Does the Prone Position During the Shockwave Lithotripsy of Kidney Stones Improve the Stone-Free Rate? Results from a Randomized Clinical Trial

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Objective: This study aimed to evaluate the impact of the skin-to-stone distance in the supine and prone positions on the outcome of shockwave lithotripsy of kidney stones.

Methods: In a prospective randomized clinical trial study, 81 patients that candidates for shockwave lithotripsy (SWL) of kidney stones were randomly divided into two groups to perform SWL in the prone position (40 patients) or conventional supine position (41 patients). Demographic data, stone characteristics, skin–to–stone distances (SSD) in CT, SSD during SWL with an ultrasound probe in prone and supine positions, total shock wave rate, total energy (kilovolt), visual analog scale (VAS), complications (Clavien-Dindo scale system), and SWL success rate evaluated in two intervention and control groups. All statistical analysis was performed by independent T-test, Chi-Square test, Fisher exact test, paired T-test, and SPSS 22.0 software for windows.

Results: There were no significant differences between demographic characteristics, SWL sessions, the median number of SWLs, the median SWL time, median total energy, VAS, and complications in the two groups. The SFR was numerically higher in the prone SWL group than in the supine SWL group (80% vs. 73.2%) but was not significantly different (P = 0.468).
Also, the inline ultrasound (US) measuring of the SSD in the prone position was significantly different from US SSD measures in the supine position in the two groups (Ps = 0.001 and 0.024). The mean SSD was lower in the US measurement during the SWL process that measured in supine and prone position than the CT measurement (73.5 vs. 101.1), which means the routine SSD measured by CT scan is higher than SSD in the US probe measurement during SWL.

Conclusion: The prone position SWL modification could be effective in obese patients with a BMI of more than 30 and increase the stone-free rate (P=0.039) with a similar safety profile and comparable VAS score. It seems the SSD measured by the ultrasound is a more accurate dynamic measurement during the SWL and needs to define the SSD according to the SSD calculation by the US probe of the therapy head. SFR was numerically higher in the prone compared with the supine treatment groups

Keywords: skin-to-stone distance; shock wave lithotripsy; supine position; prone position

INTRODUCTION

According to the recent European urology association and American urological association guidelines update, shock wave lithotripsy (SWL) can consider for the treatment of renal stones (≤ 2 cm), except in lower renal pole stones with unfavorable anatomy stated[1, 2]. The main factors that influence the success of SWL are stone size, location, composition, density, and renal anatomy characteristics. Also, the body habitus (Body mass index, BMI) affects the result of SWL as the Skin-to-Stone Distance (SSD) of more than 10 cm is associated with decreasing SWL success rate[3,4]. The conventional position of patients during SWL is the supine position. However, in some instances, the patient's position needed to be adjusted to a prone position to enhance the shock wave transmission. The most frequent situations mentioned in the literature are distal ureteral stones, pelvic kidneys, crossed ectopic kidneys, horseshoe kidneys, and proximal ureteral stones[5,6]. Among the factors mentioned earlier, the only modifiable factor is SSD.

Some studies evaluating the estimated length of the nephrostomy tube during the percutaneous nephrolithotomy (PCNL) mentioned that in the prone position redistributing adipose tissue, the SSD decreased[7]. With this concept of reducing SSD in the prone position, we designed a prospective study to evaluate the effect of the prone position on the success rate of SWL in kidney stones.

MATERIALS & METHODS

In a prospective randomized clinical trial study from 30/09/2021 to 25/04/2022 patients with kidney stones

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Table 1. A description of variables, comparing between two groups.

