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# Investigating Maternal Effects of Positions Applied in Patients Preparing for Caesarean Section Under Spinal Anesthesia: A Prospective Randomized Clinical Study

Spinal Anestezi Altında Sezaryen Doğuma Hazırlanan Hastalarda Uygulanan POzisyonların Maternal Etkilerinin Araştırılması: Prospektif Randomize Klinik Çalışma

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ABSTRACT Objective: The effectiveness of placing patients in a 15° left-lateral tilt position (LLTP) during the surgical preparation to prevent hypotension after spinal anesthesia in cesarean surgeries is discussed today, and it has not been elucidated whether it is beneficial or not. In recent years, it has been considered that more effective results can be obtained with the 30° LLTP for the patients during surgical preparation. The purpose of the present study was to compare whether there is a difference between maternal effects of supine, 15° left tilt, and 30° left tilt positions. Material and Methods: Women who underwent elective cesarean delivery under spinal anesthesia were randomized to the supine position (SP), 15° LLTP, or 30° LLTP groups. The position was changed to supine before the incision and 10 mL/kg of isotonic fluid was initiated in the patients. Hypotension [systolic blood pressure (SBP) reduction >20% baseline or SBP<90 mmHg] was treated with intravenous bolus ephedrine based on maternal heart rate. The incidence of hypotension and bradycardia until the end of surgery, as well as the time to first ephedrine use and the total amount of ephedrine administered, were investigated. Results: Time of first ephedrine HCl use was earlier in the SP group compared to the 30° left tilt position group (3 vs. 6 minutes, p=0.002). The total dose of ephedrine HCl was significantly lower in the SP group than in the  $30^{\circ}$  left tilt position group (p<0.001). Conclusion: Hypotension development can be averted in term pregnant women when they stay in the 30° LLTP after spinal anesthesia.

Keywords: Cesarean section; spinal anesthesia; tilt position ÖZET Amaç: Sezaryen ameliyatlarında spinal anestezi sonrası hipotansiyonu önlemek için cerrahi hazırlık sırasında hastaların 15° sola tilt pozisyonunda yerleştirilmesinin etkinliği günümüzde tartışılmakta olup, faydalı olup olmadığı henüz aydınlatılamamıştır. Son yıllarda hastalara cerrahi hazırlık sırasında 30° sola tilt pozisyonu verilmesiyle daha etkili sonuçlar alınabileceği düşünülmektedir. Bu çalışmanın amacı, sırtüstü 15° sola eğim ve 30° sola eğim pozisyonlarının anneye etkileri arasında fark olup olmadığını karşılaştırmaktır. Gereç ve Yöntemler: Spinal anestezi altında elektif sezaryen doğum yapılan kadınlar sırtüstü pozisyon, 15° sol-lateral tilt pozisyonu veya 30° sol-lateral tilt pozisyonu gruplarına randomize edildi. Kesi öncesi pozisyon supin pozisyona getirilerek hastalara 10 mL/kg izotonik sıvı başlandı. Hipotansiyon (sistolik kan basıncında başlangıca göre >%20 azalma veya <90 mm Hg), annenin kalp atış hızına göre intravenöz bolus efedrin ile tedavi edildi. Ameliyat sonuna kadar hipotansiyon ve bradikardi görülme sıklığı ile ilk efedrin kullanım zamanı ve toplam efedrin miktarı araştırıldı. Bulgular: Efedrin HCl'nin ilk kullanım zamanı sırtüstü pozisyon grubunda 30° sola tilt pozisyonuna göre daha erkendi (3'e karşı 6 dk, p=0,002). Toplam efedrin HCl dozu sırtüstü pozisyon grubunda 30° sola tilt pozisyonuna göre anlamlı derecede fazlaydı (p<0,001). Sonuç: Term gebelerde spinal anestezi sonrası 30° sola tilt pozisyonunda kalmaları durumunda hipotansiyon gelişmesi önlenebilir.

