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Comparison of Transobturator Tape and Single Incision Mini-sling Procedures in the Surgical Treatment of Stress Urinary Incontinence in Obese Women: Retrospective Cohort Study

Obez Kadınlardaki Stress Üriner İnkontinansın Cerrahi Tedavisinde Transobturator Bant ve Tek İnsizyon Mini-Sling Prosedürlerinin Karşılaştırılması: Retrospektif Kohort Çalışması

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ABSTRACT Objective: To compare the effectiveness of Transobturator tape (TOT) and Single incision mini-sling (SIMS) procedures in obese women, which are the most preferred methods in the surgical treatment of stres urinary incontinence (SUI). **Material and Methods:** The data of 96 female patients who underwent surgical treatment for SUI with a body mass index ≥35 kg/m^2 in our clinic were retrospectively analyzed. The patients were divided into two groups as TOT (n=54) and SIMS (n=42) according to the surgical procedure applied. The preoperative and postoperative 1-h pad test results, International Consultation on Incontinence Qestionnaire scoring form (ICIQ-SF) and the Incontinence Quality of Life (IQO-L) results of the groups were compared. **Results:** The total objective cure rate was 77.1% according to the 1-h pad test at a median 26 (12-114) month follow-up. While a median increase of 1.70 (1.27-11.92) g weight gain was detected in the TOT group in the postoperative 1-h pad test, it was 1.75 (1.5-66.25) g in the SIMS group (p=0.049). While there was no difference between the groups in terms of improvement in the postoperative ICIQ-SF score (p=0.073), the TOT group was significantly more advantageous than the SIMS group in terms of improvement in the IQO-L score (p=0.003). Median operating time was 40 (30-45) min in the TOT group and 25 (20-30) min in the SIMS group (p<0.001). Subjective and objective cure rates were significantly higher in the TOT group than SIMS group (81.5% vs 61.9% p=0.032 and 85.2% vs 66.7% p=0.032, respectively). C**onclusion:** Despite the longer operating time, the TOT procedure is more advantageous than the SIMS procedure in terms of subjective cure, objective cure and increase in quality of life score in the surgical treatment of SUI in obese women.

Keywords: Urinary incontinence; suburethral slings; complications; quality of life

ÖZET Amaç: Stres üriner inkontinansın [stres urinary incontinence (SUI)] cerrahi tedavisinde en sık tercih edilen yöntemlerden olan transobturator bant [transobturator tape (TOT)] ve tek insizyon mini-sling [Single incision mini-sling (SIMS)] prosedürlerinin obez kadınlardaki etkinliğini inceleyerek, bu 2 yöntemin sonuçlarını karşılaştırmak. **Gereç ve Yöntemler:** Kliniğimizde SUI nedeniyle cerrahi tedavi yaptığımız beden kitle indeksi≥35 kg/m^2 olan toplam 96 kadın hastanın verileri retrospektif olarak incelenmiştir. Hastalar uygulanan cerrahi prosedüre göre TOT (n=54) ve SIMS (n=42) olarak 2 gruba ayrılmıştır. Hastaların preoperatif ve postoperatif 1 saatlik ped testi sonuçları, Uluslararası İnkontinans Konsültasyon Sorgulama Anketi-Kısa Form [International Consultation on Incontinence Qestionnaire scoring form (ICIQ-SF)] ve İnkontinans Yaşam Kalitesi Ölçeği [Incontinence Quality of Life (IQO-L)] skorları belirlenerek gruplar karşılaştırılmıştır. **Bulgular:** Medyan 26 (12-114) aylık takipte 1 saatlik ped testine göre toplam objektif kür oranı %77,1 bulunmuştur. Postoperatif 1 saatlik ped testinde TOT grubunda medyan 1,70 (1,27-11,92) g ağılık artışı olurken SIMS grubunda medyan 1,75 (1,5-66,25) g ağırlık artışı olduğu saptanmıştır (p=0,049). Postoperatif ICIQ-SF skorundaki düzelme bakımından gruplar arasında fark bulunmazken (p=0,073) IQO-L skorundaki düzelme bakımından TOT grubunun SIMS grubundan anlamlı olarak avantajlı olduğu görülmüştür (p=0,003). Medyan operasyon süresinin TOT grubunda 40 (30-45) dk ve SIMS grubunda 25 (20-30) dk olduğu görülmüştür (p<0,001). Subjektif kür ve objektif kür oranları ise TOT grubunda SIMS grubundan anlamlı olarak yüksek bulunmuştur (sırasıyla %81,5 vs %61,9 p=0,032 ve %85,2 vs %66,7 p=0,032). **Sonuç:** Daha uzun operasyon süresine rağmen obez kadınlarda TOT prosedürü SIMS prosedürüne göre subjektif kür, objektif kür ve IQO-L skorundaki iyileşme bakımından daha avantajlıdır.