Variables		Groups		*p*-value
		Supine	Prone	
Sex (male), number (percent)		30 (73.2 %)	22 (55.0 %)	0.088
Stone number (one), number (percent)		38 (92.7 %)	38 (95.0 %)	0.665
Side (left), number (percent)		22 (53.7 %)	21 (52.5 %)	0.917
Location, number (percent)	LP	10 (24.4 %)	8 (20.0 %)	0.962
	MP	15 (36.6 %)	16 (40.0 %)	
	P	13 (31.7 %)	12 (30.0 %)	
	UP	3 (7.3 %)	4 (10.0 %)	
Analgesic (yes), number (percent)		22 (53.7 %)	20 (50.0 %)	0.742
CDG complication (>0), number (percent)		32 (78.0 %)	29 (72.5 %)	0.243
SWL session (one), number (percent)		41 (100 %)	38 (95.0 %)	0.241
SWL history (no), number (percent)		38 (92.7 %)	33 (82.5 %)	0.194
Previous stent (no), number (percent)		35 (85.4 %)	32 (80.0 %)	0.523
Age (year), mean (SD)		44.9 (12.6)	40.7 (8.9)	0.090
BMI (kg/m2), mean (SD)		28.8 (4.7)	28.4 (5.3)	0.662
	≥30	16 (39.0 %)	17 (42.5 %)	0.750
Size (mm), mean (SD)		11.3 (3.3)	12.1 (3.1)	0.251
AC (cm), mean (SD)		100.0 (11.7)	95.1 (17.9)	0.154
HU, mean (SD)		686.9 (283.2)	707.7 (296.8)	0.748
VAS, median (IQR)		4 (4-6)	4 (4-6)	0.891
No SWS required analgesic, median (IQR)		800 (0-1000)	400 (0-1350)	0.923
# of SWS, median (IQR)		3600 (3000-3700)	3600 (3550-3800)	0.217
SW time, median (IQR)		65 (55-65)	60 (60-70)	0.574
Total energy (kV), median (IQR)		18 (17.5-18.5)	18 (17.5-18.25)	0.948
HN grade, median (IQR)		2 (1-3)	2 (1-3)	0.856
SFR (yes), number (percent)		30 (73.2 %)	32 (80.0 %)	0.468

LP: Lower pole, MP: Middle pole, P: Pelvis, UP: Upper pole, CDG: Clavien-Dindo group, SWL: Shock wave lithotripsy, SWS(Shock waves), SW(Shock wave)BMI: Body mass index, US: Ultrasound, SSD: Skin-to-Stone distance, CT: Computed scan, HU: Hounsfield unit, AC: Abdominal circumference, VAS: Visual analog scale, HN: Hydronephrosis, SFR: Stone free rate

less than 2 cm eligible for SWL were included in our study after signing the written informed consent from Persian Registry for Stones of Urinary System (PERSUS). The ethical committee of the Tehran University of Medical Sciences approved this study (IR.TUMS.MEDICINE.REC.1399.1035) and the Iranian Registry of Clinical Trials (IRCT20190624043991N17). The exclusion criteria were age less than 18, renal anomalies (horseshoe kidney, pelvic kidney, and ureter pelvic junction obstruction), chronic kidney disease (CKD), concurrent renal and ureteral stones, severe cardiopulmonary dysfunction, single kidney, uncontrolled hypertension, and failed SWL (history of > 2 SWL).

The enrollment summary is represented based on Consort guidelines in **Figure 1**. The laboratory tests were routinely performed on all patients, including CBC. diff, creatinine, urine culture, and coagulative tests (PT, PTT, INR). The low-dose spiral computed tomography (CT) scan was performed on all patients in both standard supine and prone positions to compare the differences between SSD in the two positions. The piezoelectric (Wolf Piezo Lith 3000, GmBH, Knittlingen, Germany)) with a focal size of 2mm and 16.5 cm depth of penetration was routinely utilized in our center with the inline ultrasound-guided probe (3.5 MHZ).

The patients were divided into two groups to perform SWL in the prone or conventional supine position. Considering the stone-free proportions of 81.3 % and 82.4 % for the supine and prone positions, respective, reported by Zomorrodi et al (2006), significance level of 95 %, statistical power of 80 %, and the least detectable group difference of 30 %, the sample size for each group was estimated to be 42 patients. The patients were randomly allocated to groups using the randomization blocks of sizes 2 and 4. The prophylactic antibiotic was administrated to all patients. We started the SWL process with a standard low voltage protocol (12-15 kV) in the first 500 SW and gradually increased the energy to 24 kV with the shock wave (SW) rate between 60 to 90 SW/min. We do not routinely prescribe the per-procedure analgesic to patients, but routinely they receive light sedation. If patients have intolerable pain, we prescribe ketorolac to the patients (30 mg slow in infusion).