Anahtar Kelimeler: Sezaryen ameliyatı; spinal anestezi; tilt pozisyon

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The development of intraoperative hypotension has effects on mortality by increasing myocardial damage, acute kidney injury, and septic complications.<sup>1,2</sup> This hypotension causes birth with low Apgar scores and acidosis in the umbilical cord blood.<sup>3</sup> Therefore, the prevention of an intraoperative hypotensive occurence has important roles in reducing morbidity and mortality. Aortocaval compression may occur from as early as 19 weeks. It is thought that this compression may reduce the amount of blood returning to the heart and cause hypotension. The incidence of this condition, called Supine Hypotension Syndrome, was reported to be 8%-10%.<sup>4-6</sup> Spinal anesthesia decreased sympathetic tone, decreased systemic vascular resistance also vasodilation may cause hypotension in the patient.<sup>7</sup>

It was considered that if the uterus is tilted, the pressure on the inferior vena cava (IVC) would be removed, increasing cardiac outpout due to increasing returning blood volume so improving the fetus, blood supply, and oxygen supply.<sup>8</sup> But studies that were conducted so far have not proven significant differences and there is no routine standard practice.<sup>9,10</sup> In this study, the purpose was to investigate the maternal effects between supine, 15° tilt to the left-lateral tilt position (LLTP), and 30° LLTP.

### MATERIAL AND METHODS

The study was commenced after the approval of the Aydın Adnan Menderes University Medicine Faculty Non-Interventional Clinical Research Ethics Committee (date: June 9, 2022; no: 16) between June 15, 2022 and October 15, 2023. This study complies with the Declaration of Helsinki was performed. This clinical trial was registered in the ClinicalTrials.gov database on October 24, 2022 (NCT05595928). 95 patients, who were aged 18-35 years, and who deliverying by elective cesarean section under spinal anesthesia were included in this prospective randomization clinical trial. The incidence of ephedrine, hypotension, and bradycardia until the end of surgery was investigated. An informed consent form was obtained from patients before their inclusion in the study.

Womens deliverying by elective cesarean section under spinal anesthesia were randomized to the supine position (SP), 15° LLTP or 30° LLTP groups. Before the incision, participants were turned to a SP. Five participants were excluded from the clinical trial after 1 patient gave birth with an anomaly and 4 patients with a low birth-weight baby (consort diagram of the study) (Figure 1).

Patients with elective cesarean delivery with term pregnancy, with a height of 150-180 cm, American

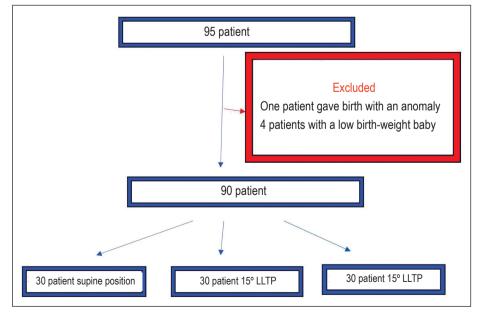


FIGURE 1: Consort diagram.

Society of Anesthesiologists II, body mass index  $(BMI) < 35 \text{ kg/m}^2$  were included in the study. Exclusion criteria were fetal macrosomia, uterine abnormalities, polyhydramnios, torn membranes, oligohydramnios, intrauterine growth restriction, gestational or non-gestational hypertension, diabetes or eclampsia and contraindications for spinal anesthesia.

### ANESTHESIA

All participants were monitored with continuous electrocardiography and pulse oximetry. Noninvasive blood pressure monitoring was performed. Noninvasive measurements were made at 2-min. intervals, after the first 15 min., and at 5-min. intervals. In the sitting position, 12 mg of hyperbaric bupivacaine (Pfizer Inc., New York, NY, USA) was injected with a 25-gauge quincke spinal needle through the L 4-5 or L 3-4 space. Spinal anesthesia was administered to all patients by the same anesthesiologist. Then, the patient was positioned according to the randomization group. A wedge made of high-density sponge (the 30° wedge was 28 cm wide 50 cm long, and 16 cm high; the 15° wedge was 28 cm wide, 50 cm long and 7.5 cm high) (Figure 2). If the participant was appointed to the 15° group or the 30° group, a wedge was smoothly placed below the patient's lumbar spine and thoracic spine immediately after anesthesia was completed. Just before the surgical incision, the wedge was withdrawn and the SP was achieved. Surgery began when the block level of spinal anesthesia reached the



FIGURE 2: Wedge made of high-density sponge image.