Anahtar Kelimeler: Üriner inkontinans; subüretral slingler; komplikasyonlar; yaşam kalitesi

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Stress urinary incontinence (SUI) is the most common type of urinary incontinence in premenopausal women and its prevalence has been reported up to 50%.[1] SUI is defined as a type of involuntary urinary incontinence seen during increased intra-abdominal pressure such as coughing, laughing and lifting heavy objects.[2] According to the guidelines of American Urological Association surgical treatment has been considered as the first line treatment of SUI in case of conservative treatment fails.[3] Although various surgical techniques have been developed since the definition of Buch colposuspension, the mid-urethral sling procedures have been taken their place as the first surgical option in many centers.[4] While the retropubic sling [tension-free vaginal tape (TVT-S)] and the transobturator sling [Transobturator tape (TOT)] procedures were most commonly used surgical treatment methods for SUI, a more minimally invasive single incision mini-sling (SIMS) procedure was defined in 2006 in order to reduce the complications of these procedures and postoperative pelvic pain and the successful results of this procedure comparable to other mid-urethral sling procedures have been reported.[5]

Obesity is one of the most important factors that significantly increases the incidence of SUI. It has been stated that every 5-unit increase in body mass index (BMI) increases the risk of SUI incidence by 20-70%.[6] Although, it is known that the obesity negatively affects the success of TOT and TVT-S surgeries to a certain extent, the success rates in studies comparing normal weight women and obese women are similar.[7] However, there are quite a limited number of studies in the literature regarding the success of SIMS surgery in obese women, and confusing and contradictory results have been reported in these studies.[8] Therefore, in this study, we aimed to report our clinical experience in this area by comparing the postoperative success, complication rates and improvement scores in quality of life of the TOT and SIMS groups we performed in obese women.

MATERIAL AND METHODS

STUDY DESIGN AND PREOPERATIVE EVALUATION

Following the ethics committee approval of Health Sciences University Keçiören Training and Research Hospital (Date: 23.02.2021 no: 2012-KAEK-15/2236), the data of 254 female patients who underwent TOT or SIMS surgery for SUI in our clinic between January 2013 and January 2020 were retrospectively analyzed. Patient data were obtained by scanning the electronic records and the patient files of our hospital. A total of 96 obese female patients with a BMI≥35 kg/m^2 and for which we obtained sufficient data were included in the study. The patients were divided into two groups as TOT (n=54) and SIMS (n=42) according to the type of operation performed. Patients with SUI diagnosed with cough test, urodynamic evaluation (UD), and who did not benefit from conservative or medical treatment were included in the study. 1-h pad test was also perfomed to indicate the objective incontinence. Patients with urge urinary incontinence or mixed urinary incontinence components other than SUI were excluded. Preoperative UD was performed to confirm the presence and type of objective incontinence and exclude bladder dysfunction. In addition, patients with intrinsic sphincter dysfunction with valsalva leak point pressure <60 cm H_2O and maximum urethral closing pressure <20 cm H_2O measured by UD were excluded from the study. Other exclusion criteria were; presence of active urinary tract infection, pelvic organ prolapse, neurological disease and the presence of secondary developed neurogenic bladder, presence of urogenital malignancy, history of pelvic radiotherapy and presence of vesicovaginal fistula. Before the operation, detailed histories of all patients were taken and routine blood tests, urine analysis, urine culture, UD (MMS-UD-200), Q-type test and vaginal examinations were performed. While the patients who had previously undergone pelvic surgery for reasons such as cesarean section or hysterectomy were included in the study, but those who had undergone Burch colposuspension or mid-urethral sling surgery were excluded.

