaluated together, it can be concluded that the needle should be applied with a sagittal approach to reduce the risk of PDPH development in patients with a plan for 25-gauge Quincke spinal needle use.

Other important factors that may play a role in the PDPH development are patient position, physician experience, and the number of puncture attempts for successful dural penetration. The effect of patient position in spinal anesthesia is still controversial. Some studies showed that the lateral decubitus position was more effective compared with sitting position (20-22), whereas the other studies showed that sitting position was better than lateral decubitus (23,24). The advantages of the sitting position may be explained as follows: sitting position facilitates the identification of the midline structure and allows better spinal flexion (23, 25). In addition to these advantages, our experiences with sitting position is more. We, therefore, preferred sitting position preferred in our study. A recent study also demonstrated that patient position during spinal anesthesia does not affect PDPH incidence and one of them may be preferred according to the experience of anesthetists (26). However, it should not be forgotten that there are some situations in which the lateral decubitus position should be preferred. On the other hand, it has been reported that the incidence of PDPH is higher in younger patients aged between 25 and 40 years compared to older patients, and the incidence of PDPH decreases with physician experience (27,28). Our study consisted of a young population aged between 18 and 40 years in whom PDPH was common, but the incidence of PDPH development was found to be relatively low. This finding can be explained by the fact that the practitioning physician in our study had 10 years of experience with spinal anesthesia. Finally, it has been shown that, the increased number of attempts for dural puncture may increase the incidence of PDPH (29). In our study, the number of patients who underwent two or more attempts for dural puncture was only 18 (6.1%). The multivariate analysis showed that two or more dural puncture attempts had an independent effect on PDPH development. These findings show that, in addition to the direction of spinal needle bevel, the number of attempts to perform dural puncture also has a significant effect on PDPH development.

Our study had some limitations. Patients with primary headache syndrome may have a higher incidence of PDPH. However, we did not evaluate the frequency of migraine/tension type headache history in this study. It could be useful to evaluate the primary headache syndrome in this study. Also, we did not exclude patients with the previous history of PDPH. It may be better to exclude these patients from the study. Nevertheless, we found no significant difference between patients with and without PDPH in terms of the previous history of PDPH. Also, the previous history of PDPH was not an independent predictor of PDPH development. We think that this information may provide an additional contributions to our study.

Conclusion

As a conclusion, transverse insertion of the spinal needle through the spinal cord fibers and repeated interventions are independently associated with PDPH development in patients undergoing spinal anesthesia for cesarean section. Further clinical studies are needed on this subject.

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Conflict of interest: The authors declare that they have no conflict of interest. The study was authorized by the Harran University Medical Faculty local ethics committee

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The relationship between anxiety and satisfaction level in women who had cesarean section with spinal or general anesthesia

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Abstract

Objective: Although regional anesthesia is frequently used in cesarean section, patient satisfaction and comfort can change with the anesthesia method preference. Our aim is to determine the level of anesthesia satisfaction in women with cesarean surgery with Spinal (SA) and General anesthesia (GA) and to examine its relationship with anxiety level.

Material and Methods: In this prospective observational cohort study, 144 pregnant women who were admitted to the Obstetrics and Gynecology Clinic between January 2019 and April 2019 were included. Demographic information of the pregnant women including age, height, weight, gestational history and education level were recorded. Hospital Anxiety and Depression Scale (HADS), preoperative anxiety levels and which anesthesia method they preferred were questioned and recorded.

Results: 72 SA and 72 GA patients were included in the study. Age, BMI (Body mass index), obstetric history, preoperative HADS were similar in both groups ($p > 0.05$). Patients with SA were significantly higher satisfaction level than those who had cesarean with GA ($p = 0.000$). Anxiety level during cesarean was correlated positively with preoperative HADS ($p = 0.001$, $p = 0.005$, respectively). First analgesia requirement didn't differ in both group ($p=0.409$).

Conclusion: The satisfaction score founded higher in those who were cesarean with SA. Evaluating anxiety levels of patients and providing support before surgery will increase postoperative comfort.

Key words: Anesthesia, Anxiety, Cesarean, Satisfaction, Spinal

Introduction

Caesarean is the most common obstetric operation in the world. During the procedure, the health and satisfaction of the mother and baby and pain management in the postoperative period show a close relationship with the selected anesthesia technique. The choice of anesthesia for any cesarean section varies depending on many factors about urgency of the surgery and the desire of the anesthesiologist, surgeon and the patient (1). Anesthesiologists should always choose the method that is the safest and most comfortable for the mother, the least depressant for the newborn and the most suitable working conditions for the obstetrician. For this reason, American Association of Anesthesiologists prioritizes regional anesthesia instead of general anesthesia (2).

Spinal anesthesia (SA) is the most used type of regional anesthesia during cesarean.

Faster, bilateral, small doses of drug compared to epidural anesthesia are minimally risky for maternal toxicity and fetal drug transfer is almost non-existent. Epidural anesthesia is less preferred due to its slower onset and lack of numbness at sacral levels, higher doses of medication, and prolonged exposure to fetal medication. Besides, regional anesthesia has been shown to result in cardiovascular collapse or seizures, especially in patients with anxiety (3). General anesthesia (GA) is not preferred in the first place due to the drug transfer to the fetus, relaxation and bleeding in the uterus, and changes in drug distribution due to physiological changes in pregnancy and an increase in cardiac output. Despite this, patient may prefer general anesthesia instead of regional anesthesia due to complications occurring during or after anesthesia, as well as conditions such as discomfort from the procedure, position and neuroaxial block, need for urgent operation, and high anxiety level.

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In this case, the anesthesiologist should determine the anesthesia method by taking into account every condition (1).

The level of anxiety among pregnant women is very variable between 11-80% (4,5). Previous studies indicated that surgery has negative effects on pregnant women, and also preoperative anxiety has been shown to have a negative effect on anesthesia, surgery, postoperative recovery and perception of pain (6,7).

A good anesthetic tecnic should ensure maternal comfort, fetal and newborn well-being and postoperative pain management (8). Although regional anesthesia has been increased in the cesarean operation in recent years, patient satisfaction and comfort differ in studies (9,10).

However patient satisfaction is a subjective criterion, it is the only one method that can be feedback from the patient for health services. Our aim in this study is to determine the level of anesthesia satisfaction in patients with cesarean surgery with SA and GA and to examine the relationship of patients with anxiety level.

Material and Methods

Setting and Study Population

For this prospective observational cohort study, 186 pregnant women who applied to our Hospital's Obstetrics and Gynecology Clinic between January 2019 and April 2019 for elective cesarian section were included in the study.

