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Original Investigation

The Level of Knowledge of Pelvic Floor Dysfunction After Delivery in Women who Attended to a Tertiary Center

Murat Ekin[1], Cihan Kaya[1], Emine Öztürk[2], Hüseyin Cengiz[1], Gülden Uzer[3], Levent Yaşar[1]

Abstract

Objective: Pelvic floor disorders affect women in all age groups and cause poor quality of life with economic burden. The aim of the present study was to investigate the attitude of women who were admitted to our clinic about the relationship between mode of delivery and pelvic floor disorders and pelvic muscle exercises.

Methods: A total of 1316 women who had attended our outpatient gynecology clinic for various complaints were interviewed by an expert gynecologist. Demographic data including age, marital status, education, health insurance, menopausal status, parity, mode of deliveries, birth weights, and also lower urinary tract symptoms were included in the interview. All the participants were asked to complete a verbal modified Pelvic Risk Knowledge Score (PRKS) questionnaire regarding their knowledge about pelvic floor disorder risks.

Results: The mean modified PRKS was 4.95±2.5. Of the patients, 26.8% had a diagnosis of stress urinary incontinence, 14.3% had urgency, 19.8% had frequency, 11.1% had >stage 2 pelvic organ prolapse (POP), 7.4% did not even hear about pelvic muscle exercises, and 17.6% did not even inform about pelvic muscle exercises by a health care provider. PRKS was significantly higher in multiparous women than in primiparous women ($p<0.0001$). Vaginal birth also significantly increased the PRKS with respect to cesarean delivery ($p=0.006$). Women with cesarean deliveries had significantly increased PRKS with respect to nulliparous women ($p<0.0001$).

Conclusion: Episiotomy, menopause, lower urinary tract symptoms, and POP are the factors that significantly increase PRKS.

Keywords: Pelvic floor disorders, pelvic muscle exercises, pelvic risk, vaginal birth

Introduction

Pelvic floor disorders affect women in all age groups and cause poor quality of life and economic burden (1). Cross-sectional studies suggest that women who had vaginal birth are more susceptible to urinary incontinence, fecal incontinence, pelvic organ prolapse (POP), and sexual dysfunction than women who had only cesarean deliveries later in life (2, 3). Pelvic floor muscle exercise is defined as the repetitive selective, voluntarily contraction and relaxation of the pelvic muscles. It aims to strengthen the pelvic muscles to support the urethra and increase the urethral sphincteric function (4). It has been established that pelvic floor muscle exercises decrease urinary incontinence in pregnancy, postpartum period, and later in life. It also reduces the episodes of postpartum fecal incontinence and improves sexual dysfunction in the postpartum period (5-7).

The aim of the present study was to investigate the perception of women on the relationship between mode of delivery and pelvic floor disorders and to investigate the knowledge on pelvic floor muscle exercises.

Methods

This was a cross-sectional observation study. Ethics committee approval was received for this study from the Ethics Committee of Health Sciences University Bakirköy Dr. Sadi Konuk Training and Research Hospital (2014/27). Written informed consent was obtained from all of the participants. Overall, 1316 women who had attended the outpatient gynecology clinic for various complaints were interviewed by an expert gynecologist. Demographic data including age, marital status, education, health insurance, menopausal status, parity, mode of deliveries, birth weights, and lower urinary tract symptoms were included in the interview. The clinical examination data for the presence of episiotomy, stress urinary incontinence (SUI), urgency, frequency, and POP were recorded.

All of the participants were asked to complete a verbal modified Pelvic Risk Knowledge Score (PRKS) questionnaire adapted from Dunbar et al. (8) regarding their knowledge about pelvic floor risks associated with the delivery methods and their awareness about the pelvic muscle exercises

The abstract of this paper has been presented as a poster presentation in 1st UHS Congress of Pelvic Floor Disorders, 5-7 May 2017, İstanbul, Turkey.

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(Table 1). For analysis of the awareness of the risk of vaginal delivery (a nine-item questionnaire), addressing this topic were scored along each subject's number of deliveries. For the yes/no questions, a score of 1 was assigned to "Yes" response and 0 to "No" response. Vaginal responses were scored as 1, and cesarean responses as 0. Then, a composite risk score modified PRKS was obtained by adding all of the scores along with 10 items of the number of deliveries. A PRKS of 0 indicates no knowledge, whereas higher scores indicate a higher level of knowledge on a linear scale.

Statistical Analysis

The Number Cruncher Statistical System 2007 statistical software (NCSS, UT, USA) was used for data analysis. Descriptive statistical analysis was expressed as mean±standard deviation. One-way analysis of variance was used for normally distributed data. The Tukey test was used for post hoc analysis of parametric data. A paired sample t-test and the chi-square test were used for comparison of qualitative and quantitative data. A univariate model was created to determine the effect of episiotomy, menopause, SUI, urgency, frequency, and POP on PRKS. A Spearman correlation analysis was performed to determine any correlation between parity and PRKS. A $p<0.05$ was accepted as statistically significant.

Results

Table 2 shows the demographic and clinical examination findings of the patients. The mean modified PRKS was 4.95±2.5. Among the patients, 26.8% were diagnosed with SUI, 14.3% had urgency, 19.8% had frequency symptoms, and 11.1% had >stage 2 POP at pelvic examination. Table 3 shows the responses that were given to a nine-item questionnaire by the patients. The responses to questions 8 and 9 were 7.4% and 17.6%, respectively, indicating that awareness of pelvic muscle exercises is really poor and health care providers hardly inform their patients about pelvic muscle exercises. For univariate analysis, presence of episiotomy, menopause, SUI, urgency, frequency and POP were the factors that significantly increase the PRKS ($p<0.0001$) (Table 4). There was a significant correlation between parity and PRKS ($p<0.0001$). PRKS was higher in nulliparous women than in primiparous women ($p<0.001$). It was also significantly higher in multiparous women than in primiparous women ($p>0.0001$) (Table 5). Vaginal birth was also significantly increased in the PRKS with respect to cesarean delivery ($p=0.006$), but women who had cesarean deliveries had also significantly higher PRKS than nulliparous women ($p<0.0001$) (Table 6).

Table 1. Questionnaire items: Pelvic risk knowledge score

1. In your opinion, does a vaginal delivery (natural childbirth) increase your risk of problems controlling your bladder (difficulty holding your water)? Yes/No
2. In your opinion, does a cesarean delivery increase your risk of problems controlling your bladder (difficulty holding your water)? Yes/No
3. In your opinion, which type of delivery could cause more harm to pelvic floor? Vaginal/cesarean
4. In your opinion, does a vaginal delivery (natural childbirth) increase your risk of problems controlling your bowels (leakage of gas and stool)? Yes/No
5. In your opinion, does a vaginal delivery have a negative effect on your sexual function? Yes/No
6. In your opinion, does a cesarean delivery have a negative effect on your sexual function? Yes/No
7. In your opinion, can exercises of the muscles in your pelvic area help lessen the chance of your developing bladder and/or bowel problems later in life? Yes/No
8. Have you ever heard about pelvic muscle exercises? Yes/No
9. Have you ever informed about or suggested to make pelvic muscle exercises to a health care provider? Yes/No

Table 2. The descriptive characteristics and clinical examination findings of the study population

	min-max	mean±SD	
Age	14-81	43.27±12.39	
Parity	0-13	2.22±1.8	
Vaginal birth	0-13	1.95±1.87	
Cesarean birth	0-4	0.28±0.62	
PRKS	0-18	4.95±2.5	
		n	%
Number of deliveries >4000 g	0	1.142	86.8
	1	147	11.2
	≥2	27	2.1
Number of operative delivery	0	1.263	96.0
	≥1	31	2.4
	≥2	22	1.7
Episiotomy	No	780	59.3
	Yes	536	40.7
Marital status	Married	1.079	82.0
	Single	107	8.1
	Divorced	69	5.2
	Widow	61	4.6
Menopause	No	835	63.4
	Yes	481	36.6
Educational status	Illiterate	127	9.7
	Primary school	818	62.2
	High school	238	18.1
	University	133	10.1
Health insurance	None	65	4.9
	Yes	1.251	95.1
Stress urinary incontinence	No	963	73.2
	Yes	353	26.8
Urgency	No	1.128	85.7
	Yes	188	14.3
Frequency	No	1.056	80.2
	Yes	260	19.8
Pelvic organ prolapse (>stage 2)	No	1.170	88.9
	Yes	146	11.1

PRKS: pelvic risk knowledge score; min: minimum; max: maximum; SD: standard deviation

Discussion

Women's attitude on vaginal delivery differs in different parts of the world in relation to traditions and socioeconomic status. The reasons for selecting preferentially vaginal delivery in a Turkish population include fear of surgery, desire of early recovery, and request for having a great number of children (9). In the present study, 49% and 68% of women were unaware that vaginal birth can cause urinary incontinence and fecal incontinence later in life, respectively. Only 37% of women thought that pelvic muscle exercises could help decrease the chance of developing bladder and bowel problems later in life. Among women, 82% did not even hear about pelvic muscle exercises. The present study suggested that there is an important lack of knowledge about the relationship between vaginal birth and pelvic floor disorders. In a previous review, pelvic floor muscle exercises significantly prevent urinary incontinence in late pregnancy and postpartum for the continent women before pregnancy (10). Consistent with these findings, another review of 22 trials by Boyle et al. (6) with 8484 pregnant or postpartum women revealed that continent pregnant women who had intensive antenatal pelvic floor muscle exercises are less likely to report urinary incontinence in late pregnancy and at 6 months of postpartum period. Pelvic muscle exercises are recommended as the first-line management for the prevention of SUI during pregnancy and postpartum period. In addition, the National Institute for Health and Care Excellence suggests pelvic floor muscle exercises to all pregnant women for the prevention of SUI (5). According to the given results to the questions related with pelvic muscle exercises, Turkish women were poorly aware of these exercises, and health care providers were reluctant to inform and teach their patients for this common health burden.

In the present study, we have observed that aging, menopause, having episiotomy, lower urinary tract symptoms, and POP were significantly related with higher PRKS. This result can be explained as Turkish women are not informed about the consequences of vaginal birth, and they only realize this situation when they are symptomatic.