Objective SUI was demonstrated by performing preoperative and postoperative 1-h pad tests and cough test in all patients. Objective incontinence was accepted as a weight gain of more than 2 grams per hour in the one-hour pad test and observation of incontinence with a standing stress maneuver.[9] In the preoperative and postoperative period, the use of 1 pads per day due to incontinence was considered as

subjective incontinence, while the absence of daily pad use was considered as a subjective cure. In order to determine the SUI degree and quality of life in the preoperative and postoperative period, International Consultation on Incontinence Qestionnaire scoring form (ICIQ-SF) and the Incontinence Quality of Life (IQO-L) forms were used.[10,11]

SURGICAL PROCEDURES

Before the operation, the patients were informed in detail about the operations and the choice of the operation type was determined by the consensus of the patient and the surgeon.The surgeries were performed under spinal anesthesia by a total of 3 surgeons in both groups. In TOT group, a 16-18 F foley catheter was placed into the bladder, then the hydrodissection was performed with a saline injection into the anterior vaginal wall, beginning from 1-1.5 cm under the urethra longitudinally. Then, a 2-cm longitudinal vaginal incision was made at the midurethral level. Dissection advanced bilaterally until reaching the inferior ischiopubic ramus. A half-moon-shaped TOT needle (I-STOP TOMS, CL Med, France) was used for a transobturator passage. TOT procedures were applied from an external to internal (out-to-in) technique, as described by Delorme (Figure 1).[12] The surgical procedure in SIMS group was performed with an about 1 cm single incision that was made on the anterior vaginal wall beginning from 1.5-2 cm under the midurethral level (Figure 2). A 8-cm long polypropylene sling material was placed on the midurethral area using by a self- attaching needle (Supro-SUI, Klasmed, Turkey) (Figure 3).

POSTOPERATIVE FOLLOW-UP

Patients in both groups were discharged on the first postoperative day and were called for a control in the postoperative 1st week in terms of possible wound infection or the presence of hematoma. Patients were advised to prohibit sexual intercourse for a minimum of 6-8 weeks postoperatively. Long-term results of the patients were evaluated and recorded at the 12th month postoperatively. Preoperative demographic data, peroperative and postoperative results of TOT and SIMS groups were compared.

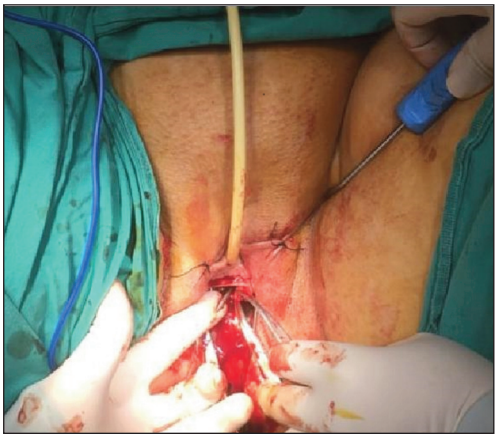

FIGURE 1: Out-to-in transobturator tape technique.

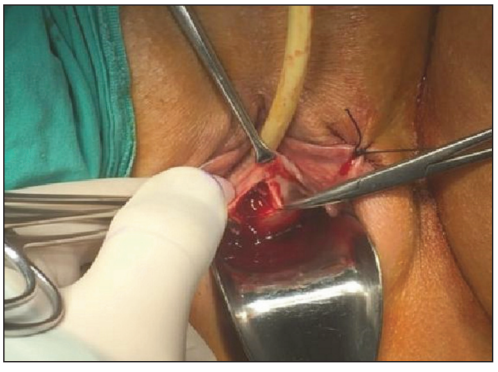

FIGURE 2: Single incision for mini-sling.

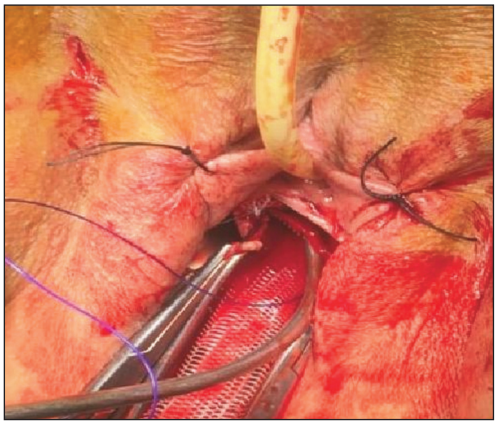

FIGURE 3: Single incision mini-sling technique.