Inclusion criteria: women aged 18-40, who completed 37 weeks, elective cesarean and planned to participate in the study. Among the exclusion criteria; having a psychological disease, having emergency access to cesarean, presence of chronic disease (hypertension, diabetes, rheumatological disease), gestational hypertension, preeclampsia, eclampsia, gestational diabetes, having previously had abdominal operation, morbid obesity (Body mass index (BMI) ⩾40 kg / m2) and not request to participate in the study.

Demographic information of the pregnant women including age, height, weight, gestational history and education level were recorded. The BMI was computed as weight in kilograms divided by the height squared (m2). In the last control before cesarean day, Hospital Anxiety and Depression Scale (HADS) was applied to the patients. HADS consisted of 14 questions. The first 7 questions were about anxiety, the next 7 were about depression. Each question was scored between 0-3, over 10 values were considered significant for anxiety and values over 7 were considered significant for depression (5).

Secondly, preoperative anxiety levels were questioned. For the level of anxiety, they were asked to give a number between 0-10 and noted. Afterwards, which anesthesia method they preferred was asked.

Rapid sequence induction with ropivacaine and fentanyl for spinal anesthesia, thiopental and succinylcholine for general anesthesia followed by inhalation of sevoflurane and nitrogen oxide and oxygen in the anesthesia department.

Postoperative analgesia, nonsteroidal anti-inflammatory (NSAI) and / or paracetamol were preferred. At the postoperative 24th hour, the degree of satisfaction from anesthesia and the time of first analgesia were questioned. Four parameters were determined as bad, moderate, good and very good for the levels of satisfaction with anesthesia. Finally, a total of 144 patients with 72 spinal anesthesia, 72 general anesthesia were included in the study.

Ethics statements

Approval of Karabuk University Clinical Researches Ethics Committee (approval date: 04.01.19, decision no: 2019-14/4) was obtained prior to the study. All patients were informed about the study objectives in details and gave verbal and written consent. The study was conducted in accordance with the Declaration of Helsinki.

Statistical analysis

Data obtained in the study were statistically analyzed using SPSS 23.0 (Statistical Package for Social Sciences, SPSS Inc., Chicago, IL, USA) package software. Kolmogornow-Smirnov test was used to determine whether the data were suitable for normal distribution.

Student’s t-test was employed to compare normally distributed data, and the Mann–Whitney U-test was used for data that were not distributed normally. The Chi-square test was used to determine for categorical variables. Pearson correlation analysis was used to determine the relationship between HADS score and anxiety. P <0.05 values were considered as statistically significant.

Results

186 elective cesarean patients were evaluated during the study period. 42 patients were excluded from the study because of didn’t meet the inclusion criteria or were removed from follow-up. Finally, a total of 144 patients who were cesarean with 72 spinal anesthesia and 72 general anesthesia were included in the study.

The average age of the study group was 31.54 ± 4.92. Most of them (82.4%) were housewife and secondary school education (70.42%). Age, BMI, obstetric history, HADS levels of patients who were cesarean with SA and GA were similar in both groups (p> 0.05) (Table 1).

Preoperative anxiety level and first analgesia requirement were similar in both groups (p=0.37, p=0.409). Satisfaction level in cesarean patients with SA was significantly higher than those with GA group (p = 0.000) (Table 2, Table 3). According to the correlation analysis, the level of anxiety during cesarean was positively correlated with the level of HADS (p = 0.001, p = 0.005) (Table 4).

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Table 1. Demographic data and Hospital Anxiety and Depression Scale of patients with cesarean section with spinal and general anesthesia

	Spinal anesthesia (n=72)	General anesthesia (n=72)	P values
Age (years)	31.72± 4.51	31.37±5.17	0.66
BMI (kg/m^2)	28.64±3.99	28.74±4.10	0.88
Gravida (n)	2.81±1.05	2.64±0.91	0.28
Parity (n)	1.40±0.64	1.40±0.63	0.75
Live birth (n)	1.35±0.59	1.34±0.60	0.86
Abort (n)	0.4±0.85	0.27±0.60	0.29
Anxiety level *(HADS-A)*	5.2±2.27	5.34±2.4	0.79
Depression level *(HADS-D)*	5.45±2.42	5.77±2.46	0.43

BMI: Body mass index, HADS: Hospital Anxiety and Depression Scale, Mean and standart deviation, p<0.05 significant.

Table 2. Relationship between anxiety, satisfaction level, and first analgesia demand in patients with spinal and general anesthesia group

	Spinal anesthesia (n=72)	Genel anesthesia (n=72)	P values
Preoperatif anxiety level	5.31±2.21	5.65±2.37	0.37
Satisfaction level	2.56±0.69	1.92±0.78	0.000
First analgesia requirement (minutes)	90.07±49.50	83.02±50.6	0.409

Mean and standart deviation, p<0.05 significant

Table 3. Satisfaction levels in spinal and general anesthesia group

	Spinal anesthesia (n=72)	General anesthesia (n=72)	P values
Satisfaction level	(n,%)	(n,%)	0.000
0	1(%1.4)	4 (%5.3)	
1	3 (%4.3)	14 (%18.7)	
2	23 (%33.3)	41 (%57.7)	
3	40 (%58)	16 (%21.3)	
4	2(%2.9)	0(%0)	

p<0.05 significant.

Table 4. Preoperative anxiety and first analgesia requirement relation of the study population with Hospital State Anxiety Score

	Preoperatif Anxiety level	First analgesia requirement
Anxiety level *(HADS-A)*	R:0.262	R:-0.74
	P:0.001	P:0.389
Depression level *(HADS-D)*	R:0.235	R:-0.061
	P:0.005	P:0.474

HADS: Hospital Anxiety and Depression Scale, Pearson correlation analysis, p<0.05 significant.

Discussion

In this study, we found that the level of satisfaction in patients who were cesarean with SA was significantly higher than GA. We also found that the preoperative HADS correlated with the anxiety score during cesarean. However, we did not find any significant difference between the applied anesthesia techniques and the need for first analgesia requirement.

In previous studies, there is no definitive evidence about which method of anesthesia is more convenient. Two types of regional anesthesia, spinal and epidural, are often used in cesarean operation. The advantages are a being awake mother at birth, minimal risk of neonatal depression (11), as well as less risk of deep vein thrombosis, pulmonary embolism, kidney failure, postoperative pneumonia and myocardial infarction. For these reasons, postoperative morbidity and mortality were observed lower than general anesthesia (12). Spinal anesthesia is the most preferred method in the regional anesthesia. This is the process of injecting some local anesthetic into the cerebrospinal fluid. It was reported that the need for postoperative analgesia, length of hospital stay, cardiac problems, and rates of venous thromboembolism was lower in SA than GA (13). However, in some studies, spinal anesthesia has been associated with postoperative back pain, dissatisfaction, and rejection (14).