Demographic data, stone size, location, laterality, and density (HU) were evaluated. The SSD was measured in supine and prone positions by mean skin–to–stone distances at 0, 45, and 90 degrees in CT scan and also with an ultrasound probe during SWL. The total shock wave rate and energy (kilovolt) were recorded for two groups. The visual analog scale (VAS) of pain was used for pain analysis during the SWL process. The complications were assessed according to the Clavien-Dindo scale system. The success rate was evaluated 1 and 3 months after SWL with a spiral CT scan. Stone-free was considered less than 4 mm residual stone fragments[8]. The patient's position is depicted in figure 2.

The discrete variables are reported using number (percent). The continuous ones are described using mean (standard deviation, SD) or median (interquartile range, IQR), depending on whether the data is normally or non-normally distributed. The Chi-squared test was used to compare discrete variables between two groups, replaced with the Fisher's exact test in the case of observation less than 5 in the table. The independent t-test and Mann-Whitney test compared the continuous variables between groups, in the case of normal and non-normal variables, respectively. The Pearson correlation coefficients measured the associations between continuous variables. The normality was assessed based on the skewness and kurtosis measures in the ranges of (-1.5,1.5) and (1.5,4.5) [Hair, J.F., 2009. Multivariate data analysis]. Moreover, homogeneity of variance was assed using Levene's test. Finally, the Mantel-Haenszel Chi-squared test assessed the heterogeneity between the BMI strata (<30 vs ≥30). All statistical analysis was performed by SPSS 22.0 software for windows.

Table 2. . The US and CT SSDs in the prone and supine measurements were compared between two groups

Variables	Groups Supine	Prone	*p*-value
US SSD/prone, mean (SD)	72.8 (13.7)	69.8 (15.6)	0.364
US SSD/supine, mean (SD)	76.2 (13.3)	72.8 (15.5)	0.292
CT SSD/prone, mean (SD)	101.1 (19.4)	96.3 (22.8)	0.308
CT SSD/supine, mean (SD)	108.7 (23.1)	97.6 (21.7)	0.029

RESULTS

A total number of 97 patients were eligible initially in our study. After excluding 12 patients depicted in flowchart 1, the total number of 85 patients was randomly divided, 43 into supine group SWL and 42 patients in prone SWL group. Two patients lost the follow-up in both groups, so the final sample consisted of 41 patients in the supine and 40 prone groups, respectively. As depicted in Table 1, there were no significant differences between age, sex, BMI, abdominal circumference (AC), and stone characteristics (number, laterality, size, location, density) in the two groups. The median number of shock waves (SW), the median SWL time, and the median total energy were not significantly different between the two groups.

We also evaluated the analgesic use, the number of SW'S needed for analgesics, and the VAS between the two groups. There were no significant differences between the two groups. There were no significant differences between the two groups regarding the previous history of SWL and ureteral stents before SWL.

There were no significant differences between the two groups regarding Clavien-Dindo complications. Most of the complications were grade 1 and 2 of clavien in two groups. The SFR was higher in the prone SWL group than in the supine SWL group (80% vs. 73.2%) but was not significantly different ($P = 0.468$). According to the SFU classification, the hydronephrosis grading that may influence the SFR was not significantly different between the two groups ($P = 0.856$).

We measured the SSD parameters in two groups using the CT imaging performed in supine and prone positions. The US and CT SSDs in the prone and supine measurements are presented in **Table 2**, comparing the two groups. The SSD measures in the patients who underwent prone SWL (CT SSD) were 97.6 and 96.3 in the supine and prone positions CT imaging, respectively, which were not significantly different ($P = 0.453$). The SSD measures in the patients who underwent supine SWL (CT SSD) were 108.7 and 101.1 in the supine and prone positions CT imaging, respectively, which means we have fewer SSD measures in the prone CT imaging this group ($P = 0.004$). Also, the CT SSD in supine position CT imaging is 108.7 and 97.6, significantly different between supine SWL and prone SWL groups ($P = 0.029$).