It is a well-known fact that parity increases urinary incontinence in premenopausal women. The first delivery has the most important effect on incontinence, whereas subsequent deliveries have a small but ongoing effect (11, 12). We have found that parity has a significant effect on PRKS, and there is a significant difference between PRKS of primiparous and multiparous women. Although PRKS was significantly lower in patients with a history of cesarean birth than in those with vaginal birth, there was also a significant difference between nulliparous women and participants with a history of cesarean birth, with nulliparous women with lower

Table 3. The responses that were given to a nine-item questionnaire by the patients

		n	%
Question 1	No	648	49.2
	Yes	668	50.8
Question 2	No	1.066	81.0
	Yes	250	19.0
Question 3	Vaginal	562	42.7
	Cesarean	754	57.3
Question 4	No	896	68.1
	Yes	420	31.9
Question 5	No	896	68.1
	Yes	420	31.9
Question 6	No	1.064	80.9
	Yes	252	19.1
Question 7	No	488	37.1
	Yes	828	62.9
Question 8	No	1.084	82.4
	Yes	232	17.6
Question 9	No	1.219	92.6
	Yes	97	7.4

Table 4. The univariate analysis of PRKS and episiotomy, menopause, SUI, urgency, frequency, and POP

		n	PRKS	p
Episiotomy	No	780	4.71±2.74	0.0001
	Yes	536	5.3±2.04	
Menopause	No	835	4.53±2.35	0.0001
	Yes	481	5.68±2.58	
SUI	No	963	4.23±2.12	0.0001
	Yes	353	6.91±2.39	
Urgency	No	1128	4.59±2.29	0.0001
	Yes	188	7.08±2.62	
Frequency	No	1056	4.53±2.27	0.0001
	Yes	260	6.66±2.67	
POP	No	1170	4.66±2.32	0.0001
	Yes	146	7.28±2.63	

PRKS: pelvic risk knowledge score; SUI: stress urinary incontinence; POP: pelvic organ prolapse

Table 5. The correlation analysis between parity and PRKS

	n	PRKS (mean±SD)	p
Nulliparity	249	2.7±1.76	0.0001
Primiparity	167	$3.49\pm1.5^{\alpha}$	
≥2 parity	900	$5.84\pm2.29^{\beta,\gamma}$	

$^{\alpha}$p=0.001, nulliparity/primiparity; $^{\beta}$p=0.0001, nulliparity/multiparity; $^{\gamma}$p=0.0001, primiparity/multiparity; PRKS: pelvic risk knowledge score

Table 6. The correlation analysis between mode of delivery and PRKS

		n	PRKS (mean±SD)	p
Mode of delivery	Vaginal birth	808	5.58±2.38	0.006
	C-section	259	5.14±2.22	
	Nulliparity	249	2.70±1.76	0.0001
	C-section	195	4.83±2.18	

PRKS: pelvic risk knowledge score; SD: standard deviation

PRKS. This result can be attributed to the negative impact of pregnancy on pelvic floor muscles and urinary incontinence.

The present study has some limitations. First, although the small sample size can be a limitation of the study, our hospital is located in the largest region of Turkey and covers a population who had migrated from different parts of the country. Second, there is a lack of Turkish validation of PRKS. It can be validated after encouraging results of our results in future studies.

Conclusion

The results of the present study indicate that parity and lower urinary tract symptoms have a significant correlation. Although pelvic muscle exercises are recommended as the first-line management for the prevention of SUI during pregnancy and postpartum period, the knowledge of the Turkish population on this issue is poor, and health care providers should exert more effort to raise awareness in society.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of Health Sciences University Bakirköy Dr. Sadi Konuk Training and Research Hospital (2014/27).

Informed Consent: Written informed consent was obtained from patients and patient's parents who participated in this study.

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Original Investigation

The Relationship Between Pain Level and Quality of Life And Sleep Disorder in Patients with Central Post-Stroke Pain

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Abstract

Objective: Stroke is the third most common cause of death and the first cause of disability worldwide. Central post-stroke pain (CPSP) resulting from the dysfunction or primary lesion of the central nervous system after stroke is a common syndrome.

Methods: A total of 75 (31 female and 44 male) patients with ischemic stroke were included in the study. Of the patients, 28 (12 women and 16 men) experienced central pain within 1 year after ischemic stroke.

Results: The pain assessment of the patients was performed using the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) pain scale and the Visual Analog Scale (VAS). The European Quality of Life-5 Dimensions (EQ-5D) and EQ-5D VAS life quality assessment conducted in the group with central pain indicated a statistically significant correlation in the quality of life (QoL) in both measurements as the VAS levelincreased ($p \leq 0.001$ and $p \leq 0.001$, respectively). Similarly, it was identified that the QoL (EQ-5D and EQ-5D VAS) was lower in the group with LANSS≥12 thaninthe group with LANSS<12 ($p \leq 0.006$ and $p \leq 0.016$, respectively). Statistically significant data were obtained in the group with CPSP as the VAS score increased and in cases with LANSS≥12 according to the Epworth Sleepiness Scale ($p \leq 0.001$ and $p \leq 0.002$, respectively). When the groups with the Epworth score between <11 and ≥11 were compared, the daytime sleepiness ratio was found to be significantly higher in the group with LANSS≥12 ($p \leq 0.018$). A positive significant correlation was detected between the VAS score and the daytime sleepiness ratio ($p \leq 0.001$).

Conclusion: The present studydemonstrated that CPSP had a clearly negative effect on the QoL of patients with stroke. It is important for the literature to emphasize that it is possible to improve the comfort of patients with a correct diagnosis and treatment of sleep disorders, depression, and anxiety accompanying CPSP.

Keywords: Central post-stroke pain, leeds assessment of neuropathic symptoms and signs, visual analog scale, quality of life, sleep disorder

Introduction

Stroke is the third most common cause of death and the first cause of disability in the world. It has a significant share in both hospitalization and health expenditures in industrializedcountries (1).

The pain caused by the dysfunction or primary lesion of the central nervous system after stroke is called post-stroke pain, and it is one of the reasons for central neuropathic pain (2, 3). Central post-stroke pain (CPSP) is a common syndrome after stroke and is observed in approximatelyoneout of three patients with post-stroke pain (4). It was first described by Dejerine and Roussy in 1906 as the pain occurring spontaneously after thalamic stroke (5). Thus, the expression of thalamic pain is sometimes used instead of CPSP. However, the researchers then comprehensively described the characteristics of the pain caused by extrathalamic lesions (6).

Central post-stroke pain is characterizedby pain and sensory abnormalities in the body (when other reasons for significant nociceptive, psychogenic, orperipheral pains are excluded) after cerebrovascular lesion of the somatosensory system (7). Symptom onset is often gradual, coinciding with the improvement of perceived sensory loss and the appearance of dysesthesia. The pain is frequently severe and unrelenting, with pain-free episodes not exceeding a few hours (8). The prevalence of CPSP has been reported to be 7.3% (7).

The quality of life (QoL) is lower by 40% a year after stroke onsetthan before a stroke. As pain is known to affect recreational activities, vocational status, and quality of sleep, it can have a major role on QoL, mood, and rehabilitation outcome (9). In our study, the QoL and sleep quality were evaluated comparatively according to the presence and level of pain in patients with ischemic stroke with and without central pain.

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Methods

The study was conducted onpatients with ischemic stroke whowere followed up by our Neurology Clinic. Ethics Committee approval was received for this study from the Ethics Committee of Sakarya University (28.02.2017-71522473/050.01.04/67). Consentwas obtained from the patients to participate in the study.

Patients diagnosedwith ischemic stroke; aged between 30 and 85 years; with thyroid and parathyroid diseases; using corticosteroid and hormone replacement therapy; withmalnutrition, cancer diagnosis, psychiatric treatment use, and chronic renal and liver diseases; without motor dysfunction due to anorthopedic discomfort, and who acknowledged their participation were included in the study.

There were 75 (31 female and 44 male) patients with ischemic stroke included in the study. While 28 patients experienced central pain within1 year after ischemic stroke, 47 (19 female and 28 male) patients did not experience central pain in 1 year following anischemic stroke. Patients were separated into two groups as thalamic and extrathalamic in terms of ischemic stroke localization.

The pain assessment of the patients was performed using the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) pain scale and the Visual Analog Scale (VAS). The life quality assessment was performedby the European Quality of Life-5 Dimensions (EQ-5D) and EQ-5D VAS. Moreover, the Beck Anxiety Inventory (BAI), the Beck Depression Inventory (BDI), and the Epworth Sleepiness Scale (ESS) were applied to the patients.

In groups with and without central pain, gender, age, and infarct location were compared. In the group with central pain, with the LANSS values <12 and ≥12 and according to the VAS values, QoL was assessed by EQ-5D and EQ-5D VAS. Among the same groups, comparisons were made by the BAI and BDI scores with the Epworth sleep score values of <11 and ≥11 (daytime sleepiness).

Table 1. The comparison of the quality of life and EQ-5D in patients with stroke with CPSP with LANSS and VAS

	LANSS<12	LANSS≥12		VAS	
	n	n	p	n	p
EQ-5D	4	24	0.006	28	0.001
EQ-5D VAS	4	24	0.016	28	0.001

LANSS: leeds assessment of neuropathic symptoms and signs; VAS: visual analog scale; EQ-5D: European quality of life-5 dimensions

Table 2. The comparison of the Epworth Sleepiness Scale in patients with stroke with CPSP with LANSS and VAS

	LANSS<12	LANSS≥12		VAS	
CPSP	n	n	p	n	p
Epworth sleepiness score	4	24	0.002	28	0.001
Epworth score<11	4	11	0.018	15	0.001
Epworth score≥11	0	13		13	

CPSP: central post-stroke pain; LANSS: leeds assessment of neuropathic symptoms and signs; VAS: visual analog scale

Statistical Analysis

The Fisher-Freeman-Halton test, independent samples t-test, one-way analysis of variance, Kruskal-Wallis H test, chi-square test, and correlation analyses were used in the assessment of data depending on the type and purpose of the characteristics. A $p<0.05$ was considered statistically significant. Statistical analysis was made using the Statistical Package for Social Sciences version 18.0 for Windows (IBM Inc.; Armonk, NY, USA).

Results

While the lowest age was 32 years and the highest age was 87 years, the average age in the group with central pain was 64.04±12.9 years, and the average age in the group without central pain was 62.8±13.9 years.

While 15 (53.6%) patients had thalamic infarct and 13 (46.4%) patients had extrathalamic infarct in the group with central pain, 7 (14.9%) patients had thalamic infarct and 40 (85.1%) patients had extrathalamic infarct in the group without central pain.

Gender and age distributions were found to be similar in the groups with and without central pain (p≤0.836 and p≤0.701, respectively). The rate of the cases with thalamic infarct was significantly higher in the group with central pain (p≤0.001).

There was a significant difference between the VAS average of 3.25±0.96 of the patients with LANSS<12 and the VAS average of 7.1±1.25 of the patients with LANSS≥12 in the group with central pain (p≤0.001). According to this result, the VAS severity of those with LANSS of ≥12 was higher.

As a result of the EQ-5D and EQ-5D VAS life quality assessment conducted in the group with central pain, there was a significant positive correlation between both values (p≤0.001), and both measurements indicated a statistically significant correlation in the QoL as the VAS level increased (p≤0.001 and p≤0.001, respectively). Similarly, it was identified that the QoL (EQ-5D and EQ-5D VAS) was lower in the group with LANSS≥12 thanin the group with LANSS<12 (p≤0.006 and p≤0.016, respectively) (Table 1).

There was no statistically significant difference between the groups with and without CPSP in terms of the ESSpoint average (p≤0522). In the assessment performed in two separate groups as the Epworth score (daytime sleepiness condition) <11 and ≥11, there was no significant difference between the cases with and without CPSP (p≤0.744).Statistically significant data were obtained in the group with CPSP as the VAS score increased and in cases with LANSS≥12 according to the ESS (p≤0.001 and p≤0.002, respectively).When the groups with the Epworth score <11and ≥11 were compared,the daytime sleepiness rate was found to be significantly higher in the group with LANSS≥12 and as the VAS score increased (p≤0.018 and p≤0.001, respectively) (Table 2).