On the other hand, known disadvantages of general anesthesia for cesarean section are difficult intubation due to pregnancy, delayed gastric emptying, possible awareness before surgery and a more depressed baby. However, general anesthesia is the fastest technique required in emergencies cesarean such as severe bleeding, uterine rupture, placental abruption, placenta previa, fetal distress, and cord prolapse. As a result, the anesthesia method to be selected during cesarean may vary depending on multiple factors including fetus, mother, obstetrician and anesthesiologist. The anesthestist should select suitable type of anesthesia for providing health and satisfaction of the mother and baby.

In our study, although the level of HADS was similar in the SA and GA groups, we found that the satisfaction rate in the spinal anesthesia group was significantly higher than the general anesthesia group. Satisfaction varies depending on the patients' expectations, physical, mental health and cultural position. The relationship between anesthesia technique and patient satisfaction differs in studies. Similar to our study, Siddiqi et al. found that the satisfaction was higher in SA than GA (9). Fassoulaki et al performed spinal and general anesthesia during the cesarean operation at different times in the same patients. Accordingly, spinal anesthesia was found to be associated with lower Visual analog scale (VAS) score, less hospital stay, and higher satisfaction score than general anesthesia (15). Dharmalingam et al. reported that spinal anesthesia satisfaction as 97%. The causes of dissatisfaction were insufficient anesthesia or spinal anesthesia failure and the rate of rejection for spinal anesthesia in the future was 8% (16). Kumar et al. reported that patients were more satisfied with SA regardless of anxiety (17). Belay et al. stated, in a cross-sectional study, the satisfaction of patients with SA was 62% and 82% of the patients declared that they would prefer SA again in the next cesarean. The patients who refused spinal anesthesia responded as fear of post-spinal headache, back pain, unconsciousness during operation, and infant voice. Belay founded that the full statement of the anesthetist about the procedure to be performed is very important for the patient's decision (18). In one study where they included women who had cesarean section under general anesthesia within 5 years and scheduled to have elective cesarean section under spinal anesthesia questioned the anesthesia satisfaction rates. They founded satisfaction was 68% in those who were cesarean with SA and 24.4% in those who were cesarean with GA. However, in this study, there was no difference between anesthesia techniques and anxiety level (19). On the contrary, according to a Cohrane review involving 29 studies in 2012, in terms of satisfaction with the anesthetic technique, more women who underwent general anesthesia compared to the group undergoing epidural and spinal anesthesia stated that they would use the same technique for CS in their next pregnancy. Also, in this review, there was no significant difference in the first and fifth minutes Apgar score of $\leqslant 5$ and neonatal resuscitation with oxygen (10). Although there are differences between studies, it is seen that SA is higher satisfaction score than GA. Moreover, mothers experiences in their first cesarean also affect their other births. In a prospective study, 96% of patients who had cesarean with regional anesthesia were shown to prefer regional anesthesia in their next cesarean section, 3% were unstable and 1% preferred general anesthesia (20). In contrast, in a retrospective study, only 20% of patients preferred general anesthesia and stated that the biggest reason for this was maternal desire (21).

In this study, it was observed that the anxiety level during surgery was high in patients with higher HADS. Similarly, in the previous studies, the level of anxiety before elective cesarean was quite high and they reported that this was related to unmet expectations (22). Jlala et al reported that being awake during cesarean was a stress factor in women, and haven't working the regional block or needle phobia was defined as the main reason for not selecting regional anesthesia (23). Maheshwari et al. founded high anxiety as 72% of patients with elective cesarean section. This difference was significant in those who were <25 years of age, working women, nulliparous, and those with previous anesthesia was GA. They explained the reason for fear of anxiety or surgery during pregnancy (24). The biggest anxiety factor seen in the studies was the fear that something would go wrong during birth (25), fear of birth (7) and cesarean, that is, the possibility of having surgery (26). There was no decrease in anxiety in the study, where video cesarean narration or information was provided by the healthcare worker to reduce the anxiety of pre-cesarean pregnants (19,27). But Kumar et al. showed that communicating during surgery or seeing the baby reduced the level of anxiety in patients (19). It is seen that women who experience anxiety during their pregnancy also have high stress during cesarean. This can change patients' anesthesia preferences and even affect postoperative comfort and indirect pain perception and breastfeeding status.

In this study, the first analgesia requirement was longer in patients with cesarean with SA than GA, but no significant difference was observed between them. Inal et al. found the severity of pain higher in the first 12 hours in patients with general anesthesia and higher preoperative anxiety score. However, there was no difference in terms of analgesic need in both groups (28). Gorkem et al. found that high anxiety score was an independent risk factor for post-cesarean painkiller use (29). In this study, preoperative anxiety scores were similar in both groups, so there was no difference in terms of pain relief needs. High preoperative anxiety may affect patients' anesthetic technical selection in relation to the level of intraoperative anxiety. Patients who are mostly afraid of surgery during cesarean are sometimes anxious about anesthesia technique. Often, this anxiety in patients is ignored. Anxiety level of preoperative pregnants is very closely related to satisfaction after surgery. Fear of feeling surgery is often to prevent the choice of spinal anesthesia. The expectations of the patients are also important in determining the anesthesia technique they will meet.

Limitations

The prospective planning and the randomization between the groups are strengths in this study. But it was conducted in a single center and included a relatively small number of

patients. In addition, it evaluates the satisfaction levels of patients from spinal and general anesthesia in the short term. With long-term prospective studies, patient satisfaction and preferences can be revealed more clearly.

Conclusion

In this study, the satisfaction level was significantly higher in patients with cesarean with spinal anesthesia compared to general anesthesia. Preoperative anxiety affected the anesthesia selection of the patients. Providing counseling about the procedure and the process before cesarean section will decrease the anxiety during and after the surgery and choosing a personal anesthesia will increase the comfort and satisfaction of the patients.

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Is early-stage breast cancer risk for marital-dissolution?

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Abstract

Objective: The effect of breast cancer on family life and marital status is one of the issues to investigate. Our aim in this study is to evaluate the frequency of divorce of breast cancer survivors and to investigate the demographic, disease, and treatment-related factors that may affect the divorce.

Material and Methods: We performed this cross-sectional study between January 2020 and May 2020. Inclusion criteria were; women who were married at the time of breast cancer diagnosis, older than 18 years of age, and completed at least 6 months after breast cancer surgery and adjuvant chemotherapy/radiotherapy. The primary aim of this study was to find the marital dissolution rate of the patients after early-stage breast cancer diagnosis and adjuvant treatment. The secondary aim was to investigate the demographics and treatment-related factors affecting the marital status of breast cancer survivors.