In both supine and prone groups, US SSD/prone and US SSD/supine were significantly different ($P = 0.001$ and 0.024, respectively). CT SSD/prone and US SSD/prone were significantly different (both Ps < 0.001).

Also, the mean SSD was lower in the US measurement during the SWL process measured in the supine and prone position than the CT measurement (73.5 vs. 101.1), which means the routine SSD measured by CT scan is higher than SSD in the US probe measurement during SWL.

Next, the Pearson correlations between BMI, AC, size, and the US and CT measurements are reported in Table 2, separated for the groups. Applying the Bonferroni correction for multiple comparisons, the significant correlations are presented in bold font.

As depicted in Table 3, the abdominal circumference increases with increasing BMI in two groups (direct correlation: 0.76 and 0.71). With increasing BMI, in the prone SWL group, the CT SSD in the supine position had a direct correlation, but this correlation was not seen in the supine SWL group. The US SSD in two positions (supine and prone) is directly correlated in two intervention groups (supine and prone). Also, the CT SSD in two positions (supine and prone) is directly associated with two intervention groups (supine and prone SWL).

Finally, the position and failure of the SFR association were assessed stratified for BMI. The risk ratios (RRs) were measured for each stratum, taking the Supine group as the reference. The findings are presented in Table 4 and Figure 3. While no position-SFR association was obtained in the non-obese patients, the Prone position revealed a significantly lower failure in the SFR in obese persons (5.9% vs. 37.5%). Besides, the

Table 3. Pearson correlation coefficients, separated for the groups.

	BMI	AC	Size	Supine group US SSD/prone		US SSD/supine		CT SSD/prone	CT SSD/
supine									
BMI	1								
AC	0.76	1							
Size	0.14	0.01	1						
US SSD/prone	0.43	0.45	0.01	1					
US SSD/supine	0.37	0.32	0.01	0.89	1				
CT SSD/prone	0.34	0.39	-0.04	0.46	0.35	1			
CT SSD/supine	0.47	0.54	0.03	0.50	0.39	0.73		1	
Prone group									
	BMI	AC	Size	US SSD/prone		US SSD/supine		CT SSD/prone	CT SSD/
supine									
BMI	1								
AC	0.71	1							
Size	0.17	0.28	1						
US SSD/prone	0.57	0.59	0.39	1					
US SSD/supine	0.42	0.35	0.31	0.87		1			
CT SSD/prone	0.72	0.63	0.29	0.69		0.58	1		
CT SSD/supine	0.71	0.59	0.29	0.76		0.67	0.88	1	

Table 4. The position and failure of the SFR association stratified for BMI.

			Groups Supine	Prone	RR (95% CI)	*p*-value
BMI	<30	No SFR, number (percent)	5 (20.0 %)	7 (30.4 %)	1.52 (0.56-4.13)	0.511
	≥30		6 (37.5 %)	1 (5.9 %)	0.16 (0.02-1.16)	0.039

RR: Risk ratio; CI: Confidence interval

RRs of non-obese and obese groups were significantly different (P = 0.039).

DISCUSSION

Shock wave lithotripsy (SWL) is a non-invasive modality for managing symptomatic renal stones up to 2cm, except in lower pole renal stones with unfavorable anatomy in many guidelines because the anatomical characteristic of lower pole influences stone-free stone rate[1,2,9]. The main factors that influence SWL success rate are stone factors, anatomical factors, patient factors, equipment availability, and good performance of the SWL process[10]. The store-related factors such as stone size, density, location, and composition are not modifiable and are related to the constitutional characteristics of the stone. The anatomical factors are especially important in the lower pole stones and include unfavorable factors that decrease SWL success rate: infundibular length> 3-4 cm, short infundibular width <4-5 mm, infundibulopelvic angle <70 degrees[11]. The other anatomical factors are renal anomalies such as ureteropelvic junction obstruction (UPJO), horseshoe kidney, ureteral strictures, and pelvic kidneys[12]. The equipment availability and operator experience are