The BAI and BDI values of the groups with and without CPSP did not indicate a significant change (p≤0.731 and p≤0.249, respectively), and the anxiety and depression levels of both groups were found to be similar. In the group with CPSP, it was identified that the anxiety level determined with the BAI scale was significantly higher in cases with LANSS≥12 thanin those with LANSS<12 (p≤0.007), and there was no significant difference in terms of the

depression level (p≤0.406). A significant positive correlation was found between the anxiety and depression levels in the group with central pain according to the VAS, BAI, and BDI(p≤0.000 and p≤0.001, respectively). In other words, as the VAS level increases, the anxiety and depression levels of patients increase significantly.

Discussion

Neuropathic pain is the pain that causes sensory symptoms and findings caused by a lesion in the peripheral or central nervous system or in both of them. It is divided into central and peripheral neuropathic pain. Post-stroke pain is one of the causes of central neuropathic pain (2, 3). Although there remain some mysteries as to the pathophysiology of CPSP, it is believed to be caused by stroke in the region of the thalamus and extrathalamic areas. The thalamus is a relay station for sensory information from all over the body (10). In our study, the patient group who had central pain after ischemic stroke was divided into two groups as thalamic and extrathalamic.

In most of the patients with stroke, central pain develops in the first month after stroke; however, it may also develop ≥6 months after stroke in some patients (11). Patients who experienced central pain within 1 year after stroke were included in the study.

Although central pain after stroke was originally described as "thalamic pain," it is currently recognized that strokes involving the sensory tracts in various brain regions can produce pain similar to central pain (12).

In some studies, higher pain intensities have been reported when the lesions were located in the brainstem or thalamus than in other areas; however, in another study, the symptoms and severity of CPSP in thalamic versus extrathalamic stroke did not differ (9). Of the 75 patients with ischemic stroke,28 had CPSP in our study. The rates of the 15 (53.6%) patients with thalamic infarct were similar with the rates of the 13 (46.4%) patients with extrathalamic infarct. There were only 7 (14.9%) patients with thalamic infarct in the group of 47 patients without CPSP. In other words, thalamic lesions are observed more frequently in the group with CPSP thanin the group without CPSP (p≤0.001); moreover, the frequency of thalamic and extrathalamic lesions was found to be similar in the group. This situation will become clearer in future studies to be conducted with more patients with CPSP.

It is hard to diagnose CPSP. In this process, it is beneficial to identify pain level with pain scales, such as the VAS and Numerical Rating Scale; however, there was no scale developed especially for CPSP (7). In our study, the pain assessment was performedusing the LANSS and VAS in the group with CPSP, and it was identified that the VAS severity was higher in the group with LANSS≥12 (p≤0.001). In other words, both tests were correlated in indicating the level of pain.

There are many studies on the fact that the presence of CPSP impairs the life quality of patients. For example, in the study conducted with 100 patients with stroke by Kılıç et al. (13), CPSP was determined in 20 patients. While CPSP was evaluated by the LANSS, the QoL was evaluated by the Nottingham Health Profile (NHP). Central pain was related to a significant difference in the pain parameter of the NHP (p≤0.001). In conclusion, CPSP is a complication that should not be ignored because it is not rare and has a negative impact on the QoL of patients with stroke. In a study conducted with 24 patients with CPSP, while pain was evaluated by the LANSS and VAS, the QoL was evaluated by the 36-item Short-Form Health Survey quality of life scale (SF-36 QoLS).The result showed that CPSP has a negative impact on the physical subscale score of the SF-36 QoLS in patients with stroke (9).In our study, the QoLof patients was assessed using the EQ-5D and EQ-5D VAS. In the assessments performed with both the LANSS and VAS, the level of pain and the QoLwere statistically significant. It was observed that as the severity of CPSP increased, the QoL decreased in correlation with this. This condition did not indicate any difference between thalamic and extrathalamic groups. It is a fact that central pain has a negative effect on the QoL; however, it is possible to increase theQoLof patients with a correct diagnosis and treatment.

In many studies, it has beendemonstrated that as CPSP affects the QoL, it also affects sleep quality. In the study conducted by Raffaeli et al. (14) with 601 patients with stroke with CPSP, half (50%) of the interviewed pain population could sleep in a restful way, 28.8% had some difficulty, and 21.8% could not sleep at all. A total of 199 patients were examined to identify sleep disorders in a 3-month period after cerebral infarct, and the nighttime sleep quality and excessive daytime sleepiness of the patients were evaluated by the Verran-Snyder-Halpernsleepscale and ESS. Bad nighttime sleep was reported in 88 (44.2%) patients, and excessive daytime sleepiness was reported in 28 (14.4%) patients. There was no significant relationship between post-stroke pain and post-stroke sleep disorders (15). In a study conducted with 3732 individuals aged ≥65 years, as a result of the assessment using the Pittsburgh SleepQuality Index in cases with subjective bodily pain, it was observed that those with serious and very serious bodily pain had the highest values; moreover, higher values were identified in the group with mild bodily pain thanin the group without any bodily pain. It is known that painful syndromes cause sleep disorders. CPSP is one of the serious painful syndromes (16).

In our study, there was no statistically significant result between the groups with and without CPSP in terms of bad nighttime sleep and excessive daytime sleepiness. However, it was identified in the group with CPSP that the nighttime sleep quality decreased as the VAS score increased (p≤0.001). The nighttime sleep quality was worse in the group with LANSS 12 in the same group (p≤0.002). In the assessment conducted according to excessive daytime sleepiness, the rate was higher in the group with LANSS 12 and as the VAS score increased (p≤0.018 and p≤0.001, respectively).

In general, it is known that painful syndromes cause sleep disorders. CPSP is one of the serious painful syndromes (16). These sleep disorders developing in patients with CPSP further deteriorate the QoL of patients.

Sleep disorders and functional disorders, such as depression and anxiety, are the important comorbid conditions accompanying CPSP (11). In our study, depression and anxiety were found at similar rates between the groups with and without CPSP; however, in the assessment using the LANSS and VAS in the group with CPSP, it was identified that the anxiety and depression levels increased as the level of pain increased. In other words, pain appears as a condition increasing depression and anxiety and deteriorating the QoL in this regard. The importance of the diagnosis and treatment

of these diseases accompanying CPSP has beenemphasized once again.

Conclusion

Central post-stroke pain is a frequently observed syndrome among post-stroke pains.In addition to our study and in many studies, it has been shown that it has a remarkable negative effect on the QoL of patients with stroke. It is important for the literature to emphasize that it is possible to improve the comfort of patients with a correct diagnosis and treatment of sleep disorders, depression, and anxiety accompanying CPSP.

Ethics Committee Approval: Ethics Committee approval was received for this study from the Ethics Committee of Sakarya University (28.02.2017-71522473/050.01.04/67).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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Original Article

The Efficacy of Mid-Urethral Sling Procedures, Transobturator Tape and Tension-Free Vaginal Tape in the Treatment of Female Stress Urinary Incontinence: A Comparative Study of Twelve Months Follow-Up After Surgery

Mustafa Aydın[1], Tuna Karatağ[2], Mustafa Kadıhasanoğlu[3], Orhan Tanrıverdi[4], Çiğdem Döndar[5], Muammer Kendirci[4]

Abstract

Objective: The aim of the study is to compare the efficacy and safety of tension-free vaginal tape (TVT) and transobturator tape (TOT) procedures in the treatment of female stress urinary incontinence (SUI) in a two-arm study with a 1-year follow-up.

Methods: The single-center retrospective study included 73 patients who underwent TVT or TOT between January 2006 and October 2012. Patients who had neurological disease or required surgical repair of cystocele or rectocele were excluded from the study. The primary outcome was treatment efficacy and safety at 12 months, defined by overactive bladder (OAB) scores and self-reported absence of symptoms. For comparisons between the groups, chi-square and Student-t tests were used.

Results: Among the women included in the analysis, 52 patients underwent TVT and 21 underwent TOT. The mean age of the patients was 48.9 years in the TOT group and 46.2 years in the TVT group (p=0.713). The patient satisfaction rate was found to be 82.5% in the TOT group and 84.6% in the TVT group (p=0.917); complete dryness rates were similar in both groups (57.5% vs. 58.3%, p=0.817). There was a significant decrease in using pads in both groups, and OAB scores also showed a statistically significant decrease.

Conclusion: Tension-free vaginal tape and TOT have similar efficacy as a minimally invasive technique for the treatment of female SUI. The symptoms of urgency urinary incontinence can also be reduced in parallel with OAB scores.

Keywords: Stress urinary incontinence, mid-urethral sling, tension-free vaginal tape, transobturator tape, follow-up, treatment outcome

Introduction

Although urinary incontinence (UI) is not a life-threatening problem, it is a public health condition that affects approximately 35%-50% of women worldwide with physical, psychological, social, and economic implications (1, 2). UI is also a major factor contributing to nursing home admission and hospital readmission among older women with comorbid conditions such as diabetes mellitus and hypertension (3, 4). Moreover, the total economic cost of urinary incontinence annually is estimated to be $19.5 billion in the United States (5) and £740 million in the United Kingdom (6).

Stress UI (SUI) is defined as a condition of involuntary leakage of urine upon effort, exertion, sneezing, or coughing or as the inability to hold urine within the bladder at times other than during voluntary micturition (7). SUI is the most common type of UI, and its prevalence ranges between 8% and 33% (8). The most common risk factors for SUI are female gender, parity, obstetric history, chronic cough, advanced age, estrogen levels, obesity, and pelvic surgery history (9). The treatment options of SUI include lifestyle changes such as weight loss, pharmacotherapy, pelvic floor muscle training, electrical stimulation, and urethral bulking agent injection. Surgical therapy is often offered to women who do not benefit from conservative treatment option (10). Mid-urethral sling [transobturator tape (TOT) and tension-free vaginal tape (TVT)] procedures are a gold standard in the treatment of female SUI (11, 12).

The objective of this study was to evaluate patient-reported outcome at 12 months after TOT and TVT for SUI in a retrospective manner and compare complication rates of both procedures.

Methods

A retrospective analysis was performed in 73 patients who underwent mid-urethral sling procedure in Şişli Etfal Training and Research Hospital between January 2006 and October 2012. We included a total of 52 TOT and 21 TVT cases in the study, and patients with neurological disease that might affect bladder function and those who required surgical repair of cystocele or rectocele were excluded from the study. The study was conducted in compliance with recognized inter-

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national standards, including the principles of the Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", (amended in October 2013) for research involving human subjects, and each patient's written, undersigned informed consent was obtained for the use of their information.

