

Lunar cycle may have an effect on Shock Wave Lithotripsy related pain outcome

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SUMMARY

Objectives: We tried to investigate the effects of lunar phase on Shock Wave Lithotripsy (SWL) related pain. In addition, correlation of various clinical parameters with the pain perception during SWL procedure, were also investigated.

Methods: A total of 378 patients who underwent first SWL sessions for renal or ureteral stones were prospectively enrolled in the study. The degree of pain perception during the procedure was evaluated with 10-point visual analog scale (VAS) and pain questionnaires. The date of SWL was allocated to dates and times of lunar phases as: newmoon, waxing crescent, first quarter, waxing gibbus, fullmoon, waning gibbus, last quarter and waning gibbus.

Results: Mean VAS scores in first quarter (2,41±1,06) were significantly lower when compared to mean VAS scores in waning crescent (3,58±1,83) and waning gibbus (3,42±1,98) ($p=0,005$ and $0,041$, respectively). No statistically significant differences were observed when other lunar phases were compared between each other. Mean pain scores were not affected from gender, age, body mass index (BMI) and stone characteristics (stone laterality, burden and location).

Conclusions: SWL procedure performed in first quarter of the lunar phase may become less painful. To the best of our knowledge, this is the first study which evaluated the effect of lunar phase on post-SWL pain outcome. Thus, additional randomized studies with larger series may be more informative.

Keywords: lunar phase, lithotripsy, pain, predictive factors, urinary stones

INTRODUCTION

Shock Wave Lithotripsy (SWL) is accepted as a less invasive approach and most guidelines recommend it as the first-line treatment if location and size of the calculi are appropriate for spontaneous passage of fragmented particles¹. As the SWL session is undertaken without anesthesia, shock wave-related pain is one of the most significant side effects of SWL. Although, with the development of SWL technology, analgesic requirements during the procedure have significantly decreased, proper pain management to ensure success and patient satisfaction is essential. However, pain perception received during a SWL session, is a multi-dimensional concept and may be affected from various factors including a wide variety of medical conditions. In addition, psychosocial factors such as expectations, emotions, and an individual's unique learning history may result in a variety of pain perception. Biological variables, including hormonal status and cardiovascular reactivity, may add further differences²⁻⁴. Seasonal, lunar and circadian rhythms may also affect human biology.

Although the seasonal and circadian rhythms have been fairly well described, little is known about the effects of the lunar cycle on the behavior and physiology of humans. Due to barometric pressure, geomagnetic and gravitational changes during different phases of the moon, human behaviour should be affected^{5,6}. In various studies, the effect of lunar cycle on human behaviour have been investigated. Moon's influence on suicides, crimes, traffic accidents, cardiopulmonary resuscitations, birth rates, renal colic, postoperative complications, patient survival after the therapy, admittance to hospitals and emergency units because of various causes (cardiovascular and acute coronary events, variceal hemorrhage, diarrhea, urinary retention) have been already investigated⁶⁻¹⁴. Although, most of the reports found no correlations, related to urology clinical practice, some researchers observed that, renal colic frequency might be correlated with lunar calendar¹⁵. From this point of view, for the first time in current literature, the effect of lunar cycle on post-SWL pain has been studied.

In our prospective study, we tried to investigate the effects of lunar phase on SWL related pain outcome. In addition, correlation of various clinical parameters such as patient age, gender, body mass index (BMI) and stone characteristics with the pain perception during SWL procedure, were also investigated.

METHODS

After the approval of the hospital ethic committee was obtained, we prospectively evaluated a total of 378 patients who underwent first session of SWL for renal/ ureteral stones. Before the procedure we evaluated patients with urinalysis, urine culture, coagulation profile and serum creatinine level. Radiological imaging was done by noncontrast helical computed tomography and, all parameters related with stone characteristics (stone location, side, burden) were determined by an experienced radiologist. Exclusion criteria were signs and symptoms of active urinary tract infection, pregnancy, moderate to severe hydronephrosis, renal insufficiency with serum creatinine >2.5 mg/ dL, multiple and/ or bladder and/ or radiolucent stones. Patients who received auxiliary procedures, such as percutaneous nephrostomy/ double-J catheter insertion or endoscopic treatment before SWL session, patients who had difficulty in understanding the pain scoring systems, and patients who underwent second or third sessions of their SWL procedure were also excluded.