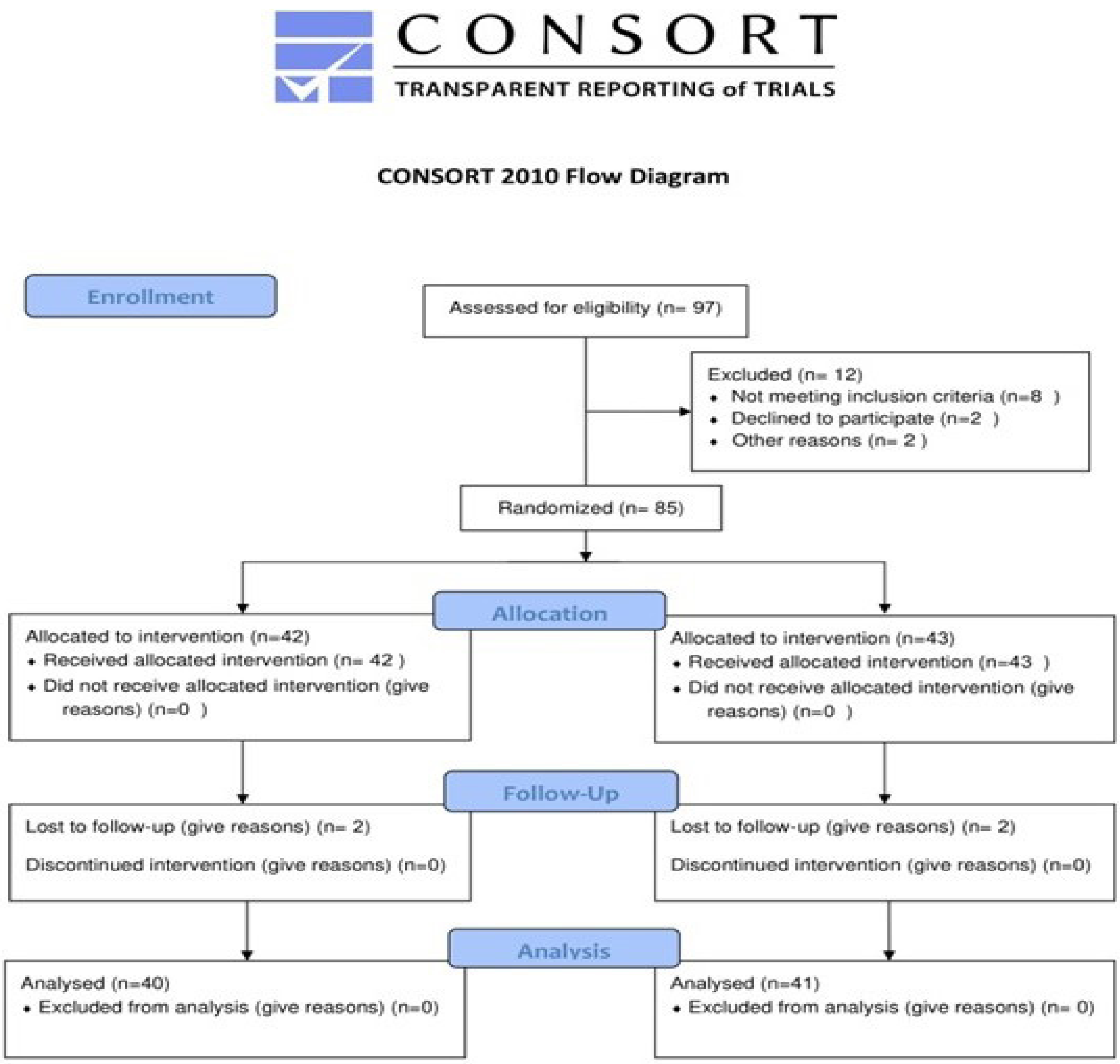

Figure 1. All participants' enrollment summary is represented based on the CONSORT (Consolidated Standards of Reporting Trials) 2010 checklist.