Results: The median age of 583 women included in the study was 47 (28-72). The median time to stay married was 291.0 months (min-max: 32.5-654.6). The most preferred surgical method in these patients was total mastectomy (n = 364, 62.4%). Adjuvant chemotherapy was applied to 505 (86.6%) patients, adjuvant endocrine therapy to 499 (85.6%) patients, and adjuvant radiotherapy to 460 (78.9%) patients. 21 (3.6%) patients divorced after diagnosis. In univariate analysis, surgery type, adjuvant chemotherapy, adjuvant radiotherapy, and adjuvant endocrine therapy were found to not affect the divorce.

Conclusion: In our study, it was observed that the frequency of divorce was higher in breast cancer survivors than the general population, and breast surgery type and adjuvant treatments did not cause an increase in the risk of divorce.

Keywords: Marital dissolution, breast cancer, divorce, chemotherapy

Introduction

Breast cancer is the most common cancer in women. It is in fourth place in cancer-related deaths (1). Adjuvant treatments applied in early-stage breast cancer led to a reduction in breast cancer-related mortality (2, 3). 25% of cancer survivors among women in the USA are breast cancer survivors (4).

Successes in breast cancer treatment ensure that these patients survive longer (2, 3). The diagnosis and treatment process of breast cancer affects breast cancer survivors both physically and psychosocially (5). Some of the difficulties that breast cancer survivors facing in their daily lives are continuing working life, restrictions in social life, difficulties in childcare, and problems with their spouses (6-16).

The effect of breast cancer on family life and marital status is one of the issues to investigate. Is the promise of 'in sickness and in illness' working for breast cancer survivors?

Our aim in this study is to evaluate the frequency of divorce of breast cancer survivors and to investigate the demographic, disease, and treatment-related factors that may affect the divorce.

Materials and Methods

Study design and setting

We performed this cross-sectional study between January 2020 and May 2020 at the University of Health Sciences, Ankara Oncology Research and Training Hospital, Department of Medical Oncology. We obtained local ethical committee approval before the study.

Our hospital is a tertiary-care comprehensive oncology center that admits an average of 400 solid malignancy patients per day to the medical oncology outpatient clinics. Approximately one-third of these patients are cancer survivors.

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All patients diagnosed with breast cancer who applied to our out-patient clinic between January 2020 and May 2020 were evaluated for eligibility for the study. Inclusion criteria were; women who were married at the time of breast cancer diagnosis, older than 18 years of age and completed at least 6 months after breast cancer surgery and adjuvant chemotherapy/radiotherapy. Patients in the metastatic stage, those who continued chemotherapy or radiotherapy were excluded. Patients who received adjuvant endocrine therapy were included in the study.

Eligible patients were informed in detail about the study. Informed consent forms were given to those wishing to participate in the study, and sufficient time was given to read. A questionnaire was conducted with face-to-face interviews in a separate room by the oncologist and the patients who approved to participate in the study. The medical records of the patients regarding breast cancer were accessed through the manual files and electronic medical record system. Age, education, employment status, marital status, parental status before and after the breast cancer diagnosis and the stage of cancer, type of breast cancer surgery, adjuvant chemotherapy, radiotherapy, and endocrine therapy were recorded.

The primary aim of this study was to find the marital dissolution rate of the patients after early-stage breast cancer diagnosis and adjuvant treatment. The secondary aim was to investigate the demographics and treatment-related factors affecting the marital status of breast cancer survivors.

Statistical analysis

The data were evaluated by the IBM Statistical Package for Social Sciences (SPSS®) v.21 (IBM Inc.; Armonk, NY, USA).

Married time is defined as the duration from the date of marriage to the date of interview or divorce. Follow-up time is defined as the duration from breast cancer diagnosis to the date of the interview.

The association between categorical variables and divorce was evaluated by univariate analysis. The Odds Ratios (ORs) with 95% confidence intervals (CIs) were calculated for comparing marital dissolution risk. $p<0.05$ was considered as statistically significant level.

Results

2912 women with breast cancer who applied to the outpatient clinic were evaluated for eligibility for the study. Of the 782 patients who met the inclusion criteria, 702 accepted to be included in the study. Of the patients who completed the face-to-face questionnaire, 583 patients who were married during breast cancer diagnosis were analyzed.

The median age of 583 women included in the study was 47 (28-72). 353 (60.5%) of these patients were primary school graduates and 370 (63.5%) were not working. 469 (80.4%) patients lived in the city center. Mean time to stay married was 291.0 months (min-max: 32.5-654.6). 540 (92.6%) of the patients had at least one child. Patient characteristics are shown in Table 1.

Table 1. Patient characteristics

	n: 583	%
Age (years)		
Median (range)	47 (28-72)	
Place of residence		
City center	469	80.4
District	87	14.9
Village	27	4.6
Education level		
Illiterate	3	0.5
Primary	353	60.5
Secondary	117	20.1
Higher	110	18.9
Smoking status		
Smoker	69	11.8
Non-smoker	514	88.2
Stage of breast cancer		
I	102	17.5
II	290	49.7
III	191	32.7
Type of surgery		
Lumpectomy	210	36.0
Mastectomy	373	63.9
Adjuvant treatment		
Chemotherapy	505	86.6
Radiotherapy	460	78.9
Endocrine therapy	499	85.6

Table 2. Univariate analysis of the patients' characteristics for marital dissolution risk

Characteristics	OR (95% CI)	*P*
Age (years)	0.93 (0.92-1.05)	0.425
Education level		
Primary education	Ref	
Secondary education	0.61 (0.31-1.35)	0.198
Higher education	0.65 (0.14-0.49)	0.211
Working status		
Unemployed	Ref	
Employee	0.96 (0.46-1.91)	0.651
Having children	1.16 (0.61-2.11)	0.672
Surgical method		
Total mastectomy	Ref	
Breast-conserving surgery	0.68 (0.45-0.86)	0.22
Adjuvant chemotherapy	0.89 (0.68-1.42)	0.511
Adjuvant radiotherapy	0.86 (0.65-1.39)	0.482
Adjuvant hormone therapy	0.85 (0.66-1.25)	0.475

The median follow-up time of the group was 41.6 (11.7-251.8) months. The most preferred surgical method in these patients was total mastectomy (n = 364, 62.4%). Adjuvant chemotherapy was applied to 505 (86.6%) patients, adjuvant endocrine therapy to 499 (85.6%) patients, and adjuvant radiotherapy to 460 (78.9%) patients.

Of the 583 patients who were married before breast cancer diagnosis, 21 (3.6%) of them divorced after diagnosis. While 18 (85.7%) of divorced patients thought that breast

cancer caused the divorce, 12 of them (57.1%) stated that they wanted to divorce.