T6 level. After spinal injection, 10 mL/kg of 0.9% Sodium Chloride (Polifarma Drug., Tekirdağ, Türkiye) was instilled within 10-15 minute. Patients with a 20% decrease in systolic blood pressure (SBP) from baseline was considered to have hypotension. Atropine (Pfizer Inc., New York, NY, USA) 0.5 mg was administered when the maternal heart rate was below 40 beats/minute. The randomization was made with the following pattern; 1<sup>st</sup> patient supine, 2<sup>nd</sup> patient 15°, 3<sup>rd</sup> patient 30°. The primary outcome was planned to include the course of maternal BP, the quantity of vasoconstructive drug applied during the operation, and the incidence of hypotension during operation.

Taking the study named "Liu T, Zou S, Guo L, Niu Z, Wang M, Xu C, Gao X, Shi Z, Guo X, Xiao H, Qi D. Effect of Different Positions During Surgical Preparation With Combined Spinal-Epidural Anesthesia for Elective Cesarean Delivery: A Randomized Controlled Trial. Anesth Analg. 2021;133(5):1235-43" as the reference, when hypotension before fetal delivery was compared between the groups, the effect size was found to be 0.346.<sup>11</sup> In order to reach sufficient sampling, it was aimed to reach 81 patients with 80% power, 5% margin of error, 0.346 effect size, and 90 patients with 10% spare.

Descriptic statistics were provided as mean±standard deviation and median values for continuous variables depending on their distributions. The numerical variables normal distributions were analyzed using the Shapiro-Wilk, Kolmogorov-Smirnov, and Anderson-Darling tests

The Pearson chi-square and Fisher's exact tests were used to comparing the differences between categorical variables in 2x2 tables. The Fisher-Freeman-Halton test was used in RxC tables.

The one-way analysis of variance test was used to compare more than two independent groups where numerical variables had a normal distribution. For variables without normal distribution, the Kruskal-Wallis test was applied.

The R software package for the Nonparametric Analysis Method of Longitudinal Data in Factor Experiments was used to analyze the significance of the "group<sup>\*</sup> time" interactions between the groups.

# RESULTS

Ninety five patients were included in the study. Four of the patients included in the study were excluded from the study because they gave birth to a low birth weight baby and one patient gave birth to a baby with an anomaly. Each group was formed with 30 patients (Consort diagram of the study).

Demographic and clinical features of the mothers and newborns included our trial are given in Table 1. There were 90 pregnants with a median age of 27 years our study. The mean BMI value was  $29.4\pm4.0 \text{ kg/m}^2$ .

The mean birth weight of the newborns was 3305.2±457.7 g. Based on the surgical positions, there

were 30 pregnant women who were operated on in the SP,  $15^{\circ}$  and  $30^{\circ}$  LLTP. There was no difference between groups in BMI, hemoglobin value, age, birth weight, and APGAR scores (p<0.05) (Table 1).

The comparison of the groups according to the intraoperative findings is shown in Table 2. There were significant differences in the interval between the onset of anesthesia and incision (p=0.050), the first use of ephedrine HCl (Akorn Pharmaceuticals, Lake Forest, IL, USA) (p=0.003) and its total dose (p<0.001), the number of patients with nausea/vomiting (p< 0.001) and hypotension (p<0.001) between the groups (p<0.05) (Table 2).

The median time between the onset of anesthesia and incision was significantly longer in

<b>TABLE 1:</b> Maternal and fetal demographic and clinical characteristics.								
	Groups							
	Overall (n=90)	Supine position (n=30)	15° left tilt position (n=30)	30° left tilt position (n=30)	p value			
Age (year)§	27.0 (19.0-54.0)	26.5 (20.0-34.0)	27.0 (21.0-54.0)	27.0 (19.0-35.0)	0.528*			
BMI (kg/m <sup>2</sup> ) <sup>†</sup>	29.4 ±4.0	29.8±4.0	29.0±4.4	29.4±3.7	0.729**			
Birth weight (g) <sup>†</sup>	3305.2±457.7	3278.5±506.6	3336.7±442.7	3304.6±428.1	0.900**			
APGAR score <sup>§</sup>								
1. min	9.0 (8.0-10.0)	9.0 (8.0-9.0)	9.0 (8.0-10.0)	9.0 (8.0-9.0)	0.616*			
5. min	10.0 (10.0-10.0)	10.0 (10.0-10.0)	10.0 (10.0-10.0)	10.0 (10.0-10.0)				
Hemoglobin (g/dL)§	11.1 (2.2-13.5)	11.2 (9.1-13.5)	11.1 (2.2-13.3)	11.2 (7.1-13.3)	0.857*			