The study compared surgical treatment of SUI with either TOT (Boston Scientific; Natick, MA, USA) or TVT (Gynecare, Ethicon Inc.; Johnson & Johnson, Somerville, NJ, USA). Preoperative evaluation of the patients included a detailed urological and gynecological history and a physical examination. Data on age, body mass index (BMI), parity, gravidity, mode of delivery, complications during delivery, menopausal status, postmenopausal hormone therapy and anticholinergic medication usage preoperatively, pad usage, intraoperative complications, and follow-up duration were collected. All patients were examined in the lithotomy and standing positions at maximal bladder capacity, including a standardized cough test to assessment of the type UI. An ultrasonography was performed to determine the fullness of the bladder before the cough test and possible urinary retention. The primary efficacy end point was evaluated with an eight-item overactive bladder (OAB) questionnaire (OAB-V8). OAB-V8 is a self-administered form of OAB questionnaire, containing eight questions related to irritating symptoms such as frequency, urgency, urgency UI, or nocturia (13). A score of 8 indicates a positive diagnosis. A score <8 suggests that the OAB diagnosis may be either questionable or absent. The terms used in this questionnaire are given in detail: frequency (eight or more micturitions per day), nocturia (waking at night with the need to void two or more times), urgency (a sudden urge to pass urine), and urgency UI (involuntary loss of urine with urgency).

The success of procedures, defined as having no postoperative SUI at 12 months, was assessed subjectively and objectively. Objective success was determined by a cough stress test with a naturally filled bladder during pelvic examination in the outpatient clinic. Subjective success was determined by patient-reported outcome as the absence of any leakage with coughing, laughing, sneezing, or exertion. At 12 months postoperatively, the patients were questioned about their satisfaction with the operation. The patients were also asked whether they leak urine. In the study, the primary outcome measure was cure of SUI. Secondary outcome measures included perioperative and postoperative complications.

Statistical Analysis

The statistical analyses were performed using Statistical Package for Social Sciences version 20.0 (IBM Corp.; Armonk, NY, USA) software. The Student-*t* test was used for testing the relationship between continuous variables and the chi-square test was used for testing nominal variables. Wilcoxon sum rank test was used to compare statistical significance between preoperative and postoperative OAB scores and daily pad usage. A $p<0.05$ was considered significant.

Table 1. Demographic characteristics and primary outcomes of the patients

	TVT (n: 21)	TOT (n: 52)	p
Age (years)	46.2±7.8	48.9±8.2	0.713
BMI (kg/m^2)	29.2±5.1	28.9±4.6	0.468
Complete dryness rate (%)	58.3	57.5	0.817
Satisfaction rate (%)	84.6	82.5	0.917

BMI: body mass index; TVT: tension-free vaginal tape; TOT: transobturator tape

Results

The mean age of the patients was 48.9 years in the TOT group and 46.2 years in the TVT group, with their age ranging from 26 to 72 years (p=0.713; Table 1). There was no statistically significant difference in terms of BMI between the two groups (p=0.468). Baseline data for parity, gravidity, mode of delivery, complicated delivery, menopausal status, preoperative use of postmenopausal hormone therapy, and anticholinergic medications were similar in both groups.

We achieved a cure rate of 57.5% in the TOT group and 58.3% in the TVT group, whereas patient satisfaction rates were 82.5% in the TOT group and 84.6% in the TVT group at the end of the first year postoperatively. Moreover, there were no statistically significant differences in either cure or satisfaction rates between the two groups (p=0.817 and p=0.917). There was a statistically significant decrease in the number of pads used daily in the TOT and TVT groups ($p<0.05$). Moreover, there was a statistically significant decrease in OAB scores in both groups ($p<0.05$). Secondary outcomes are summarized in Table 2.

Regarding complications, we observed only bladder perforation as an intraoperative complication in one case during control cystoscopy, whereas no intraoperative complication was observed in the TOT group. This case was managed by urethral catheterization for a while without requiring any surgical repair. In the early postoperative period, mesh erosions were seen in three patients. These patients underwent a second-look surgery for mesh revision. Meanwhile, urinary retention observed in one case in the TOT group and in one case in the TVT group on postoperative day two (Table 3). These two patients were sufficiently treated with anti-inflammatory drugs and urethral catheterization for a while.

Discussion

Following introduction of TVT in 1996, minimally invasive sling procedures have become a choice of treatment for female UI (12). Thereafter, in 2001, another minimally invasive procedure, TOT, was developed because of increased bladder perforation complications associated with TVT (14). However, the success and complication rates of TVT and TOT procedures have been a subject of debate in several studies. Enzelsberger et al. (15) reported that success rates for TVT and TOT were 86% and 84%, respectively, as compared with the objective cure that was defined as the absence of UI in a negative stress test and urodynamic studies at the end of a follow-up of 15 months. In another comparative study, Porena et al. (16) reported that objective cure rates for TVT and TOT were 70.2% and 78.6%, respectively, at the end of 13.4-month follow-up; however, the objective cure rate was not defined in their study.

Although complications, such as necrotizing fasciitis, ischiorectal abscess, bowel injury, and urethrovaginal fistula, have been reported, they were thought to be in a very limited number when the randomized controlled trials were evaluated (17). Herein, we highlight that we have also observed no major complications such as those mentioned above. However, we observed a case of blad-

Table 2. Secondary outcomes of the study

	Pre-op OAB score	Post-op OAB score*	p	Pre-op daily pad usage	Post-op daily pad usage*	p
TVT	27.3±7.9	9.8±6.1	p<0.05	4.9±4.2	0.7±1.2	p<0.05
TOT	25±8.9	11.4±7.9	p<0.05	4.1±2.9	0.95±1.5	p<0.05
All patients	25.6±8.7	11±7.5	p<0.05	4.3±3.3	0.9±1.4	p<0.05

*at the end of first year TVT: tension-free vaginal tape; TOT: transobturator tape; OAB: overactive bladder

Table 3. Complications rates of groups

	TOT	TVT	p
Urinary retention (n)	1	2	0.197
Bladder perforation (n)	-	1	0.288
Mesh erosion (n)	3	-	0.355

TVT: tension-free vaginal tape; TOT: transobturator tape

der perforation without requiring surgical repair in the TVT group, whereas no intraoperative complication was observed in the TOT group. Mesh erosion occurred in three patients in the early postoperative period, and these patients underwent mesh revision.

Regarding the meta-analysis of randomized controlled trials, complication rates were reported to be lower in TOT with regard to bladder perforation and hematoma in two systematic reviews (17, 18). However, no significant differences with respect to erosion rate and OAB scores were found in these meta-analyses. These meta-analyses presented the result of a short-term follow-up because of the heterogeneity of outcome measures and the lack of the randomized controlled studies with long-term follow-up. Furthermore, it was also highlighted that many studies had limited methodological and clinical qualities in these trials. Therefore, good quality and adequately powered trials with long-term follow-up are required. In a meta-analysis, Novara et al. (19) reported that mid-urethral and pubovaginal slings had similar efficiency in the treatment of SUI, although pubovaginal slings were associated with storage lower urinary tract symptoms Moreover, they emphasized that bladder perforations were less common in pubovaginal sling procedures. The Cochrane Review also demonstrated that minimally invasive suburethral sling procedures were as effective as traditional surgical approaches in short-term, and there was no clear evidence to suggest that either of the procedures was preferable to the other (16). Although the maximum follow-up time was 36 months up to the present, one of the common points of this meta-analysis was the lack of long-term follow-up studies (19). A recently published meta-analysis involving the long-term (≥5 years) results of TVT and TOT demonstrated that objective and subjective cumulative cure rates for TVT and TOT were 61.6% and 76.5% and 64.4% (95% CI: 61.4-67.4) and 81.3% (95% CI: 78.9-83.7), respectively, and both TVT and TOT are associated with similar long-term objectives (p=0.62) and subjective (p=0.58) cure rates. In addition, this study also shows that there was no significant difference in the complication rates for all comparisons: TVT versus TOT (p=0.40) (20).

Despite the nonavailability of long-term follow-up studies comparing the cost-effectiveness of sling procedures till date, TOT was found to be a better alternative to TVT in terms of cost-effectiveness at the end of a 12-month follow-up period (21). Although our present study does not include a comparison of economic evaluation, TVT might be costlier if a routine control cystoscopy is performed in all TVT procedures (22). Therefore, TOT is an economic alternative to TVT, because of the lack of a routine cystoscopy after the operation to check the bladder injuries.

The retrospective nature and the small sample size are the principal limitations of the present study. Moreover, the evaluation of patients with OAB-V8 is another limitation of the study. The evaluation of severity of SUI with a validated questionnaire such as the modified Incontinence Impact Questionnaire and the Urogenital Distress Inventory may be helpful in clinical assessment. Despite these facts, we believe that we have contributed to the literature on female SUI in terms of achieving a decrease in OAB scores in both TOT and TVT procedures.

Conclusion

Our clinical outcomes demonstrate that TOT and TVT have similar success rates. Although the present study was not a comparison with traditional colposuspension methods, either TOT or TVT can be performed safely for the treatment of female SUI as a minimally invasive approach. In addition, the symptoms of urgency UI can be relieved by these surgical interventions along with decreasing OAB scores.

Ethics Committee Approval: Authors declared that the research was conducted according to the principles of the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", (amended in October 2013).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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Early-Term Pain Management After Laparoscopic Total Extraperitoneal Inguinal Hernia Repair

Laparoskopik Total Ekstraperitoneal İnguinal Fıtık Onarımı Sonrası Erken Dönem Ağrı Kontrolü

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Abstract / Öz

Introduction: The aim of the present study was to determine if the use of local anesthesia by different ways would reduce postoperative pain after laparoscopic total extraperitoneal inguinal hernia repair.

Methods: Thirty patients were randomly divided into three groups. Upon completion of the prolene mesh repair, Group 1 (mean age: 45.8±8.6 years) received 5 cc levobupivacaine installed into the preperitoneal space every 6 h for 24 h via a catheter placed to the preperitoneal space. In Group 2 (mean age: 44.9±11.5 years), levobupivacaine-soaked spongostan was placed into the preperitoneal space after the placement of the prolene mesh. Group 3 (mean age: 45.4±10.7 years) was determined as the control group and received 75 mg diclofenac sodium after inguinal hernia repair. Pain was assessed by using a Visual Analog Scale of 1 (minimal pain) to 10 (worst pain) at fixed time intervals of 0, 6, 12, 18, and 24 h after surgery.

Results: The trend of postoperative pain in 0, 6, and 18 h of Group 1 was significantly lower than that of Group 3 ($p<0.001$). There was no significant difference between Group 1 and Group 3 in terms of postoperative 12 ($p=0.012$) and 24 ($p=0.037$) hour pain levels. The trend of postoperative pain in 0, 6, 12, 18, and 24 h of Group 2 was lower than that of the other two groups ($p<0.001$).

Conclusion: Placement of bupivacaine-soaked spongostan into the preperitoneal space resulted in least postoperative pain between the three groups. The application of placement of bupivacaine-soaked spongostan is a safe and effective method.

Keywords: Inguinal hernia, laparoscopic repair, postoperative pain, local anesthesia

Amaç: Bu çalışmanın amacı, laparoskopik total ekstraperitoneal fıtık onarımı sonrası gelişen erken dönem ağrıya yönelik farklı yöntemler ile uygulanan lokal anestezik ilacın etkinliğini ortaya koymaktır.