In univariate analysis, surgery type, adjuvant chemotherapy, adjuvant radiotherapy and adjuvant endocrine therapy were found to not affect the divorce. It was observed that age, having children, educational status, and working status did not have any relation with divorce, either (Table 2).

Discussion

Aim of this study was to evaluate the divorce rates in breast cancer survivors and to evaluate the factors that may have an impact on divorce. As a result of our study, it has been observed that surgical methods and adjuvant treatments applied for breast cancer treatment do not increase the risk of divorce.

Studies investigating the relationship between cancer diagnosis and divorce generally consisted of heterogeneous patient groups, which include all types of cancer. In the population-based study conducted in the Danish population, no difference was found between the survivors other than cervical cancer and the general population in terms of divorce risk (17). Similarly, in another study conducted on approximately 1.5 million people in Norway, it was observed that cancer types other than testicular and cervical cancer did not affect the divorce (18). Unlike these studies, it has been reported that the risk of divorce is 25% higher in women with breast cancer in Sweden (19). Unlike the other two (17, 18) studies, in this registered-based study, data on variables that may affect divorces such as having children and comorbidity are missing (19).

While in the studies we have mentioned so far, all cancer groups have been included, the first study to investigate the frequency of divorce only in patients with breast cancer is the study of Dorval et al. In this study, the frequency of divorce was compared with the general population in patients with nonmetastatic breast cancer, and no difference was observed in the frequency of divorce (20). In a Finland study concluded in 2015, the risk of divorce for only early-stage breast cancer patients was investigated. In this prospective study of approximately 135,000 volunteer women, it was found that the diagnosis of early-stage breast cancer does not pose a risk for divorce (7).

According to the latest data of Turkey Statistics Institution, the crude divorce rate is 0.159% (21). This ratio was 3.6% in our study population of breast cancer survivors. Although the indirect comparison is not correct, the divorce rate in breast cancer survivors seemed higher than the general population. While none of the studies mentioned earlier, other than the Swedish records, there was no increase in the risk of divorce in breast cancer survivors, our study showed a higher divorce rate than the general population. The fact that our study is single-centered and does not represent patients living in all regions of our country may have caused this difference. Also, due to cultural differences, psychosocial changes caused by breast cancer may be different from other countries.

Six different types of cancer survivors were included in a large cross-sectional study in the US. As a result of this study, it was observed that unemployment (or not working) and low-income levels increase the risk of divorce in female cancer survivors (22). Neither type of breast surgery nor adjuvant treatments were associated with marital dissolution in the Finnish population (7). In our study, neither patient characteristics nor surgical or adjuvant treatment modalities were directly related to the risk of divorce.

One of the limitations of our study was its cross-sectional and single-centered design. Therefore, we cannot generalize our results to all breast cancer survivors. Another limitation was that we did not have data on variables such as depression and quality of life, which are thought to have an impact on divorce.

Conclusion

In our study, it was observed that the frequency of divorce was higher in breast cancer survivors than the general population, and breast surgery type and adjuvant treatments did not cause an increase in the risk of divorce.

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Conflict of interest: The authors declare that they have no conflict of interest.

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Factors affecting general or regional anesthesia preference in patients with elective surgery

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Abstract

Objective: This study aimed to investigate the factors that affect the preference of the anesthesia method in patients who were indicated for general or regional anesthesia.

Material and Methods: A descriptive questionnaire was used to evaluate the opinions of 123 patients who were planned to undergo elective surgery in the orthopedics and traumatology outpatient clinic between January 2018 and June 2019.

Results: 73 women (%59) and 50 men (%41) participated in the study. The mean age was 58.62±11 years. General anesthesia was preferred in 58% of the patients. The most common reason for rejection was that the patients who preferred general anesthesia did not want to receive visual and auditory stimuli during the surgical procedure. There was a significant positive correlation between education level and regional anesthesia preference rate. There was a significant positive correlation between the regional anesthesia preference rate of patients receiving hand and foot surgery indications.

Conclusion: The preference of the majority of patients was found to be general anesthesia method. Additionally, the type of surgery and education level of the patients was found to be effective in preference of the anesthesia method.

Keywords: Anesthesia, Preference, Regional, Patient, Elective

Introduction

The principal aim of anesthesia is to carry out the surgical procedure with minimal pain and discomfort as possible. One of the most disturbing aspects of anesthesia for the surgery patient is the fear and anxiety caused by the spinal or local injections. As in all surgeries, the type of anesthesia method determines by the current systemic or regional problems, coexisting diseases, indications of surgery (ie, outpatient or inpatient), type of surgery (emergency or elective), patient' age, and preference (1-3). General or regional anesthesia methods, appropriate under these conditions, are often at the physician's preference. However, in some cases, depending on the patient health status, it may be possible to choose the method according to patient preference (1).

Regional anesthesia techniques have some advantages such as patient awareness, the continuation of spontaneous breathing, protection of reflex functions (coughing, swallowing), low intraoperative bleeding, low postoperative thromboembolism risk, and providing postoperative effective analgesia. However, hypotension, bradycardia, inability to extend the duration of anesthesia, and late mobilization may comprise disadvantages for regional preference (2, 3). In some cases, anesthesia methods can be superior to another. However, in some patients, each method may be equally suitable. Anesthesia method preference of the patients may be affect by factors such as previous anesthesia experiences of themselves and their relatives, wakefulness or sound effect during operation, information or advice of anesthesiologist and surgen (4, 5).

In a study conducted on orthopedists in order to determine which anesthesia method is preferred by surgeons who play an active role in the determination of anesthesia method, regional anesthesia was found to be more preferred than general anesthesia (6). In another study, it was stated that the opinion of the clinical physician forefront significant for the patient in preference and orientation of the anesthesia method (4, 7).

This study aimed to determine the effect of the patients information, gender, age, education level and type of operation on the selection of the anesthesia methods.

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Material and Methods

A descriptive questionnaire was used to evaluate the opinions of 123 patients who were planned to undergo surgical treatment in the orthopedics and traumatology outpatient clinic between January 2018 and June 2019.

The study was initiated on 272 patients over the age of 18 who agreed to participate in the study. Patients who refused to participate in the study, who did not complete the anesthesia premedication process, or who were out of follow-up, who did not meet general or regional anesthesia, were excluded from the study.

Verbal and written informed consent was obtained from patients -Patient Informed Consent Form- over 18 years of age who had accepted to participate in the study. Ethical consent was obtained from the University Of Health Sciences Sureyyapasa Chest Diseases and Thoracic Surgery Training and Research Hospital (116.2017.185).