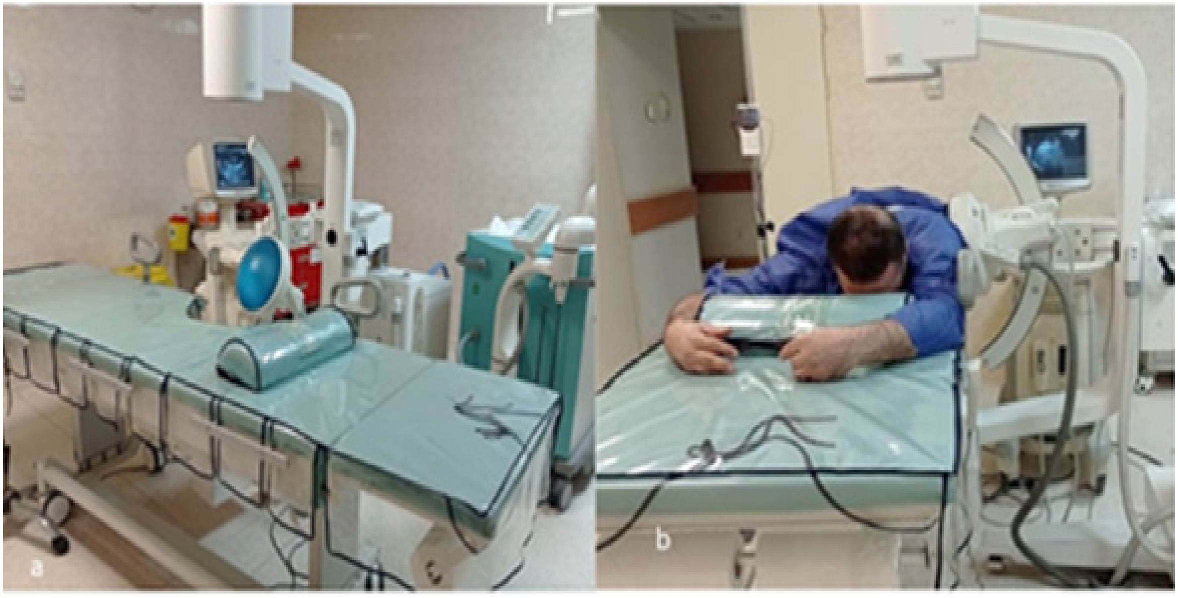

Figure 2. The SWL machine(a) and the SWL in the prone position(b)

also essential for the SWL's success[13]. Some studies investigated the inclined body position (30 degrees of head-down position) on SWL success and concluded that this body modification increases the stone-free rate of lower pole stones[14]. Among the patient factors, the main factor is BMI reflected in many studies on the skin-to-stone distance (SSD) and correlated to the patient's BMI. The SSD, more than 10-11cm, was a negative factor in the success of SWL[15]. The conventional position of the patient during SWL is the supine position.

Sometimes, we cannot perform SWL in the supine position, and the prone position is suggested for the SWL process. The first report of prone SWL stated lower ureteral stones, pelvic kidneys, horseshoe kidneys, and recently proximal ureteral stones[5,6,16]. The prone