\*Mann-Whitney U test; \*\*Independent samples t-test; \*Mean±standard deviation; \*Median (minimum-maximum); BMI: Body mass index.

TABLE 2: Comparison of the intraoperative findings in the groups.								
	Groups							
	Supine position (n=30)	15° left tilt position (n=30)	30° left tilt position (n=30)	p value				
Interval between anesthesia and incision (min) $^{\mbox{\tiny \$}}$	4.0 (2.0-7.0)	4.5 (4.0-7.0)	5.0 (3.0-9.0)	0.050*				
Interval between anesthesia and fetal delivery (min)§	10.0 (5.0-13.0)	9.0 (7.0-12.0)	10.0 (7.0-15.0)	0.064*				
Participants Intraoperative blood loss§	450.0 (55.0-600.0)	450.0 (60.0-550.0)	450.0 (55.0-1250.0)	0.613*				
Intraoperative fluid resuscitation (ml) <sup>§</sup>	1225.0 (120.0-1400.0)	1250.0 (800.0-1500.0)	1200.0 (120.0-1500.0)	0.794*				
Vasoactive medications								
Atropine (0.5 mg) requirement <sup>‡</sup>	1 (3.3)	2 (6.7)	1 (3.3)	0.999**				
Time for the first ephedrine HCI (min)§	3.0 (1.0-7.0)	5.0 (1.0-20.0)	6.0 (3.0-11.0)	0.003*				
Ephedrine HCI-total dose (mg)§	20.0 (10.0-50.0)	20.0 (10.0-40.0)	10.0 (10.0-20.0)	<0.001				
Complications								
Nausea/vomiting <sup>‡</sup>	27 (90.0)	16 (53.3)	10 (33.3)	<0.001*				
Bradycardia <sup>‡</sup>	7 (24.1)	3 (10.0)	3 (10.0)	0.233**				
Hypotension <sup>‡</sup>	27 (93.1)	22 (73.3)	14 (46.7)	<0.001*				
Pre-incisional hypotension <sup>‡</sup>	16 (53.3)	13 (43.3)	3 (10.0)	0.001**				
Post-incisional hypotension <sup>‡</sup>	18 (60.0)	11 (36.7)	12 (40.0)	0.146**				
Pre-fetal delivery hypotension <sup>‡</sup>	27 (90.0)	18 (62.1)	13 (43.3)	0.001**				

\*Mann-Whitney U test; \*\*Pearson chi-square/Fisher-Freeman-Halton test; \* n (%); \*Mean±standard deviation; \*Median (minimum-maximum).

the 30° LLTP group than in the SP group (5 vs. 4 minute, p=0.050).

Time of first ephedrine HCl use was earlier in the SP group compared to the  $30^{\circ}$  LLTP group (3 vs. 6 minutes, p=0.002). The total dose of ephedrine HCl was significantly lower in the SP group than in the  $30^{\circ}$  LLTP (p<0.001). The groups were similiar regarding atropine use (p=0.999).

Nausea/vomiting developed in 27 (90%) of the supine group patients. The incidence of nausea/vomiting was significantly higher than in the 15°, and  $30^{\circ}$  LLTP (p<0.001).

The incidence of hypotension was lower in the 30° LLTP than in the 15° left tilt and SP groups. The incidence of hypotension was significantly lower in the 15° LLTP group than in the SP group.

Pre-incisional and pre-fetal delivery hypotension was lower in the 30° LLTP group compared to the 15° LLTP and SP groups (p=0.001 and p=0.001). Other findings were similar between the groups (p>0.05).

There was no significant difference between the groups intraoperative baseline ( $0^{th}$  minute) hemodynamic and respiratory parameters (p<0.05) (Table 3).