The questionnaire, which was prepared by the researcher based on the literature, was filled out by the orthopedic physician after the anesthesia polyclinic evaluation. The questionnaire consisted of 13 questions about the demographic characteristics of the patients, educational background, level of knowledge about anesthesia and surgical treatment type, previous operations, experiences, and preferences of anesthesia. Table-1

Table 1: Patient demographic characteristics and anesthesia preference evaluation questionnaire

1. Gender
Female
Male
2. Age
18-35
35-55
55-70
Above 70
3. Education
High school and below
College or Facult
4.Civil Status
The married
Single
5. Surgical indication
Knee or Hip Arthroplasty
Knee Arthroscopy
Mass Excision
Hand and Foot Surgery
6. Reasons to choose regional anesthesia
Inhaler anesthetic drug unwanted
Less nausea or vomiting
Being conscious
Having postop pain less
Postop sedation to be less
Safe
Having simple surgical intervention
Previous satisfaction
Other (Please specify):
7. Reasons for not choosing regional anesthesia
Risk of general anestesia transition
Pain during application
Being conscious
Headache / Back pain
Fear of permanent paralysis
Loss of effect in surgical procedure fear / anxiety
Other (Please specify):
8. Reasons for choosing general anesthesia
Not wanting to see and hear
Painless application
Safe
Regional anst. insufficiency fear / anxiety
Other (Please specify):
9. Reasons for not choosing general anesthesia
Sleeping / Waking worry
Nausea and vomiting
Postop sedation
Risk of thromboembolism
Postop analgesia needs
Previous bad experience
Other (Please specify):
10. Surgical / anesthesia intervention process information
Yes
No
11. History of surgery / anesthesia
Yes
No
12. ASA score?
13. Which type of anesthesia do you prefer?
Regional anesthesia
General anesthesia

Statistical Analysis

Descriptive statistical methods (mean, standard deviation, frequency) and paired sample t-test was used for comparisons between the groups. IBM SPSS Statistics 22 program was used for statistical analysis. While evaluating the data of the study, the suitability of the parameters to the normal distribution was evaluated by the Kolmogorov-Smirnov test and the parameters were found to be suitable for the normal distribution. Mann-Whitney U test was used to compare the mean age and education level between the groups. Significance ($p < 0.05$) was evaluated.

A structured questionnaire was used based on the cross-sectional study. Assuming that the effect size (Cohen's d = 0.3), alpha error (p-value = 0.05) and 1-beta error (power) value calculated with the correct response rates given to the questions were 0.92, it was understood that 104 people would be sufficient to test the absence hypothesis. For analysis, G Power Statistics Program version 3.1.9.2 was used.

Results

A total of 123 patients, 73 women (59%) and 50 men (41%), participated in the study. The mean age of the patients was 58.62 (range: 20-77) years. According to their educational background, the majority of the patients were high school and under-graduates (65%, n = 81) and the rest were college and university graduates (35%, n = 42).

58% of the patients preferred general anesthesia and 30% preferred regional anesthesia, 12% did not specify any preference.

Patients who prefer general anesthesia; 43% did not want to receive visual and auditory stimuli during the procedure, 31% wanted to feel less pain or ache, 8% thought that general anesthesia was safer, 6% worried about feeling pain

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during the regional procedure, 5% did not trust regional anesthesia, 5% stated general fear and anxiety, and 2% did not give any reason. Patients who prefer regional anesthesia; 41% thought it was safer, 32% thought that surgical intervention was not a major procedure, 11% did not want general anesthetic inhaler drug toxicity and side effects, 5% thought to be awake, 5% thought it was easier, 3% stated that they were previously satisfied with regional anesthesia and 3% were affected by the doctor. (Fig.I)

According to the surgical indications of the patients, 61% of those who were indicated for hip or knee arthroplasty, 60% of those who were indicated for knee arthroscopy (meniscectomy or ACL reconstruction), 66% of those who were indicated for mass excision of the lower and upper extremities, 12% of the patients who had indications for foot surgery (hallux valgus, hallux rigidus, finger arthrodesis, trigger finger, wrist ganglion cyst, dupuytren's contracture, etc.) stated that they preferred general anesthesia. Patients demographic characteristics and anesthesia method preference distribution was shown in Table 2.

Age, gender, and marital status were not found to have a significant effect on anesthesia preference distribution ($p > 0.05$). There was a significant positive correlation between education level and regional anesthesia preference rate ($p = 0.001$). There was a significant positive correlation between the regional anesthesia preference rate of patients receiving hand and foot surgery indications ($p = 0.003$).

Table 2. Regional and general anesthesia preference distribution according to demographic and surgical indications.

	Regional Anesthesia [Mean±sd] n (%)	General Anesthesia [Mean±sd] n (%)	No preference	p
Age	[60.9±13]	[63.2±8]		
	38(30)	71(57)		
18-35	8	20	1	0.238
35-55	4	13	3	
55-70	17	28	4	
Above 70	9	10	6	
Gender				
Female	22	41	10	0.988
Male	16	30	4	
Education				
High school and below	13	47	5	0.0013
College or Facult	25	24	9	
Marital Status				
Married	24	33	12	0.966
Single	14	38	2	
Surgical indication				0.0015
Knee or Hip Arthroplasty	7	19	5	0.79
Knee Arthroscopy	9	18	3	0.13
Mass Excision	8	22	3	0.96
Hand and Foot Surgery	14	4	3	0.032
Surgical/Anesthesia intervention process information				0.814
Yes	12	24	3	
No	26	47	11	

*Chi Square Test,statistically significant between groups $p < 0.05$

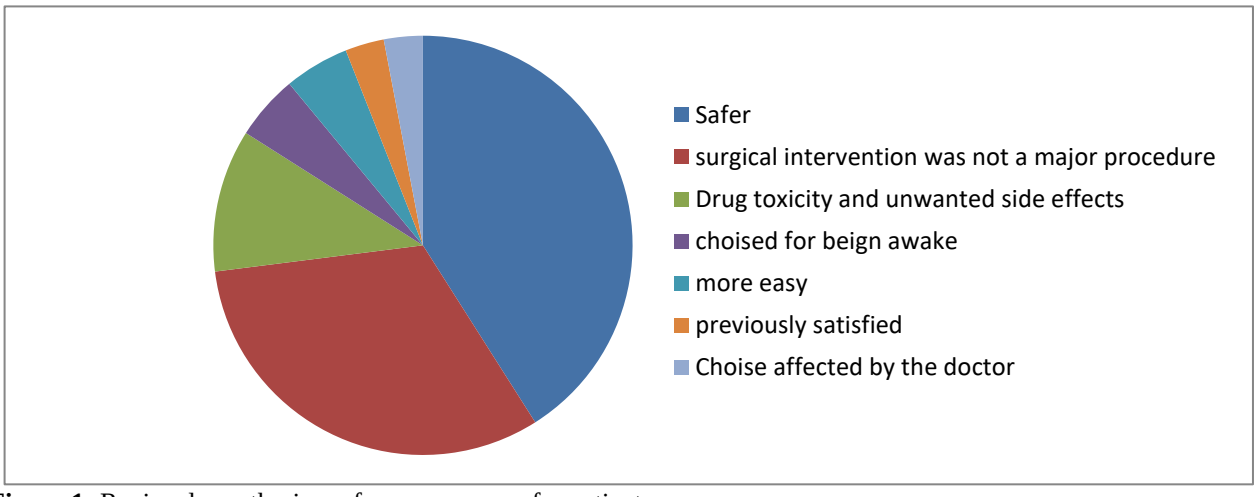

Figure 1: Regional anesthesia preference reasons for patient.