STATISTICAL ANALYSIS

Categorical variables were compared using a χ^2 test, while continuous variables were compared using a Mann-Whitney U test for univariate analyses. Kolmogorow-Smirnov test was used for testing the distrubition of variables. Median and interquartile range

were used for defining variables. Data were analyzed with SPSS 25.0 (IBM Corp.) software. Statistical significance was set at p<0.05.

RESULTS

At a median 26 (12-114) month follow-up, the total objective cure rate according to the 1-h pad test was 77.1% (Table 1). The median age of the patients in the TOT group was 51.5 (45-58.25) years, while the median age of the SIMS group was 54 (42-59) years (p=0.909). Median BMI of the patients were similar in both groups (p=0.141). In preoperative 1-h pad test, the median 45 (34.5-45) g weight increase was measured in the TOT group, while the median 53 (30-57) g weight increase was measured in the SIMS group (p=0.547) (Table 2). The median operating time was 40 (30-45) min in the TOT group and 25 (20-30) min in the SIMS group (p<0.001). The median weight gain in the postoperative 1-h pad test was 1.70 (1.27-11.92) g in the TOT group, while it was 1.75 (1.5-66.25) g in the SIMS group (0.049). While the median improvement in postoperative ICIQ-SF scores in TOT group was 8 (6-12) points, there was a median improvement of 7 (2-11) points in the SIMS group (p=0.073). In the postoperative period, IQO-L scores improved by a median of 44 (20.25-67.00) points in the TOT group, while a median improvement of 23 (2.75-50.25) points was observed in the SIMS group (p=0.003). Urinary tract infection, wound hematoma and presence of urinary retention were found similar in both groups (p=0.801, p=0.712, p=0.204, respectively). Postoperative subjective cure rate was 81.5% in the TOT group and 61.9% in the SIMS group (p=0.032). It was also observed that the TOT group was significantly more advantageous than the SIMS group in terms of the objective cure rate (85.2% vs 66.7%, p=0.032) (Table 3).

TABLE 1: Demographics and characteristics of the patients (n=96).

	Median (IQR)
Age, years	52.5 (44.25-58.75)
Body mass index, kg/m^2	37 (36-41)
Parity, n	3 (3-4)
Operation time, minutes	30 (25-40)
Hospital stay, days	1 (1-1)
Preoperative 1-h pad, g	46 (31.50-55.75)
Postoperative 1-h pad, g	1.7 (1.30-8.67)
Subjective cure (n, %)	70 (72.9)
Objective cure (n, %)	74 (77.1)

IQR: Interquartile range.

DISCUSSION

Currently, the mid-urethral sling procedures in the treatment of SUI are considered to be the first choice surgical procedure due to their high success rates, ease of application, short hospitalization time, minimally invasive method and cost effectiveness.[13] TVT-S procedure was first applied by Ulmsten in 1996, and subsequently TOT procedure was defined in 2001 to reduce the risk of bladder perforation.[14] Following this development, a more minimally invasive SIMS method was developed in 2006 to reduce postoperative inguinal pain.[5] The less postoperative pain provided by the SIMS procedure and its comparable success with the other mid-urethral sling methods have

TABLE 2: Demographics and preoperative outcomes in the groups.

	TOT (n=54)	Mini-sling (n=42)	p value
Age, median (IQR), years	51.5 (45-58.25)	54 (42-59)	0.909
Body mass index, median (IQR), kg/m^2	37.5 (36-43)	36 (35-41)	0.141
Parity, median (IQR), n	3 (2-4)	3.5 (3-5)	0.064
Preoperative hormone therapy, n (%)	6 (11.1)	5 (11.9)	0.904
Peoperative pelvic surgery, n (%)	8 (14.8)	7 (16.7)	0.804
Preoperative 1-h pad, median (IQR), g	45 (34.5-45)	53 (30-57)	0.547
Preoperative ICIQ-SF score,median (IQR)	16.5 (14-19)	15.5 (14-19)	0.614
Preoperative IQO-L score, median (IQR)	16 (11-19.25)	15 (10-19)	0.188

TOT: Transobturator tape; IQR: Interquartile range; ICIQ-SF: International Consultation on Incontinence Qestionnaire scoring form; IQO-L: Incontinence Quality of Life.