The hemodynamic parameters at each time point are presented in Figure 3A-3B-3C. The systolic, diastolic, and mean blood pressure measurements showed significant changes between the onset of the anesthesia and the  $40^{\text{th}}$  min of the surgery in all three groups (p<0.001).

For systolic, diastolic and mean blood pressure measurements, there were significant group by time interactions from the onset of anesthesia to the  $40^{th}$  min of surgery (p<0.001, p<0.001 and p<0.001) (Figure 3A-3B-3C). The groups were similiar in terms of the variation of heart rate and saturation

<b>TABLE 3:</b> Distribution of the intraoperative baseline (0 <sup>th</sup> minute) hemodynamic and respiratory parameters in the groups.								
	Groups							
	Supine position (n=30)	15° left tilt position (n=30)	30° left tilt position(n=30)	p value				
Systolic blood pressure (mmHg)§	129.5 (93.0-153.0)	131.5 (98.0-148.0)	126.5 (107.0-179.0)	0.576*				
Diastolic blood pressure (mmHg) <sup>†</sup>	77.6±12.7	78.4±15.8	80.2±12.9	0.722**				
Mean blood pressure (mmHg) <sup>†</sup>	94.3±13.0	95.1±13.3	94.9±14.9	0.976**				
Heart rate (beat/min) $^{\text{s}}$	98.0 (64.0-129.0)	98.0 (75.0-142.0)	93.0 (68.0-117.0)	0.213*				
Saturation (%)§	99.0 (89.0-100.0)	99.0 (89.0-100.0)	100.0 (97.0-100.0)	0.150*				

\*Mann-Whitney U test; \*\*Independent samples t-test; †Mean±standard deviation; §Median (minimum-maximum).

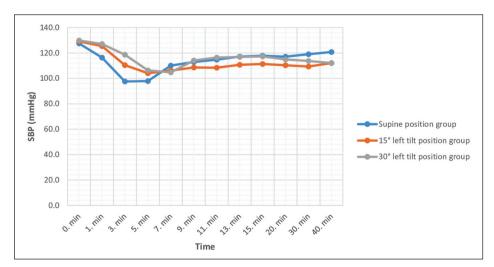


FIGURE 3A: Temporal variation of systolic blood pressure (SBP) for each group.

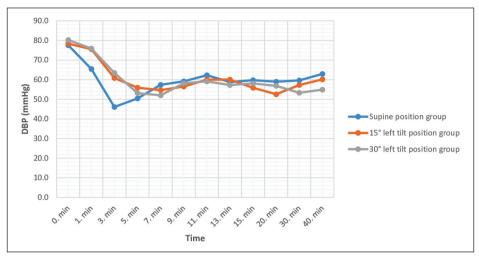


FIGURE 3B: Temporal variation of diastolic blood pressure (DBP) for each group.

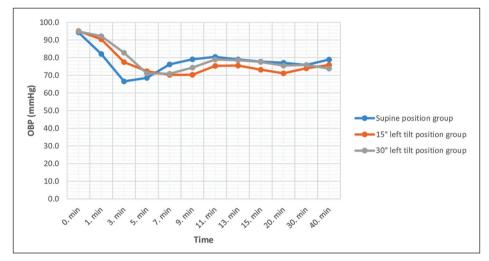


FIGURE 3C: Temporal variation of mean blood pressure (OBP) for each group.

measurements according to time between the onset of anesthesia and the  $40^{th}$  min of the surgery (p=0.300 and p=0.747).

In the SP group, the values of all blood pressure measurements showed greater reductions starting from the onset of anesthesia to the first  $5^{th}$  min of surgery than the  $15^{\circ}$  and  $30^{\circ}$  LLTP groups. Then, we observed a gradual increase in the measurements to the end of  $40^{th}$  min of surgery (Figure 3A).

## DISCUSSION

With this prospective randomized study, the preventability of hypotension developing in pregnant

women with spinal anesthesia was investigated through the position to be given during surgical preparation. In the study, a 30° LLTP in preparation for cesarean section after SA application reduced the development of maternal hypotension and ephedrine consumption. Also, the presence of pre-incision and prenatal hypotension developed less in the 30° LLTP.