The date of SWL was allocated to the dates and times of the lunar phases defined as: Newmoon, waxing crescent, first quarter, waxing gibbus, fullmoon, waning gibbus, last quarter and waning gibbus. Sun illuminates the side of the moon facing Earth. The portion of this hemisphere that is visible to us on Earth can vary from about 100% (full moon) to 0% (new moon). Between these 2 phases, the degree of illumination varies. This parameter was defined as "illumination percent" in our trial. The calendar month that we already use is about 30.44 days, while the Moon's phase cycle repeats on average every 29.53 days. Therefore, the timing of the Moon's phases shifts by an average of almost one day for each successive month. So, a lunar year has 354 days. The eight phases of the moon were categorized; new moon to waxing crescent (0 to 3.69), wax crescent to first quarter (3.69–7.38), first quarter to waxing gibbus (7.38–11.07), waxing gibbus to full moon (11.07–14.76), full moon to waning gibbus (14.76–18.45), waning gibbus to last quarter (18.45–22.14), last quarter to waning crescent (22.14–25.83), and waning crescent to new moon (25.83–29.53). "Lunar day" was also calculated in the same manner with ordinary used computer programs.

Just before the procedure, patient data including age, gender, weight and height were collected. The BMI was calculated for each patient by dividing weight in kilograms by height in meters squared. The stone burden was calculated by multiplying the largest length of the stone by the shortest perpendicular length and was recorded in square millimeters.

By the same technician under the supervision of a urologist, all patients underwent first session of their SWL procedure using EMD E-1000® (EMD Medical, Turkey) Lithotripter, an electrohydraulic unit that permits us to use X-ray for stone focusing. All patients were given pain therapy with diclofenac sodium 75 mg. Intramuscularly (I.M.), 30 minutes before the SWL session. The patients were previously informed not to use oral/ intravenous/ intramuscular analgesics at least in 3 days before the procedure. If the patient scheduled for SWL suffered pain (renal colic) at the day of the procedure, the SWL session was postponed.

In 2010, we designed a randomized, double-blind clinical trial to assess the analgesic efficacy of single dose IM injection of 50 mg. dexketoprofen compared with single dose IM injection of 75 mg. diclofenac sodium, and we observed that, severity of post-SWL pain was better tolerated with dexketoprofen trometamol.¹⁶ But, in current trial, we decided to use diclofenac sodium. It is among the most widely used non-steroidal anti-inflammatory drugs with lower side effects. Pharmacodynamic studies related with diclofenac sodium reported that, after i.m. administration of 75 mg diclofenac sodium, maximum plasma concentrations had been reached approximately in 25 minutes.^{17,18} Thus, in our trial, injections were made 30 minutes before the procedure as a routine part of the treatment. No side effect related with the drug was observed in our study population.

The number of shock waves (x 2500) delivered for each patient and energy (13 to 19 kilovolts with constant gradual increase) used in each SWL session were same for each patient. Immediately after the procedure, the degree of pain perception was rated by the patients using a 10-point visual analog scale (VAS), and patients were asked about the experience and to rate the severity of pain as no, minor, tolerable, and intolerable.

All analyses were performed using IBM SPSS Statistics Version 20.0 statistical software package (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corporation). Categorical variables were expressed as numbers and percentages, whereas continuous variables were summarized as mean and standard deviation.

To evaluate the correlations between measurements, Pearson correlation coefficient was used. Differences in mean VAS scores in each parameters were assessed with Mann-Whitney U test. For the evaluation of differences in categorical variables, chi square test was used. The statistical level of significance for all tests was considered to be 0.05.

RESULTS

Demographic data and stone characteristics were demonstrated in Table 1. Mean VAS scores were comparable between males and females. Similarly, VAS scores were comparable for renal and ureteral; and right- and left-sided urinary stones. When a cut-off value for BMI was taken as 30 kg/ m², no statistically significant difference was observed between groups. When the cut-off value for stone burden was accepted as 100 mm², no significant difference was observed.