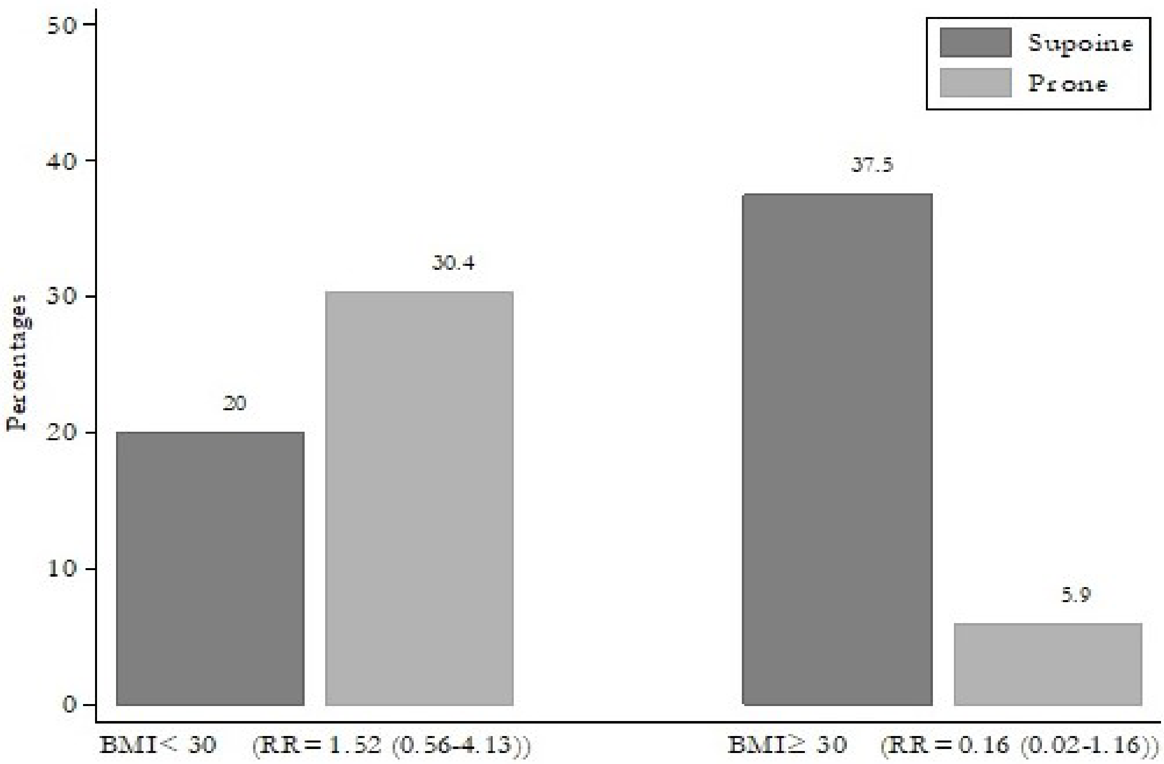

Figure 3. The position-SFR association, which is not SFR percentages, is stratified for body mass index. RR: Risk ratio

position success in proximal and distal ureteral stone was explained in many studies and mentioned that this position is a safe and effective supine position with the same safety profiles[17]. There is contradictory evidence regarding changing the skin-to-stone parameter in different body positions. In a study by Abouelleil et al., they evaluated the effect of body position (prone and supine) in changing the SSD before PCNL. They performed CT urography on 48 patients in supine and prone positions. The SSD significantly decreased in the prone position compared to the supine position[7]. With the concept that the prone position probably decreases the SSD and this change may favor the SWL success rate, we designed a study to compare the SSD measures in prone and supine positions with low dose protocol CT scan before SWL. We also recorded the SSD measures during SWL in prone and supine positions with an ultrasound probe of the therapy head. Then SWL was performed in renal stone in two different (prone and supine) positions.

Some concerns exist regarding increasing the complication in a prone position, such as bowel perforation. However, this complication rate is rarely mentioned in case reports and the literature[18,19]. The other drawback of the prone position may cause interference of bowel gas with the shock wave and reduce the transmission of energy. However, our study did not find a problem with the bowel gas due to the patients' instructions before SWL (light meal and dimethicone the night before SWL). In a survey by Göktas et al. on 96 patients with proximal ureteral stones, the patients were divided randomly to perform SWL in prone and supine positions; their results revealed that the supine position decreases the number of shocks per session with a better pain profile. However, in our study, the pain profile was similar in Supine and prone positions[20]. In an exciting study by Ossandon et al., to increase the SWL stone-free rate, they evaluated the effect of the modification in lithotripsy table height (LTH) on SWL success; with the rising the table height on Z-axis, the distance between stone and propagated SW decreased and efficacy of SWL will be increased[21].

In a study by Ziaee et al., they evaluated the impact of sleep position on the effectiveness of shock wave lithotripsy (SWL) in renal calculi. They concluded that stone-free patients was higher in the group of patients who slept ipsilaterally relative to the kidney stone compared with patients who slept on the contralateral side[22].