Yöntemler: Çalışmaya tek taraflı laparoskopik total ekstraperitoneal inguinal herni onarımı uygulanan 30 hasta dahil edildi. Hastalar randomize olarak 10' ar kişilik üç ayrı gruba ayrıldı. Yaş ortalaması 45,8±8,6 olan 1. gruba, fıtık onarımı sonrasında, operasyon sahasına, trokar giriş yerinden laparoskopik olarak yerleştirilen epidural (perifix) kateter yardımı ile ameliyat sonrası 0. saatten başlamak üzere 6 saat ara ile 24 saat süresince, 5cc levobupivakain hidroklorür uygulandı. Yaş ortalaması 44,9±11,5 olan 2. gruba, yapılan fıtık onarımı sonrasında, ameliyat sahasına vücut içerisinde eriyebilen bir materyal olan spongostan, dilimlenip hazırlanarak, levobupivakaine hidroklorür emdirilmiş olarak yerleştirildi. Yaş ortalaması 45,4±10,7 olan 3. grup ise kontrol hasta grubu olup, hastalara nonsteroid antiinflamatuvar (Diklofenak Sodyum 75mg intramuskuler) tedavisi verildi. Yapılan işlemler sonrasında hastalar 24 saat süresince (0, 6, 12, 18 ve 24. saatlerde) ağrı yönünden vizüel analog skala ile (en düşük 1, en yüksek 10 puan) değerlendirildi.

Bulgular: Gruplar arasında ağrı açısından visual analog scale (VAS) ile yapılan değerlendirme sonucunda, kateter yolu ile levopubivakaine uygulanan grup ile diklofenak sodyum tedavisi verilen grup arasında 0, 6, 18. saatlerde anlamlı fark ($p<0,001$) saptanırken, 12 ($p=0,012$) ve 24. ($p=0,037$) saatlerde fark saptanmadı. Levobupivakain emdirilmiş spongostan uygulanan 2. grup ile diğer iki grup karşılaştırıldığında ise ağrı değerlerinin diğer iki gruba kıyasla, değerlendirmenin yapıldığı tüm saatlerde anlamlı olarak düşük olduğu görüldü ($p<0,001$).

Sonuç: Ameliyat sonrası kateter yolu ile verilen aralıklı levobupivakain hidroklorür infüzyon tedavisinin, ameliyat sonrası gelişen erken dönem ağrıyı azaltmasına rağmen ağrı kontrolü açısından yeterli olmadığı düşüncesindeyiz. Levobupivakain hidroklorür emdirilmiş spongostanın preperitoneal alana uygulanması yönteminin, diğer iki tedavi yöntemine göre ameliyat sonrası gelişen erken dönem ağrı üzerine anlamlı derecede etkili ve güvenli olduğu görüldü.

Anahtar Kelimeler: İnguinal fıtık, laparoskopik onarım, postoperatif ağrı, lokal anestezik

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Introduction

Defined as an abnormal prolapse of a tissue or organ through a defect in the overlying wall, hernia can involve any body site although it most commonly involves the abdominal wall, especially the inguinal region. Advances in hernia repair coinciding with the history of surgery have gained momentum with the description of the first true hernia repair by Eduardo Bassini (1). This was followed by the introduction of tension-free hernia repair and, after 1990s, laparoscopic hernia repair techniques. Today, total extraperitoneal (TEP) hernia repair, a laparoscopic technique, is used in many centers worldwide. Pain is one of the major complications of hernia surgery. Multiple recently performed studies have used various methods to control early postoperative pain (2-4). The aim of the present study was to investigate the efficacy of a local anesthetic and some other methods considered to prolong the duration of action of local anesthesia in early postoperative pain control after laparoscopic TEP hernia repair.

Methods

Among patients who presented to our clinic, 30 male patients diagnosed with unilateral inguinal hernia who met the below specified study inclusion criteria were enrolled in the study. Patients were randomized into three groups, and all were operated by laparoscopic unilateral TEP inguinal hernia repair under general anesthesia in the operation theater. The present study was performed according to the framework of the Declaration of Helsinki. Postoperative pain was rated by the Visual Analog Scale (VAS) for 24 h postoperatively. Informed consent was obtained from the patients who participated in the study. Study data were analyzed using the Statistical Package for Social Sciences for Windows ver. 11.5® software package (SPSS Inc.; Chicago, IL, USA).

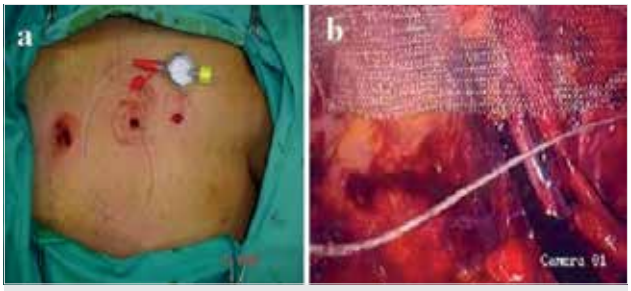

Figure 1. a, b. Catheter placement to the preperitoneal area after hernia repair

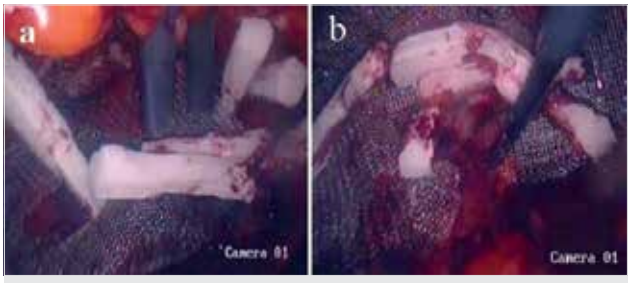

Figure 2. a, b. Spongostan placement after hernia repair

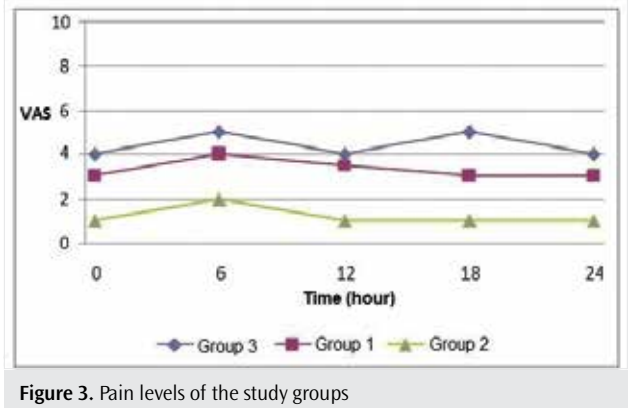

Figure 3. Pain levels of the study groups

Inclusion criteria were as follows:
1. Aged 20-60 years old,
2. Being in the American Society of Anesthesiologists (ASA) I-II risk group,
3. Having unilateral inguinal hernia,
4. Providing consent to participate in the study.

Exclusion criteria were as follows:
1. Having known allergy to one of the study medications,
2. Having morbid obesity (body mass index >35 kg/m^2),
3. Having current renal, hepatic, cardiovascular, and neuromuscular disorders; atrioventricular conduction disorder; or bleeding diathesis,
4. Having a history of opioid and analgesic abuse and using opioid, non-steroidal anti-inflammatory medications,
5. Having a history of inguinal hernia or abdominal surgery,
6. Being in the ASA III risk group,
7. Having a history of surgery to the Retzius space.

Levobupivacaine

Levobupivacaine (Chirocaine; Abbott Inc., Norway) is a novel member of an amino acid class of local anesthesia. Local anesthesia block the production and conduction of nerve impulses by raising the electrical excitation threshold of the nerves, slowing nerve impulses and reducing the rate of the increase of the action potential. In general, anesthesia propagation is correlated with diameter, myelinization, and conduction rate of the involved nerves. Epidural anesthesia, local infiltration can be applied with the purpose of peribulbar block in oral and ophthalmological surgery. The dose of administration for local infiltration is 1.25-2.5 mg/kg, with a maximum dose of 150 mg.

Spongostan

Spongostan (absorbable hemostatic gelatin sponge; Ethicon Inc., USA) is a sterile, water insoluble, shapeable, white, porous gelatin sponge designed for applying hemostasis on the bleeding surface. It can be administered dry or impregnated with isotonic saline.

Rating of postoperative pain

Rating of pain provides important clues for baseline severity, perception quality, and temporal course of pain. Rating these variables allows differential diagnosis for pain etiology. It is also necessary to determine the most efficacious pain treatment and compare different treatment methods. It involves the use of VAS, which is a numerical scale. The most commonly used form of VAS contains a vertical or horizontal line anchored by the two verbal descriptors, one for each symptom extreme, that is, "no pain" and "unbearable pain." Patients mark the severity of their pain on this 10 cm line. The distance in centimeters between the marked point and the point for the lowest pain on the VAS is recorded in digits from 1 to 10 as the numerical measure of pain severity.

Procedures applied to the study participants

Our study included 30 patients with unilateral inguinal hernia meeting the criteria specified above. Patients were randomized into three groups, each with 10 patients. All patients were operated by laparoscopic TEP hernia repair operation using a unilateral graft (15×10 cm) and three trocars (one is 10 mm and two are 5 mm). All operations were performed under general anesthesia at the operating theater.

Group 1: After hernia repair, when the operative field was still sterile, 5 cc levobupivacaine hydrochloride mixed with 5 cc isotonic saline was applied to the operative field with the aid of an epidural (Perifix) catheter laparoscopically placed via the trocar entry site (Fig. 1a, b). Then, it was re-applied every 6 h beginning from hour 0 for 24 h. The catheter was removed after the procedure at postoperative day 1.

Group 2: A 7×5×1 cm spongostan, a material that is soluble in the human body and used as a hemostat during the operation, was sliced, impregnated with levobupivacaine, and placed on the operative field (Fig. 2a, b). Spongostan was adjusted to cover the entire width of the operative field and impregnated with levobupivacaine hydrochloride in a way that the maximum dose of the latter would not exceed 20 ml.

Group 3: The control group was administered a non-steroidal anti-inflammatory drug (diclofenac sodium 1 mg/kg via intramuscular (IM) route).

Patients were monitored for early postoperative pain for 24 h after the operation. Pain severity was rated by the VAS (0-10 points).

Table 1. Distribution of the study groups by age and history of comorbidity

Variables	Group 1	Group 2	Group 3	p
Age (years)	45.8±8.6	44.9±11.5	45.4±10.7	0.981
Comorbidity	2 (20%)	3 (30%)	4 (40%)	0.617

Table 2. Distribution of the study groups by frequency of hernia types

Hernia type	Group 1	Group 2	Group 3
Direct	1 (10%)	1 (10%)	1 (10%)
Indirect	8 (80%)	8 (80%)	9 (90%)
Direct+indirect	1 (10%)	1 (10%)	-

Table 3. VAS levels of the study groups by follow-up time points (Group 1-3)

Variables	Group 1	Group 3	p
0 h	3 (2-4)	4 (4-5)	<0.001
6 h	4 (3-5)	5 (3-6)	<0.001
12 h	3.5 (3-5)	4 (4-6)	0.012
18 h	3 (3-5)	5 (4-7)	<0.001
24 h	3 (2-5)	4 (3-5)	0.037

Group 1: Patient group in which levobupivacaine was administered via a catheter.
Group 3: Patient group in which diclofenac sodium was administered.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences for Windows ver. 11.5® (SPSS Inc.; Chicago, IL, USA) software package. Descriptive variables were expressed as mean±standard deviation for age, median (minimum-maximum) for VAS, and number (percentage, %) for nominal variables.