Discussion

The aim of general anesthesia is sedation, analgesia, loss of reflexes, and muscle relaxation. Regional anesthesia is an alternative to general anesthesia. Nowadays, regional anesthesia applications have been given more importance and used more frequently (8, 9). In both methods, the patient's age, general condition, medical drug usage, the type of surgical intervention, depending on the existing disease may be preferred to each other. In our study, the cases where both anesthesia methods had equal superiority in terms of patient and that both methods accepted equally by surgeon and anesthesiologist were selected. There upon, based on these cases, independent patient preference study planning was developed. It is known that regional anesthesia has less negative effects on vital signs, endocrine, and metabolic responses in which occur during operation compared to general anesthesia (10, 11). However, regional anesthesia has difficulties in achieving the desired level of anesthesia, adverse hemodynamic changes, delayed onset of effect, and toxicity of high volume drug use so constitute the difficulties of application. Patients' rejection of regional anesthesia, previous negative experience, pain that may occur during and after the administration, and possible persistent symptoms due to nerve block are among the most common causes. In our study, it was found that anesthesia preference could change according to the type of surgery. Regional anesthesia was preferred more especially in patients who needed surgical treatment such as hand, foot, and finger. Hip or knee prosthesis surgery in elderly patients may have a high risk of morbidity and mortality due to the characteristics of both the patient and the surgery (4, 10). Although the age, gender, marital status, and ASA values of our patients did not have any effect on preference. It was seen that the preference for general anesthesia higher in parallel with the increase in surgical risk. Sargin et al. In the survey conducted by the anesthesiologists on regional anesthesia preferences, 72.2% of the participants expressed their opinion about regional anesthesia. They stated that age, gender, mental status, education level, previous satisfaction, operation site and surgery characteristics were effective in their preferences in varying percentages (12). The choice of anesthesia method may differ depending on the type of surgery performed and postoperative pain treatment due to the physiological changes occurring in the elderly patient. The patient's awareness during the operation process, the continuation of spontaneous breathing, protection of reflexes (coughing, swallowing) may cause regional anesthesia to come to the forefront in determining the method of anesthesia in elderly patients. Salam et al. prospective survey study, in which regional and general anesthesia preference in the group of elderly patients who underwent orthopedic hip and knee prosthesis surgery, indicated that regional anesthesia was generally rejected. The most common reason for rejection was the surgeon's preference, back pain, and fear of being awake during the operation (13). It is accepted that regional anesthesia reduces morbidity and mortality in terms of early results. However, values cannot be standardized within the scope of comorbidities, surgical procedures, and case variables (2, 14). In our study, postoperative findings related to morbidity and mortality in RA and GA patients were not included in the study. It was the limiting effect of the study. Age, gender, and marital status did not have any effect on the distribution of anesthesia preference in our study and this finding was found to be consistent with the literature (5, 15). Patient's education level as well as giving detailed information about GA or RA is important for approaching and informing patients preference anesthesia method (16). In this study, there was a relationship between the preference of anesthesia method in patients with high educational level. The number of patients who had general anesthesia preference without any reason was higher in patients with low educational levels compared to those with university or higher education. ASA (American Society of Anesthesia) risk classification values did not have a significant effect on RA and GA preference distribution in this study.

Conclusion

Anesthesia premedication and method decisions are made in line with the prediction of anesthesiologists. In terms of patients, it was observed that general anesthesia methods were more preferred. Also, patient education level and type of surgical treatment method were found to be effective in preference of anesthesia method.

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Renal colic secondary to ureteral metastasis: Rare presenting manifestation of prostate cancer

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Abstract

Objective: Ureteral metastasis of prostate cancer is a very rare pathology, that can be confused with an upper urinary tract urothelial carcinoma, with great implications in the surgical management and therapy of the disease.

Case: A 56-years old male patient admitted to the emergency room with 2 weeks history of left flank pain without low urinary tract symptoms or hematuria. PSA level was 43,4 ng/ml. The patient underwent prostate needle biopsy and ureteral biopsy using flexible ureteroscopy, after the Lich-Gregoire ureterovesical reimplantation. In this case, renal colic as the first symptom of a ureteral metastasis secondary to prostate cancer is extremely rare which diagnosed in the patient.

Conclusion: Neoureterocystostomy is a safe and effective treatment for ureteral obstruction due to prostate cancer metastasis, with low morbidity and significant benefits in terms of quality of life for patients with life expectancy more than 10 years.

Keywords: prostate cancer, ureteral metastasis, ureteral reimplantation

Introduction

Prostate cancer represents the first cause of malignancy in 2018 for the male population in Europe, with an incidence of 62,1 per 100,000 (age-standardized rate), and the second cause worldwide with an incidence of 29,3 per 100,000 (1). Ureteral metastasis of prostate cancer is a very rare pathology, wich only 51 cases have been reported in the literature. We report a rare case of symptomatic distant ureteral metastasis from prostate cancer as the first manifestation of this disease.

Case

A 56-years old male was applied to the emergency room in march 2017 because of left flank pain for about 2 weeks with no low urinary tract symptoms or hematuria. He had no significant past medical history. The ultrasound revealed a grade II left ureter-hydronephrosis and a prostate with a volume of 43,4 cm3. The prostate was a left indurated nodular lesion with no sign of local extension according to a digital rectal examination.

The laboratory work-out showed an increase in serum creatinine level (1,14 mg/dl) and the increased PSA level was found as 43,4 ng/dl. The eventuated long-delayed left renal function with a late-nephrogram image (120 min) and normal right kidney function have been determined with an intravenous urogram.

A needle transrectal ultrasound-guided prostate biopsy was performed followed by a urethra cystoscopy that revealed no bladder invasion, with permeable ureteral orifices. In order to evaluate the upper urinary tract, we performed a flexible uretero-nephroscopy that highlighted a small tumor at 5 cm proximal of the left ureteral orifice which was biopsied, with no other lesions of the urinary collecting system. A left double J stent was inserted.