Table 1 Demographic data and stone characteristics (n=378)

Variables		
Age (years)*		41.87 ± 1.33
Weight (kg)*		76.20 ± 1.49
Height (cm)*		167.76 ± 11.20
BMI (kg/ m ²)*		27.58 ± 1.08
Stone burden (mm ²)*		114.59 ± 92.27
Gender	Female	136 (36 %)
	Male	242 (64 %)
Side of stone	Right	191 (50.5%)
	Left	187 (49.5%)
Stone location	Renal pelvis	142 (37.6 %)
	Upper calyx	30 (7.9 %)
	Middle calyx	29 (7.7 %)
	Lower calyx	18 (4.8 %)
	Ureter	159 (42.1 %)
	Upper	111 (29.4 %)
	Middle	37 (9.8 %)
	Lower	11 (2.9 %)

* Values are presented as means ± standard deviations

However, when mean VAS scores were compared with regard to the phases of the moon, first quarter was found to be significantly the least painful period (Table 2). No statistically significant correlation was found between mean VAS scores and "Illumination percent", moon age, BMI, stone burden or patient age (Table 3).

Table 2 Descriptive statistics for moon phases, BMI, gender and stone characteristics

Variables	[VAS Score (Mean±SD)]	p *
Moon phase		
New moon (n=10)	3.00 ± 1.63	
Waxing crescent (n=90)	3.23 ± 1.76	
First quarter (n=17)	2.41 ± 1.06 †‡	
Waxing gibbus (n=73)	3.20 ± 1.77	
Full moon (n=11)	3.00 ± 1.61	
Waning gibbus (n=71)	3.42 ± 1.98	
Last quarter (n=13)	2.76 ± 1.36	
Waning crescent (n=93)	3.58 ± 1.83	
BMI (kg/ m²)		
< 30	3.28 ± 1.81	0.936
≥ 30	3.26 ± 1.68	
Gender		
Female	3.38 ± 1.83	0.320
Male	3.22 ± 1.76	
Stone location		
Renal	3.22 ± 1.74	0.586
Ureteral	3.36 ± 1.85	
Stone burden (mm²)		
≤ 100	3.34 ± 1.79	0.461
> 100	3.21 ± 1.78	
Side of stone (Laterality)		
Right	3.29 ± 1.81	0.937
Left	3.26 ± 1.76	

* Mann-Whitney U test

† p=0.005, when compared to waning crescent

‡ p=0.041, when compared to waning gibbus

For the whole study population, mean VAS scores in “no pain” (n=6), “minor pain” (n=181), “tolerable pain” (n=164) and “intolerable pain” (n=27) groups were 1.66± 1.03; 2.40±0.76; 3.68±1.59 and 7.11±2.01, respectively. However, no statistically significant difference was demonstrated when moon phases were compared according to pain questionnaire results (Table 4). During the study period, no major complication such as bleeding was encountered, and none of the patients required an inpatient stay after SWL

Table 3 Correlation of variables with mean VAS scores

Variables	Correlation coefficient	p value*
Illumination (%)	-0.017	0.741
Moon age (days)	0.086	0.095
Age	-0.022	0.667
Weight	-0.078	0.131
Height	-0.019	0.714
BMI	-0.028	0.591
Stone burden	-0.019	0.715

* Pearson correlation analysis

Table 4 Results of pain questionnaire according to moon phases

Pain question- naire (n-% of total)	New moon (n=10)	Waxing crescent (n=90)	First quarter (n=17)	Waxing gibbus (n=73)	Full moon (n=11)	Waning gibbus (n=71)	Last quarter (n=13)	Waning Crescent (n=93)	p-value*
No pain	0 (0%)	2 (0.5%)	1 (0.3%)	2 (0.5%)	0 (0%)	0 (0%)	1 (0.3%)	0 (0%)	0.705
Minor pain	6 (1.6%)	45 (11.9%)	8 (2.1%)	34 (9%)	6 (1.6%)	31 (8.2%)	8 (2.1%)	43(11.4%)	
Tolerable pain	3 (0.8%)	40 (10.6 %)	7 (1.9%)	33 (8.7%)	4 (1.1%)	32 (8.5%)	4 (1.1%)	41(10.8%)	
Intolerable pain	1 (0.3%)	3 (0.8%)	1 (0.3%)	4 (1.1%)	1 (0.3%)	8 (2.1%)	0 (0%)	9 (2.4%)	

* chi square test

DISCUSSION

Although, diclofenac sodium does not seem the perfect choice for pain management in SWL treated patients, it provides considerable amount of analgesia. Because, in current study, for the whole study group, mean pain score was 3.28±1.79. In addition, among 378 cases, only 27 (7.1%) cases defined the SWL procedure as intolerable (Table 4). So, we think that, adequate pain relief and patient comfort could be achieved with diclofenac sodium.