Differences between the mean ages of the groups were tested using the one-way analysis of variance test. Nominal variables were compared using the Pearson's chi-square test. A p-value <0.05 was accepted as statistically significant.

Differences between the VAS levels at each follow-up time point was analyzed using the Kruskal-Wallis test with Bonferroni correction. A non-parametric multiple comparison test was used to determine which groups were contributing a significant difference. A p<0.01 was accepted as statistically significant for Bonferroni correction.

Differences between the VAS levels of each group at different time points were tested using the Wilcoxon signed-rank test with Bonferroni correction. A p-value <0.0017 was accepted as statistically significant for Bonferroni correction.

Results

A total of 30 patients were enrolled in the present study, including 10 control group patients with a mean age of 45.4±10.7 years who were administered diclofenac sodium IM, 10 patients with a mean age of 45.8±8.6 years who were administered levobupivacaine via a catheter placed intraoperatively, and 10 patients with a mean age of 44.9±11.5 years in whom a spongostan impregnated with levobupivacaine was placed on the preperitoneal area intraoperatively. None of the enrolled subjects had any complications during or after the procedure. All procedures were performed using the laparoscopic approach. In Group 1, one patient had hypertension, and one patient had hypertension and asthma. In Group 2, two patients had hypertension, and one patient had diabetes mellitus. In Group 3, one patient had cataract, two patients had diabetes mellitus, and one patient had hypertension (Table 1). There were no significant differences between the groups with respect to age and comorbidities. There were no significant differences between the groups with respect to hernia types (Table 2).

According to Bonferroni correction, the VAS levels at different time points were not significantly different within each group (p>0.0017) (Tables 3-5).

Group 1 had significantly lower pain severity than Group 3 at 0, 6, and 18 h (p<0.001). Although Group 1 had lower pain severity than Group 3 at 12 and 24 h, the difference lost statistical significance in Bonferroni correction (p=0.012 and p=0.037, respectively).

Group 2 had significantly lower pain severity than Group 3 at 0, 6, 12, 18, and 24 h (p<0.001).

Group 2 had significantly lower pain severity than Group 1 at 0, 6, 12, 18, and 24 h (p<0.001).

Table 4. VAS levels of the study groups by follow-up time points (Group 2-3)

Variables	Group 2	Group 3	p
0 h	1 (1-3)	4 (4-5)	<0.001
6 h	2 (1-2)	5 (3-6)	<0.001
12 h	1 (1-3)	4 (4-6)	<0.001
18 h	1 (1-2)	5 (4-7)	<0.001
24 h	1 (1-2)	4 (3-5)	<0.001

Group 2: Patient group in which spongostan impregnated with levobupivacaine was placed
Group 3: Patient group in which diclofenac sodium was administered

Table 5. VAS levels of the study groups by follow-up time points (Group 1-2)

Variables	Group 1	Group 2	p
0 h	3 (2-4)	1 (1-3)	<0.001
6 h	4 (3-5)	2 (1-2)	<0.001
12 h	3.5 (3-5)	1 (1-3)	<0.001
18 h	3 (3-5)	1 (1-2)	<0.001
24 h	3 (2-5)	1 (1-2)	<0.001

Group 1: Patient group in which levobupivacaine was administered via a catheter
Group 2: Patient group in which spongostan impregnated with levobupivacaine was placed

Discussion

Today, inguinal hernia repair continues to be one of the most commonly performed procedures by general surgeons. Complications, such as bleeding, recurrence, pseudorecurrence, orchitis, organ injuries, wound infection, seroma, osteitis pubis, and pain, may occur after both open and laparoscopic hernia repair. Pain, one of the chief problems after hernia surgery, may occur early after surgery or persists chronically (5, 6). As it is a subjective symptom, previous studies have provided a wide range of figures and descriptions for its prevalence, quality, and severity. Recent studies have shown that the incidence of postoperative pain ranges between 0% and 53% (7). In addition to analgesic medications administered via IM, intravenous, oral, or rectal route, many different treatment methods to relieve early postoperative pain after inguinal hernia repair have been described (8-15).

LeBlanc et al. (16) investigated the effect of postoperative local anesthetic infusion on pain severity in patients undergoing unilateral tension-free open hernia repair. Their study involved 52 patients in whom a catheter was placed between the patch and the fascia, and bupivacaine was infused for 48 h after hernia repair with a standard prolene patch; pain severity was rated with the aid of the VAS at the postoperative period. The other group was administered isotonic solution infusion. Local anesthetic infusion significantly lowered pain severity and reduced the need for analgesic drugs.

Similar to our study, Suvikapakornkul et al. (17) explored the efficacy of preperitoneal bupivacaine for pain control after laparoscopic inguinal hernia repair. Similarly, they excluded patients with bleeding diathesis, an ASA III risk group, cardiac or respiratory disorders precluding general anesthesia, drug or alcohol addiction, history of surgery to the Retzius space, or morbid obesity. They randomized 40 patients into two groups to receive either bupivacaine or isotonic solution after a TEP procedure performed by a single surgeon. After placing one 12 mm and two 5 mm trocars and performing dissections, they placed a 15×12 or 15×15 cm patch on the operative field and fixated it with an endotucker. Then, they administered a single dose of 40 ml bupivacaine or isotonic saline to the preperitoneal area and monitored patients using the VAS for 24 h postoperatively. Similar to our results, they found lower postoperative pain scores in the intervention group than in the control group, with borderline significant difference. However, they found no significant difference between the groups with respect to analgesic requirement at the postoperative period. Our study also revealed a lower postoperative pain severity in patients who were administered local anesthesia via a catheter than in the control group. In contrast to the study by Suvikapakornkul et al. (17), our study used a local anesthetic administered via a catheter as intermittent infusions during postoperative monitoring. Group 1 and Group 3 had significantly different results at 1, 6, and 18 h but not at 12 and 24 h.

O'Riordain et al. (18) enrolled 56 male patients with a mean age of 48 years into two groups: one was randomized to receive bupivacaine (0.25%, 40 ml) and adrenaline mixture (n=29) and the other isotonic solution (n=27). Indirect hernia was diagnosed in 40 patients, direct hernia in 13, and trousers hernia in 1. All patients were applied the TEP procedure, and no stapler was used for patch fixation. A 40 ml bupivacaine or isotonic solution was applied to the preperitoneal area. Patients were discharged at 6 h after surgery at the latest, and they were re-evaluated for pain at 1, 7, and 30 days. The bupivacaine group had a significantly lower mean pain severity at 24 h than the isotonic solution group. Additionally, analgesic need was eliminated earlier, and time to return to activities was shortened with bupivacaine. In conclusion, their study stressed the superior efficacy of local anesthesia for adequate pain control.

With the advances of hernia repair techniques and reduced rates of recurrences and other complications, pain has currently become one of the main problems after hernia repair (14,16-18). Previous studies with local anesthesia have suggested that the two most important factors related to adequate pain control are a better local anesthetic diffusion into the operative field and a longer duration of action at a greater dose (16, 19). The first studies using local anesthetic applications to control pain after hernia repair used direct applications of these agents to the operative field, whereas later studies aimed to diffuse the anesthetic agent into the whole operative field with the aid of a catheter (20). This was followed by studies where the anesthetic agent was administered intermittently or as a continuous infusion via a catheter placed intraoperatively, in an attempt to preserve its efficacy for longer periods (16). In an arm of our study, we administered the local anesthetic agent as intermittent infusions via a catheter placed intraoperatively.

Several studies have emphasized the importance of local anesthetic agents acting longer at a more effective dose in the operative field. Several studies used adrenaline, which is reported to prolong diffusion time and, thereby, to reduce toxic effects, to achieve that goal in addition to intermittent or continuous local anesthetic in-

fusion via a catheter (19, 21). We believe that the duration of action of the local anesthetic agent was longer with spongostan used in our study. Placed in a sliced form in a way to cover the entire retroperitoneal area, as well as some anatomic structures that may be well associated with pain, such as spermatic cord and nervous structures, spongostan increased the duration of action and the efficacy of the local anesthetic agent.

The pain score of Group 1 was lower than that of the control group for 24 h. However, local anesthetic treatment administered via a catheter was not associated with a significant benefit at all time points; the difference between pain levels was significant at 0, 6, and 18 h ($p<0.001$) but not at 12 ($p=0.012$) and 24 h ($p=0.037$). Our clinical observations also indicated that levobupivacaine administered via catheter did not provide adequate control of early postoperative pain. Suvikapakornkul et al. (17) also reported that this treatment method reduces pain scores, although at a borderline significance. In their study, the intervention and control groups did not differ significantly with regard to analgesic requirement. Whereas some studies in the medical literature have reported that local anesthetics infused via a catheter are effective for pain control (22), other studies have suggested otherwise (19, 20). We think that local anesthetics administered postoperatively via a catheter were ineffective for pain control at the early postoperative period.

Spongostan, a protein-based, absorbable, hemostatic gelatin sponge, is primarily used to control bleeding in the clinical practice, although it can also be utilized for other purposes. Having the ability to absorb up to 45 times its own weight, spongostan, impregnated with chemotherapeutic, analgesic, and antibiotic medications, has been used in a number of studies (23-26). Ferroli et al. (24) placed spongostan impregnated with mitoxantrone on the operative field following resection of glioblastoma multiforme. Ragusa et al. (25) obtained a higher drug concentration and longer duration of action on the wound surface with spongostan impregnated with an antibiotic than systemic therapy. Kafalı et al. (26) investigated the efficacy of spongostan impregnated with bupivacaine for pain control after episiotomy. They applied lignocaine to episiotomy line in the first group and spongostan impregnated with bupivacaine in conjunction with lignocaine in the second. A total of 110 patients were enrolled in their study, where pain control was rated by the VAS at 0, 1, 1.5, 2, 6, and 24 h postoperatively. They demonstrated that bupivacaine significantly reduces postpartum pain and analgesic requirement. They attributed these results to a significantly prolonged duration of action and increased concentration of the anesthetic agent in the operative field. Similarly, our study demonstrated that spongostan impregnated with a local anesthetic agent was efficacious for pain management. In agreement with Kafalı et al. (26), we suggest that this method increased the duration of action and efficacy of the analgesic treatment.

We found significantly lower pain scores in Group 2 than in Group 3 (control group) ($p<0.001$). In addition, Group 2 demonstrated significantly lower pain levels than Group 1 ($p<0.001$). Although spongostan has been reported to have various clinical uses, it has not been used yet for analgesia in hernia surgery. In this sense, to the best of our knowledge, this is the first study in the medical literature demonstrating the efficacy of this method. We suggest that pain severity was lower in the spongostan group as a result of a longer local anesthetic diffusion time and a longer, high-concentration contact between the local anesthetic agent and peritoneum, spermatic cord, and nervous structures, which are traditionally considered as a source of postoperative pain. We think that the technique of the application of spongostan impregnated with levobupivacaine on the preperitoneal area may effectively reduce early postoperative pain (Figure 3). A reduced early postoperative pain would in turn lead to a lower risk of chronic pain after laparoscopic hernia repair.