In their first study conducted with fewer patients, Liu et al. compared the 30° LLTP with the SP after spinal anesthesia for CS, and the decrease in ephedrine consumption and the stability of maternal hemodynamics were found to be significant.<sup>11</sup> However, they did not find the 15° LLTP significant in comparison with the SP.<sup>11</sup> In the present study, the need for ephedrine decreased and the stability of maternal hemodynamics was more preserved when compared to the 30° LLTP, 15° LLTP, and the SP.

Calvache et al. conducted a study on CS operations and found that nausea and vomiting were less in 20° LLTP when compared to the SP.<sup>10</sup> You et al. found nausea-vomiting similar to 15° LLTP in the SP.<sup>12</sup> In our study, nausea-vomiting was less than in 30° LLTP, 15° LLTP, and SP. As the amount of left-lateral tilt increased, nausea-vomiting decreased in the present trial.

Bamber et al., who made maternal cardiac output (CO) measurements for the SP, 5°-12.5° LLTP, and 5°-12.5° right-lateral tilt position, reported that the lateral table does not provide an advantage in these aspects.9 In the study of Fujita et al., they investigated IVC compression in the SP, 15°-30° LLTP uterus, and 15°-30° right-lateral tilt position with magnetic resonance imaging.<sup>13</sup> They reported that only the 30° LLTP removed IVC compression in the pregnant uterus effectively.<sup>13</sup> In the present study, the absence of a significant difference in the incidence of hypotension in the 15° LLTP (as in the SP) was attributed to the absence of CO change because of the inability to remove IVC compression. We think that the development of maternal hypotension is less in the 30° LLTP as it reduces the pressure of the pregnant uterus on the IVC.

A study of 80 term women undergoing elective cesarean section with spinal anesthesia randomized the women to SP or use of a 20° lumbar-pelvic wedge. Researchers did not detect a difference in the incidence of hypotension, but did show higher use of vasopressors (ephedrine boluses).<sup>10</sup> Lee et al., in their study, there were statistically significant differences in SBP between groups during the first 15 minutes; SBP was lower and phenylephrine administration was significantly higher in the SP.<sup>14</sup> There was no difference in the present study between total ephedrine consumption in the supine group and 15° LLTP groups, and it decreased in the 30° LLTP group. Initial use of ephedrine was required later in the 30° LLTP. However, all groups showed a prenatal

requirement for ephedrine. The development of preincision hypotension in the  $30^{\circ}$  LLTP was significantly reduced when compared to the SP and the  $15^{\circ}$  LLTP. This can be explained by the fact that the  $30^{\circ}$  LLTP prevents IVC compression until the incision time, in other words, until the wedge position cushion is lifted and shifted to the SP.

In the present study, non-invasive and intermittent blood pressure monitoring was among the limitations. One of the limitations of our study was that we did not consider the postoperative effects of intraoperative hypotension.patient and surgeon dissatisfaction occurred due to wedge made of high density sponge. In the study, the purpose was to evaluate only the maternal effects of positions during surgical preparation. However, there will be a need to evaluate the effects of the application of these positions on the acid-base of the fetus. Patients were included in the study and these results cannot be evaluated for morbidly obese patients. Also, since the increased fetal weight would increase the pressure on the IVC, patients with macrosomic babies and multiple pregnancies were not included in this study.

## CONCLUSION

Maternal hypotension development and ephedrine consumption were decreased in the 30° LLTP when compared to the supine and 15° LLTP during surgical preparation. The development of hypotension can be prevented in term pregnant women when they are in the 30° LLTP after spinal anesthesia.

### 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: Ferdi Gülaştı; Design: Ferdi Gülaştı; Control/Supervision: Ferdi Gülaştı; Data Collection and/or Processing: Ferdi Gülaştı, Sercan Kantarcı; Analysis and/or Interpretation: Ferdi Gülaştı; Literature Review: Ferdi Gülaştı, Sercan Kantarcı; Writing the Article: Ferdi Gülaştı; Critical Review: Ferdi Gülaştı, Sercan Kantarcı; References and Fundings: Ferdi Gülaştı; Materials: Ferdi Gülaştı.

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