In another interesting study by Karatzas et al., they studied impact of modified lateral position on success of the SWL. They compared a group of obese patients (19 patients) that SWL performed in lateral position with a similar group of obese patients (17 patients) that SWL was done on standard supine position. They concluded that the modified lateral position for renal calculi in obese patients was feasible and safe. In addition, it was faster than in the supine position since it overcomes technical difficulties[23].

Cakiroglu et al. evaluated the effect of mild hydronephrosis and different position during SWL on the success rate of SWL in 371 patients with lower pole renal stones. The patients were randomly divided into three supine, prone, and prone positions with a full bladder and positions with mild hydronephrosis. They concluded that mild hydronephrosis and prone position increase stone-free rate in lower pole stones after SWL. Because the entire bladder and oral hydration may increase the hydrostatic pressure of the renal system and enhance the stone fragments' passage, the prone position due to the effect of gravity may increase the stone-free rate [24]. In our study, the SSD parameter was not significantly decreased during the prone position; however, in obese patients, the efficacy of SWL was amplified in the prone SWL process.

Some proposed drawbacks for a prone position include increasing intra-abdominal pressure, so we excluded severe cardiopulmonary disease patients from our study. Some studies on SWL of the lower ureteral stone stated that the prone position is associated with more discomfort, but others mentioned contradictory results[25]. Our study did not show a difference between the two groups regarding the VAS. In a comprehensive review study by Li et al. on SWL of lower ureteral stone in two different supine and prone positions, the number of SW, total SW energy, and SWL session were not significantly different in the two groups. However, the stone-free rate was higher in the supine group. The safety profile was the same in the two groups, and complications were reported as rare[17]. There was no significant difference between the two groups regarding the number of the SWs, SWL sessions, pain scales, and total energy in our study. However, the stone-free rate was better in the prone position than the supine position in obese patients with BMI >30. In a study by Hara et al. on SWL of ureteral stones, it was concluded that the rotated-prone position (30-degree deviation to the ventral plane) results in a better SW transmission than the conventional prone position for distal ureteral stones[26].

Many studies confirmed the positive effects of the combination of hydration, local mechanical percussion, and inversion therapy after SWL in the stone passage, especially in lower pole stone[27]. In a prospective study by Leong et al., they evaluated the effect of SWL with simultaneous inversion in patient position (head down position to 30 degrees) during the SWL process on two matched groups of patients with lower pole renal stone. They concluded that this modification in patient position during SWL had a 1.28 times improvement in stone-free rate and could be used during SWL[28]. In a study by Bohris et al., they evaluated the impact of abdominal compression on decreasing kidney movement during breathing. They found that the stone targeting and efficacy of SWL significantly were improved[29]. We believe that with proper analgesic administration to patients during SWL, the kidney movement related to breathing will be reduced. A study by Kang et al. evaluated the relation between the patient's position and pain score (VAS) during SWL; their patients were positioned in the lateral and supine positions and concluded that the supine position is associated with higher pain scores[30]. There was no significant difference between the two groups regarding the VAS in our study.

To our knowledge, this study is the first one that compares the two different Supine and prone positions in kidney stones SWL. Although seems that the prone and supine have equivalent outcome, this study confirms the positive effect of prone position SWL on the stone-free rate in patients with BMI>30. Also, the important point that should be considered in practice is that the SSD measures were significantly lower in the US than the CT measures; this finding may be realized that the standard definition of the SSD according to the CT should be changed to the US parameters as the therapy head compression on the skin during the SWL decrease the SSD. Our study had some strengths and limitations. The study was prospective; the patient was followed up for three months for stone-free rate status, and the follow-up imaging was a CT scan with high accuracy for detecting residual fragments. Our limitation is the small number of cases and lack of stone samples for analysis. We believed this prone modification could be effective in obese patients and increase the stone-free rate.

CONCLUSIONS

The prone position SWL modification could be effective in obese patients with a BMI of more than 30 and increase the stone-free rate with a similar safety profile and comparable VAS score. It seems the SSD measured by the ultrasound is a more accurate dynamic measurement during the SWL and needs to define the SSD according to the SSD calculation by the US probe of the therapy head.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests

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