Conclusion

We believe that postoperative intermittent levobupivacaine hydrochloride treatment administered via a catheter was not adequate enough for pain control despite reducing early postoperative pain to some extent. The application of spongostan impregnated with levobupivacaine hydrochloride to the preperitoneal area was significantly more effective on early postoperative pain than the application of diclofenac sodium and intermittent levobupivacaine administration via a catheter. We think that this yet untested method is an effective means for reducing early postoperative pain.

Ethics Committee Approval: Authors declared that the research was conducted according to the principles of the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", (amended in October 2013).

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

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Original Investigation

Diagnostic Accuracy of Tru-Cut Biopsy for Soft Tissue Tumors

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Abstract

Objective: Biopsy is an essential step in the diagnosis of patients with soft tissue tumors. Tru-cut biopsy is a simple procedure that could be performed in the outpatient setting under local anesthesia. It is cost-effective and less time consuming compared with the open biopsy. The aim of the present retrospective study is to assess this biopsy technique with regard to the diagnostic accuracy for soft tissue tumors.

Methods: Patients with suspected soft tissue tumors undergoing tru-cut biopsy and a subsequent tumor resection at our hospital between January 2011 and June 2015 were evaluated retrospectively. Tru-cut biopsy results were compared with the final histopathological diagnosis of the resected tissue specimens. All specimens were routinely stained with hematoxylin and eosin. Immunohistochemistry was performed whenever indicated for differential diagnosis. The sensitivity, specificity, and diagnostic accuracy were calculated and compared using Kappa analysis.

Results: Overall, 41 patients were enrolled in the study. The mean age of the patients was 52.8±16.8 years. Of the 41 patients, 36 had primary soft tissue tumors, and 5 were diagnosed with secondary soft tissue tumors. The diagnostic correlation of the tru-cut biopsy and the resected tissue specimen was 89% (Kappa analysis, $p<0.001$), whereas sensitivity and specificity was 93.3% and 90.9%, respectively.

Conclusion: Tru-cut biopsy is a safe and efficient procedure for the diagnosis of soft tissue tumors. In high grade malignant mesenchymal tumors, the biopsy may not reveal the specific type but may be useful by demonstrating malignant features. In contrast, for low grade, benign, and well-differentiated tumors, a preoperative radiological correlation is essential for the final diagnosis. Although tru-cut biopsy is not diagnostic by itself, it is useful in leading the clinician in the diagnostic pathway. Tru-cut biopsy is a safe, minimally invasive, and time- and cost-effective technique for identifying soft tissue tumors.

Keywords: Soft tissue neoplasms, diagnosis, pathology, biopsy, needle

Introduction

Biopsy is a crucial initial diagnostic step for the identification of soft tissue lesions of the musculoskeletal system (1). Benign and small soft tissue lesions, such as cysts, small lipomas, inflammatory nodules, dermatofibroma, or other benign fibrous lesions, do not require surgical treatment. However, for lesions >4 cm, a histological confirmation is necessary for the diagnosis (2). A fine needle aspiration, tru-cut, or open biopsy may have specific advantages and disadvantages with the aim of obtaining a representative tissue sample with minimal trauma leading to a correct surgical approach for a subsequent resection to facilitate limb-sparing procedures (3).

Open biopsy is the conventional gold standard for obtaining tissue samples for the histological diagnosis. The overall diagnostic accuracy of open biopsies ranges from 91% to 96% (4). Complications of biopsy procedures include seroma, hematoma, infection, wound dehiscence with tumor fungation, and fracture. These complications arise more frequently after open or excisional biopsies. The complication rate of percutaneous techniques ranges from 0% to 1%, whereas the rate is between 4% and 19% for surgical open biopsies (1, 4, 5). Inappropriate biopsy incisions may lead to complications in the subsequent surgical resections, and the high complication rate of an open biopsy procedure affects the treatment plan in 8% of the patients (5).

Fine needle aspiration and tru-cut biopsy have been developed as alternatives to surgical biopsy. These minimally invasive techniques can be easily performed under local anesthesia using computerized tomography, magnetic resonance imaging, or ultrasound (1, 6-9). The accuracy of tru-cut biopsy varies between 76% and 99% (6) and is highly sensitive for primary, locally recurrent, or metastatic lesions in various anatomic locations (10). Despite the reported high accuracy of tru-cut biopsy, majority of the authors focus on the fact that the diagnosis of musculoskeletal tumors requires a team approach with the expertise of the orthopedic oncologist, radiologist, and pathologist. The pathologist's interpretation of the biopsy specimen constitutes the most crucial step in the treatment plan (3, 6).

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Cost-effectiveness, avoidance of diagnostic delays, low complication rates, and minimal invasiveness are the advantages of tru-cut biopsy. The potential disadvantages are decreased diagnostic accuracy and possible tumor sampling error. The aim of the present study was to evaluate the accuracy of tru-cut biopsy with regard to its diagnostic yield and to investigate the factors associated with the diagnostic outcomes for distinguishing benign and malignant soft tissue tumors.

Methods

This study was approved by the noninvasive ethical committee of Bağcılar Training and Research Hospital (2015/410). The pathology results of 41 patients (21 females) who underwent a tru-cut biopsy using the tru-cut system (Matek Opticore tru-cut biopsy needle, Matek, İstanbul, Turkey) and received subsequent tumor resection at our hospital, Pathology Department from January 2011 to June 2015 were evaluated retrospectively. All biopsies were performed by an experienced radiologist under ultrasonography. All specimens were fixed with 10% neutral-buffered formalin and processed routinely using hematoxylin and eosin stain for permanent and subsequent immunohistochemical studies performed at the discretion of the interpreting pathologist.

The samples were evaluated by a pathologist experienced in the field of orthopedic oncology and soft tissue pathology. Diagnostic biopsies were analyzed for accuracy with regard to the final histopathological diagnosis of the resected tissue. Reactive and inflammatory soft tissue lesion samples were excluded from the analysis. The final diagnosis was made using the histopathological examination of the resected lesions.

Confirmatory histological specimen reports were available from previous tru-cut histological specimens in one patient presenting with soft tissue masses and from definitive surgical resections. The pathological diagnosis was performed according to the WHO 2013 soft tissue tumor classification system (11). All samples were assessed for the benign or malignant nature of the lesion and for a definite histological diagnosis. Written informed consent was obtained from each patient.

The Statistical Package for Social Sciences software version 22.0 (SPSS Inc.; Chicago, IL, USA) was used for statistical analysis. Tru-cut biopsy and subsequent resection pathology results from were compared. Sensitivity, specificity, and diagnostic compatibility (Kappa analysis) were calculated. A p value less than 0.05 was accepted as statistically significant.

Results

Thirty-six primary and five secondary soft tissue tumors were evaluated in the study based on final diagnosis. The mean age of the patients was 52.8±16.8 years. Tru-cut biopsy was positive for malignancy in 12 patients. Two patients were diagnosed as gastrointestinal stromal tumor (GIST) according to mitosis, location, and size, whereas one patient was diagnosed as high and the other as an intermediate potential risk after the histopathological evaluation of the resected lesions. Two out of four patients with aggressive fibromatosis were misdiagnosed as benign mesenchymal proliferation through tru-cut biopsy (Figure 1). Ten patients had descriptive diagnosis (pieces of lipomatous tissue, connective tissue, skeletal muscle, etc.) through tru-cut biopsy, whereas nine had lipoma and one had xanthoma as the final diagnosis (Figure 2). Of these cases, seven were compatible with lipoma because of preoperative radiological evaluation. One case was equivocal for atypical lipoma through radiological evaluation, and the final diagnosis was fibrolipoma. Another case was evaluated as xanthoma through excisional biopsy, but the previous radiological diagnosis was reported as soft tissue tumor. One patient's diagnosis was vascular neoplasia through tru-cut biopsy, and the final diagnosis was cavernous hemangioma. Two of the primary soft tissue tumors with myxoid features were correctly identified with tru-cut biopsy (Figure 3). We did not observe any significant complications, such as hematoma, infection, or impaired wound healing following tru-cut biopsy.

The tru-cut biopsy and pathological final diagnosis of the resected tissues showed an 89% (Kappa analysis, $p<0.001$) correlation excluding the patients with a descriptive tru-cut biopsy diagnosis. The diagnostic sensitivity was 93.3% and the specificity was 90.9% in our study. The distribution of the lesion sites and diagnoses were highly variable. The patient characteristics, results of tru-cut biopsy, and final diagnosis are shown in Table 1.

Discussion

A tru-cut biopsy helps reveal the tumor structure and cell configuration and is the fundamental step for the diagnosis of soft tissue

Figure 1. Aggressive fibromatosis. Hypocellular tumor composed of bland fibroblasts in the middle and the right sides (case 7; H&E 40X)

Figure 2. This case is diagnosed as a descriptive diagnosis. Skeletal muscle fibers in the left upper and lipomatous tissue fragments in the right and lower quadrant (case 33; H&E 40X)

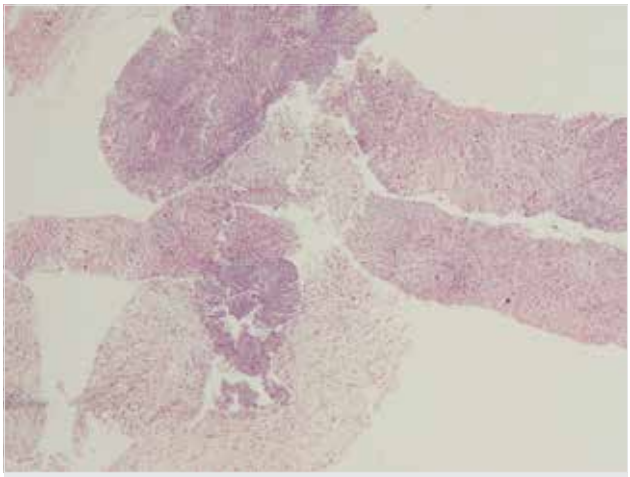

Figure 3. A case of myxofibrosarcoma. Spindle cell mesenchymal tumor containing pleomorphic cells in a myxoid background (case 28; H&E 40X)

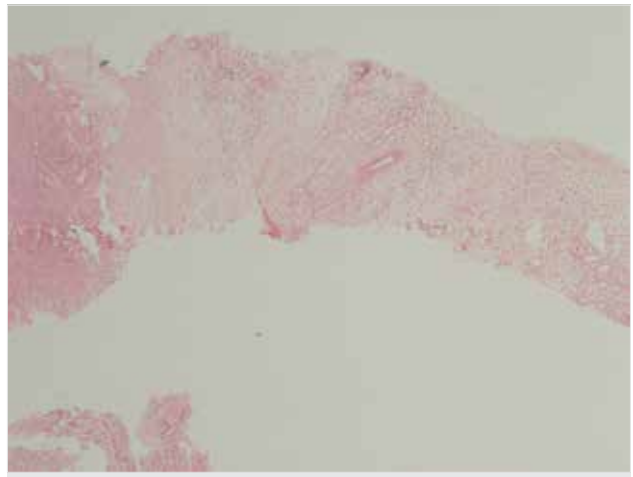

Figure 4. Spindle and focal chronic inflammatory cells in a myxoid and loose stroma. Misdiagnosis is because of sampling from the reactive zone of the adenocarcinoma metastasis (case 40; H&E 40X)

tumors. The diagnostic accuracy of tru-cut biopsy has been reported between 69% and 99% (12). The sensitivity ranges between 82% and 95% with a negative predictive value between 76% and 91% (12, 13). The false negative results or diagnostic inaccuracy may depend upon several factors, such as the lesion type, location, experience of the radiologist, and the pathologist. Each of these factors may have comparable influences on the outcome, and false negative biopsies may deleteriously affect the treatment strategy.