TABLE 3: Postoperative outcomes in the groups.

	TOT (n=54)	Mini-sling (n=42)	p value
Operating time, median (IQR), minutes	40 (30-45)	25 (20-30)	**<0.001***
Hospital stay, median (IQR), days	1 (1-1)	1 (1-1)	0.109
Postoperative 1-h pad, median (IQR), g	1.70 (1.27-11.92)	1.75 (1.5-66.25)	**0.049***
Postoperative ICIQ-SF score, median (IQR)	7 (5.75-9)	8 (6-12.25)	0.094
Improvement in ICIQ-SF score, median (IQR)	8 (6-12)	7 (2-11)	0.073
Postoperative IQO-L score, median (IQR)	59.5 (38.25-85.25)	35.5 (15.75-63)	**0.001***
Improvement in IQO-L score, median (IQR)	44 (20.25-67.00)	23 (2.75-50.25)	**0.003***
Complications, n (%)			
Urinary tract infection	6 (11.1)	4 (9.5)	0.801
Wound hematoma	2 (3.7)	1 (2.4)	0.712
Urinary retention	2 (3.7)	0	0.204
Subjective cure	44 (81.5)	26 (61.9)	**0.032***
Objective cure	46 (85.2)	28 (66.7)	**0.032***

TOT: Transobturator tape; IQR: Interquartile range; ICIQ-SF: International Consultation on Incontinence Qestionnaire scoring form; IQO-L: Incontinence Quality of Life.
*Bold text indicates a statistically significant difference.

been demonstrated in numerous studies. In the study conducted by Karataş et al., which included 54 women with SUI, 27 of whom had SIMS and 27 had TOT, the objective cure rates of both procedures were found to be similar (92.6% vs 85.2%, p=0.386).[15] In the same study, postoperative pain score was reported significantly lower in the SIMS group (p=0.019). In another similar study conducted by Chang et al. including 136 patients, the cure rates of SIMS and TOT groups at 1-year follow-up were found to be similar (81.7% vs 73.7%, p=0.273).[16] In a meta-analysis in which Zhang et al. examined the results of 154 studies involving 678 patients, it was reported that the subjective cure and the objective cure rates of SIMS and TOT procedures were similar (p>0.05 and p>0.05 respectively).[17] In a meta-analysis in which Xia et al. reported the results of 11 studies involving 2,846 patients, it was reported that the subjective cure rate in mid-urethral sling surgery was not affected by BMI.[18] In another recent study by Frigerio et al. including 192 patients, it was reported that the single incision miniarch system was quite successful regardless of BMI.[19] They also stated that the operative data,complications,objective and subjective cure rates were found similar in normal weight,overweight and obese women.

Although the comparable high success rates have been reported in many studies of TOT and SIMS procedures, it is known that the success rates of these procedures decrease, especially in obese patients.[20] Although there are studies in overweight or obese women with a BMI of <35 kg/m^2, data on the effectiveness of the SIMS procedure is quite limited, especially in obese women with a BMI of ≥35 kg/m^2. Anding et al. reported the results of 100 overweight (BMI<30 kg/m^2) or obese (BMI≥30 kg/m^2) female patients who underwent SIMS surgery for SUI.[21] According to this study, 56 patients with a BMI of <30 kg/m^2 had an average daily pad use of 1.6±2.3, while 44 patients with a BMI≥30 kg/m^2 had an average daily pad use of 2.8±2.9, and the postoperative daily pad use was significantly higher in patients with high BMI (p=0.004). In another recent study, Lau et al. reported the results of SIMS or TOT procedure of 217 overweight or obese women with SUI.[22] According to this study, mean weight gain in postoperative 1-h pad test in patients with BMI<30 kg/m^2 were similar in both groups (3.0±18.4 g vs 3.3±15.1 g, p=0.361). However, in the same study, the mean weight gain in the postoperative 1-h pad test was significantly higher in the SIMS group in patients with a BMI≥30 kg/m^2 (9.2±27.5 g vs 3.6±16.5 g, p=0.047). On the other hand, in this study, the mean operating time and the mean visual analog scale (VAS) pain score were found to be significantly lower in the SIMS group compared to the TOT group (p=0.017 and p<0.001, respectively). However, it was reported that there was no dif-