Pathological examination of the prostate biopsy revealed an acinar adenocarcinoma, Gleason 3+3, and the ureteral biopsy showed an adenocarcinoma suggestive of prostatic cancer.

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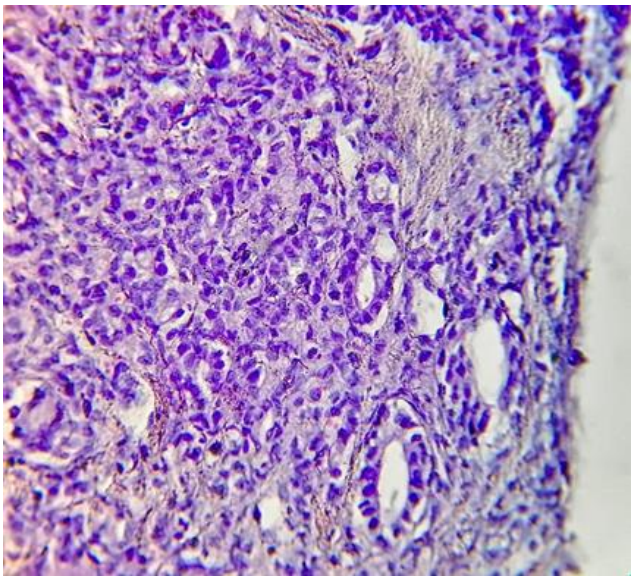

Figure 1: Histopathological specimen from prostate biopsy

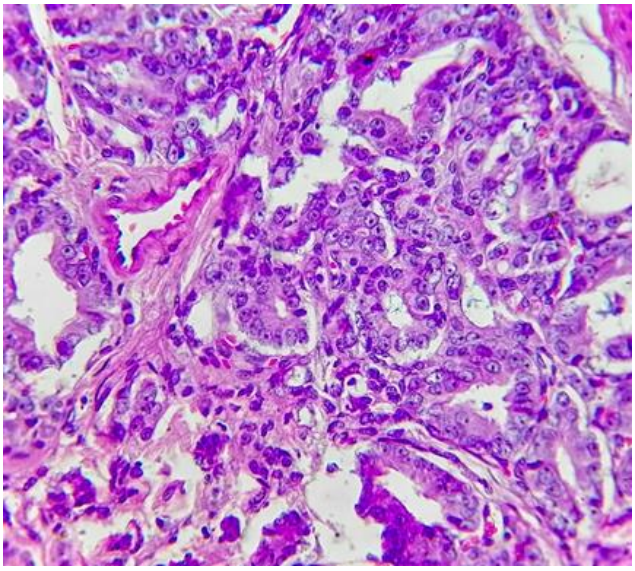

Figure 2: Histopathological specimen from ureteral biopsy

The CT scan showed bilateral iliac and retroperitoneal lymph node enlargement (involvement). The patient received hormonal therapy for prostate cancer consisting of goserelin 10,8 mg subcutaneous implant once 3 months.

According to Calculator for Estimating Overall Life Expectancy and Lifetime Risk for Prostate Cancer Death in Newly Diagnosed Men Managed without Definitive Local Therapy nomogram the predicted survival of the patient was of 16.0 years, so we decided to perform partial ureterectomy with Lich-Gregoire ureterovesical reimplantation (2).

Pathological findings after the surgery consisted of tumor infiltration of the entire ureteral wall of an adenocarcinoma suggestive for prostate cancer.

After the surgery the patient received radiotherapy for prostate cancer as follows: Total 78 Gy in 39 fractions for the prostate, Total 56 Gy in 28 fractions for seminal vesicles, and total 50,4 Gy in 28 fractions for pelvic lymph nodes.

The patient was evaluated, using ultrasound examination, CT scan, and PSA levels, every 3 months for a year and every 6 months for the second year. PSA levels had decreased to under the 2 ng/ml, with normal serum creatinine levels, with no dilatation of the upper urinary tract at 24 months.

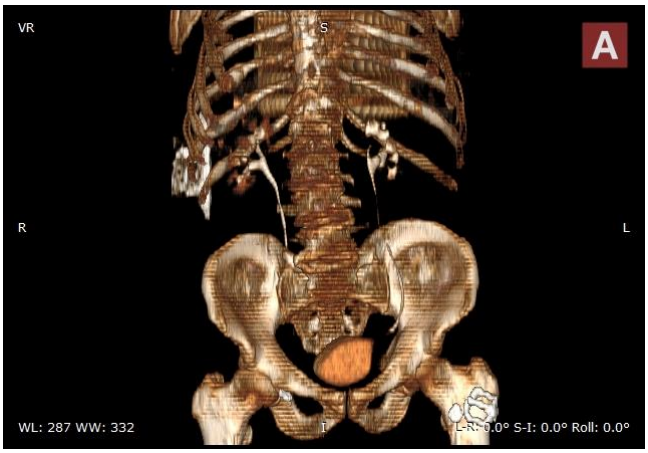

Figure 3: 3-D reconstruction of 6 months postoperative CT scan

Discussion

Metastatic prostate cancer involvement of the ureter is extremely rare. A population-based analysis of metastatic sites in patients with prostate cancer published by Gandaglia et al. showed that the most frequent sites of metastases are the bones, lymph nodes, liver, thorax, and brain. In the same study were mentioned metastases of the retroperitoneum, kidney, and adrenal glands, but with no mention of the ureter (3)

For complete obstruction of the ureter from tumoral involvement, the treatment of choice for long term obstruction relief is the placement of a nephrostomy tube, which is associated with important complications such as febrile UTI, perirenal abscess, dislodgement of a nephrostomy tube, local inflammation and dermatitis of nephrostomy tract, and hemorrhage during nephrostomy placement. (4,5)

The difficulty of diagnosis was high because of the lack of bone metastasis in the presence of iliac and retroperitoneal lymph nodes involvement, which could also be suggestive for upper tract urothelial carcinoma.

Conclusion

The ureter represents a rare site of distant prostate metastasis in the natural evolution of this disease. Tumoral obstruction of the ureter and kidney are usually asymptomatic, and the association of other clinical sings as renal colic or hematuria may lead to some difficulties in the diagnosis.

Correct diagnosis of primary tumor pathology is essential in the correct setting of therapeutic conduct, which is why clinicians need to be aware of the possibility of metastasis in the ureter and suspect it when they encounter ureteral obstruction in clinical practice along with clinical and paraclinical suspicions of cancer prostate (PSA or digital rectal examination).

Neoureterocystostomy is a safe and efective treatment of ureteral obstruction due to prostate cancer metastasis, with low morbidity and significants benefits in terms of quality of life for patients with life expectency more than 10 years.

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Conflict of interest: The authors declare that they have no conflict of interest.

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