In the present study, the sensitivity was 93.3% and the specificity was 90.9%. These findings correlate well with the recent studies. Cooperation of the orthopedist, radiologist, and pathologist may increase the diagnostic yield of tru-cut biopsy because of sampling error, by identifying the convenient or satisfactory tumor area for biopsy. Besides, tru-cut biopsy is a safe technique with a negligible complication rate ranging from 0% to 7.4% in recent studies (14, 15). We did not observe any significant complications associated with the tru-cut biopsy procedure in our patients.

The treatment of soft tissue tumors has focused on limb-salvage surgery during the last two decades. This approach has privileges of accurate diagnosis compared to invasive procedures for guiding the treatment options. Mankin et al. (5) demonstrated a complication rate of 17% for open musculoskeletal biopsies. The complication rate increased two-fold when the biopsy was performed outside of a primary musculoskeletal treatment institution (5). In a multidisciplinary setting of established treating centers for musculoskeletal neoplasms, nondiagnostic tru-cut biopsy and tru-cut biopsy errors can be identified and addressed appropriately without resultant surgical errors (1). The results of our study indicate that the diagnostic utility of tru-cut biopsy highly depends on the multidisciplinary team work of the radiologist, orthopedic surgeon, and the pathologist.

For malignant lesions where a confirmatory diagnostic tissue and features were unavailable, pathologists used immunohistochemistry to confirm the histopathological interpretation and concordant clinical findings to determine the accuracy of the biopsy diagnosis. The lowest diagnostic accuracy rate was obtained with the needle biopsies for myxoid, infectious, and round cell histology lesions (15, 16). Peer et al. (16) have found inconclusive biopsy results for myxoid schwannoma, myxoid liposarcoma, hemangioendothelioma, and lipomatous lesions. Ogilvie et al. (15) revealed a low diagnostic ratio for myxoid lesions. Various studies have also reported that the tumor subtype is the essential dilemma for the interpretation of tru-cut biopsy specimens (2, 15, 17, 18). In our study group, two primary soft tissue tumors with myxoid features were identified correctly as malignant because they had high-grade features. Sung et al. (18) reported a low diagnostic yield and accuracy in heterogeneous tumors, such as angiosarcoma, liposarcoma, synovial sarcomas, and hemangiomas. A case was diagnosed only as a vascular neoplasia in our study because fibrinous deposits and thrombi were present in most of the vascular lumen. Tru-cut biopsy was also diagnostic in a hemangioendothelioma case. As a result, the total excision specimen should be imperative for an adequate identification of the malignancy potential for vascular neoplasia. Mitsuyoshi et al. (17) reported difficulties in differentiating low-grade liposarcoma from benign lipoma. In our study, a descriptive diagnosis was reported for nine cases of benign lipomatous tumors because of the fragments representing the lesion and the surrounding tissues. Consequently, a radiological evaluation appeared imperative as the initial step for the diagnosis of lipomatous tumors. In contrast, lack of atypical histological features supported the benign diagnosis. Malignant and atypical lipomatous tumors were correctly diagnosed using tru-cut biopsy. Three of these cases were well-differentiated liposarcomas and were diagnosed as atypical lipomatous tumor through tru-cut biopsy. A dedifferentiated liposarcoma had been diagnosed as malignant mesenchymal tumor by tru-cut biopsy. Well-differentiated liposarcomas can be diagnosed using tru-cut biopsy with regard to the presence of atypical cellular features, whereas other high-grade malignant mesenchymal tumors should be included in the differential diagnosis of high-grade liposarcomas.

Multiple factors may affect the quality of the guided tru-cut biopsy. Some of these may be lesion specific, such as the tumor type, size, and location, whereas others may be technical in nature, such as the needle size, needle diameter, experience of the clinician, number, and size of the acquired tissue specimens (16). It is well known that as tumors enlarge they may outgrow their blood supply, leading to necrotic areas within the tumor. Sampling of such necrotic areas may lead to inadequate biopsy specimens. The best biopsy samples are typically localized at the margins of the tumor

Table 1. Characteristics of the patients, lesions, results of the tru-cut biopsy, and final pathological diagnosis

Case #	Age	Diameter	Sex	Tru-cut biopsy diagnosis	Resection-excisional diagnosis
1	56	26 cm	M	Malignant mesenchymal tumor	Dedifferentiated liposarcoma
2	61	U	F	Atypical lipomatous mesenchymal tumor	Liposarcoma (well differentiated)
3	38	12 cm	F	Benign spindle cell proliferation	Aggressive fibromatosis
4	55	8 cm	F	Intramuscular lipoma	Intramuscular lipoma
5	35	21 cm	M	Fibrolipoma	Fibrolipoma
6	83	7,5 cm	F	Pleomorphic malignant tumor	Undifferentiated pleomorphic sarcoma
7	36	5,5 cm	F	Aggressive fibromatosis	Aggressive fibromatosis
8	62	6,5 cm	M	DD	Lipoma
9	38	6,5 cm	M	C with Lipoma	Lipoma
10	54	23 cm	M	Atypical lipomatous tumor	Liposarcoma (well differentiated)
11	74	4 cm	F	Epithelioid hemangioendothelioma	Epithelioid hemangioendothelioma
12	47	15 cm	F	C with Lipoma	Lipoma
13	63	9 cm	M	Lipoma	Lipoma
14	60	5 cm	F	DD	Fibrolipoma
15	27	9,3 cm	F	Benign mesenchymal proliferation	Aggressive fibromatosis
16	83	26 cm	F	Atypical lipomatous tumor	Liposarcoma (well differentiated)
17	46	16 cm	M	Compatible with GIST	GIST
18	24	8 cm	F	Compatible with aggressive fibromatosis	Aggressive fibromatosis
19	54	8 cm	M	DD	Lipoma
20	57	11 cm	M	DD	Angiolipoma
21	79	3,5 cm	F	Schwannoma	Schwannoma
22	68	8 cm	M	GIST	GIST
23	17	22 cm	M	DD	Intramuscular Lipoma
24	66	17 cm	F	DD	Xanthoma
25	55	4 cm	F	Granular cell tumor	Granular cell tumor
26	42	3,5 cm	M	Malignant spindle cell mesenchymal tumor (recurrent tumor)	Clear cell sarcoma
27	50	22 cm	M	DD	Intramuscular Lipoma
28	54	7 cm	M	Myxoid sarcoma	Myxofibrosarcoma
29	46	25 cm	M	DD	Lipoma
30	43	9 cm	M	Compatible with intramuscular lipoma	Intramuscular Lipoma
31	17	4,7 cm	M	Giant cell tendon sheath tumor	Giant cell tendon sheath tumor
32	37	10 cm	F	DD	Fibrolipoma
33	55	9 cm	F	DD	Lipoma
34	15	4 cm	M	Compatible with giant cell tendon sheath tumor	Giant cell tendon sheath tumor
35	73	13 cm	M	C with malignant myxoid mesenchymal tumor	Undifferentiated pleomorphic sarcoma
36	70	7 cm	F	C with vascular neoplasm	Cavernous hemangioma
37	36	5 cm	F	Endometriosis	Endometriosis
38*	66	U	F	Carcinoma	Serous Ca met
39*	57	U	F	Adenocarcinoma met	Endometrioid Ca met
40*	39	17 cm	F	C with malignant myxoid spindle cell neoplasm	Adeno Ca met
41*	66	U	M	Adenocarcinoma met	Colonic adeno Ca met

F: female; M: male; Ca: carcinoma; C: compatible; DD: descriptive diagnosis; U: undetermined; met: metastasis
* Secondary tumors

because of the poor diagnostic quality of central tumor mass. One of the secondary soft tissue tumors was diagnosed as a myxoid spindle cell neoplasm, but the final diagnosis of the resected tumor was an adenocarcinoma metastasis (Figure 4). This erroneous diagnosis was because of the sampling of the reactive zone in the peripheral tumor area by tru-cut biopsy. Besides, metastatic tumors are the most frequent secondary soft tissue tumors as it is in our study. These usually may simulate primary soft tissue tumors both clinically and radiologically.

The essential point for a successful tru-cut biopsy in the diagnosis of soft tissue lesions depends upon a careful algorithmic procedure planning by an experienced orthopedic surgeon or a well-trained interventional radiologist in this field with respect to the suspected lesion, extent of necrosis, and the location for avoiding erroneous results or inadequate biopsy specimens (3). Besides its diagnostic facility, tru-cut biopsy is also useful for the treatment strategy including the surgical approach and the neo-adjuvant chemotherapy. The complication rate is even less than 5% when performed by

experienced clinicians (5, 19). The most frequent complications are hematoma, bleeding, and infection of the biopsy site. We have not observed any of these complications in our patients.

The limitation of the present study is the small sample size. Further studies with larger populations and heterogeneous tumors are needed to identify the real diagnostic utility of the tru-cut biopsy. Tru-cut biopsy usually allows a definitive diagnosis and is useful for further treatment strategy options, but its limitations must also be recognized. Clinicians should be aware of the uncertainties of this technique when descriptive diagnosis or nonspecific tissue specimens are reported (20). Our diagnostic criteria fundamentally depend upon the histomorphological, clinical, and radiological features. Because of the presence of heterogeneous features of the soft tissue tumors and particularly the small size of the biopsy samples, diagnosis of such lesions are reported in large category groups, such as malignant myxoid neoplasm or spindle cell malignant tumor. For the evaluation of heterogeneous areas, multiple biopsy samples are needed for tru-cut biopsy. We were unable to perform genetic studies for these patients because we did not have a molecular pathology laboratory. Immunohistochemical staining was used for the differential diagnosis of these lesions.

Conclusion

Although the sample size was small, tru-cut biopsy for diagnosing in soft tissue tumors proved to be a safe and efficient procedure. The diagnostic accuracy of tru-cut biopsy is high. If the procedure is not diagnostic at the initial step, it is useful for leading the clinician in the correct path for the further diagnostic work-up of the patient. Advantages are low cost, avoidance of diagnostic delay, low complication rates, and the small incisions compared to surgical open biopsy. In contrast, decreased diagnostic accuracy because of possible tumor sampling error and tumor heterogeneity may be considered a disadvantage.

Microscopic features of low-grade and well-differentiated tumors, which have an initial descriptive diagnosis by tru-cut biopsy, should be evaluated with preoperative radiological assessment. In high-grade malignant mesenchymal tumors, the biopsy may not reveal the specific type but is useful by identifying the malignant tumors, thereby leading to a correct treatment plan.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethic Commitee of İstanbul Bağcılar Training and Research Hospital (2015/410).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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