ference between the groups in terms of urinary tract infection, wound hematoma and urinary retention rates (p=0.468, p=0.132 and p=0.526, respectively). In the same study, objective cure and subjective cure rates of the groups were found to be similar (p=0.465 and p=0.372, respectively). In the present study, similar results were obtained with the literature data, and while the median weight gain was found to be significantly higher in the 1-h pad test in the SIMS group in the postoperative period compared to the TOT group, the median operating time was found to be significantly lower in the SIMS group. In the present study, in accordance with the literature, no significant difference was found between the groups in terms of postoperative urinary tract infection, wound hematoma and urinary retention rates. These results support the idea that the efficacy of the SIMS procedure is significantly lower in obese women with ≥35 kg/m^2 BMI compared to TOT, although the SIMS procedure is more advantageous than TOT in terms of operating time and has similar complication rates.

According to the results of TOT (n=20) and SIMS (n=20) surgery performed by Bayrak et al. in a total of 40 overweight patient with SUI (BMI≥25-29.9 kg/m^2), the improvement in ICIQ-SF and IQO-L scores were significantly higher in TOT group than the SIMS group (76.20% vs 64.10%, p=0.001 and 81.31% vs 69.28%, p=0.001, respectively).[23] They stated that the subjective cure rate was also higher in the TOT group (75% vs 55%, p=0.190). In the present study, similar to the literature data, the TOT group was found to be significantly advantageous in terms of improvement in the postoperative IQO-L score; however, improvement in postoperative ICIQ-SF scores were similar in both groups. As a result of that, the subjective and the objective cure rates were significantly lower in the SIMS group compared to the TOT group may explain the low postoperative IQO-L score in the SIMS group.The significant increase in incontinence recurrence in the SIMS group in the postoperative 1-h pad test also supports this idea.The factor that causes this result can be explained by the fact that the suspension material is advanced and released only into the internal obturator muscle with the help of the self-fixation anchoring system in the SIMS procedure and has less tissue support compared to TOT. In addition, the pressure caused by obesity on the sling material, may lead to insufficient fixation of the mid-urethral sling material, which may result with SUI recurrence. The significant decrease in the effectiveness of the SIMS procedure with the increase of BMI in both previous studies and the results of the present study supports this prediction.

LIMITATIONS

The most important limitation of our study is its retrospective nature. In addition, the fact that the postoperative VAS scores of the patients were not determined and therefore no comparison could be made between the groups can be considered as another important limitation.

CONCLUSION

Both SIMS and TOT procedures are highly effective methods that provide high patient satisfaction in the surgical treatment of female SUI. However, the subjective cure rates, objective cure rates and the improvement in quality of life scores significantly decreases in obese patients with a BMI of ≥35 kg/m^2 in SIMS procedure. Therefore, TOT should be prioritized in the choice of surgical procedure in obese women undergoing mid-urethral sling surgery.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: *Kubilay Sarikaya, Fahri Erkan Sadioğlu, Muhammed Arif İbiş;* ***Design:*** *Kubilay Sarikaya, Muhammed Arif Ibiş;* ***Control/Supervision:*** *Çağrı Şenocak, Mehmet Çiftçi, Ömer Faruk Bozkurt;* ***Data Collection and/or Processing:*** *Kubilay Sarikaya, Fahri Erkan Sadioğlu, Mehmet Çiftçi;* ***Analysis and/or Interpretation:*** *Çağrı Şenocak, Ömer Faruk Bozkurt;* ***Literature Review:*** *Kubilay Sarikaya, Fahri Erkan Sadioğlu, Muhammed Arif Ibiş;* ***Writing the Article:*** *Kubilay Sarikaya, Muhammed Arif Ibiş;* ***Critical Review:*** *Çağrı Şenocak, Ömer Faruk Bozkurt, Mehmet Çiftçi.*

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