Up to 18% of German population, believe that the moon cycle influences the follow up of diseases¹³. Holzheimer et al.¹³ investigated the influence of lunar phase on surgical quality, but they could not find any correlation of postoperative complications with the lunar phase. Similarly, Komann et al.¹⁹ observed that lunar phases have no effect on post-surgical pain or its side effects. Related to urology practice, May et al.⁵ studied the effect of lunar phase on quality of radical cystectomy. They could not find any significant difference in terms of the perioperative mortality rates, early re-operation rates, postoperative complications and progression-free survivals. Researchers from Switzerland, investigated whether the incidence of symptomatic renal colics would increase at the time of the full and new moon because of increased lunar gravitational forces²⁰. However, they could not observe any statistically significant difference.

In contrast, Ghalae et al.¹⁵ evaluated renal colic frequency in different seasons and around full moon. They did not find any correlation with solar calendar.

But, among 1481 patients with renal colic, most of the admissions to emergency department were on day 15 in lunar calendar (p<0.05). So, on full moon period, significantly increased admissions for renal colic were noticed. In addition, various studies have been published demonstrating positive correlations between the full moon and incidence of psychological crisis, suicide, child behavior disorders, accidents and injuries²¹⁻²⁴. Ghiandoni et al.²⁵ showed a significant connection between the distribution of spontaneous full-term deliveries and the lunar month. Mikulecky et al.²⁶ also revealed that, the maximal occurrence of gout attacks coincides with the peaking lunisolar tidal effect. Thus, we cannot fully neglect the effect of lunar phase on human body. We observed statistically significant differences only in "first quarter" period (Table 2). Mean VAS score for this moon period was only 2.4 points, which is low enough (Table 2). Only 1 (5.9%) patient had intolerable pain during this period (Table 4). Of course, this data might be coincidental and must be supported by randomized trials with larger series, but according to the results of this trial, we can say that SWL performed in first quarter may be less painful.

In our study, pain scores during the SWL procedures, were not affected by stone characteristics like laterality, location and burden. Similarly, patient age, gender and BMI were not found to be the predictors of SWL related pain outcome (Tables 2 and 3). Six years ago, we published a paper investigating the correlation of those parameters with post-SWL pain²⁷. We evaluated 88 cases who underwent 165 SWL sessions for renal and ureteral calculi, and we noticed that SWL session, stone burden and gender might alter post-SWL pain. Although, in former study, the differences in mean VAS scores between groups (male/ female, first/ second/ third session, $>100\text{ mm}^2 / \leq 100\text{ mm}^2$) were approximately 1 point, significant *p* values were reached. In current study, we excluded cases undergoing second/ third sessions of their SWL therapy in order to eliminate the possible effect of session on pain outcome. Current study was including a larger study population, and we did not observe any gender and burden effect. We already mentioned in our paper that this result could be coincidental. Because, although the *p* value was significant, the correlation coefficient for stone burden was 0.176, concluding mild correlation²⁷. Similarly, Franceschi et al.²⁸, evaluated possible predictive factors for severe pain leading to an indication for analgesia during SWL and concluded that, pain received during SWL cannot be predicted by age, anxiety state, side of the stones and size, diameter of the contact between patient and convergence dome of the lithotripter. In contrast, they observed that the size and location of the stone were correlated with the pain level. The superior caliceal, middle caliceal and pelvic stones were significantly the most painful calculi²⁸. In another study, Oh SJ et al.²⁹ observed that, subjective pain score was not affected by laterality, size of stone; but was affected by patient age, gender and location of stone. So, for today, it is still difficult to conclude which factors would predict SWL related pain outcome. Because, as we discussed in limitations section, pain is a subjective phenomena.

Potential limitations to our study should be considered. First of all, visual analog scale is easy, commonly used but a subjective way in the evaluation of pain perception. Secondly, the cause of pain is multifactorial in nature and, we were unable to discriminate renal capsular pain and pain caused by movement of stone during SWL, from cutaneous or costal pains (for renal stones). Thirdly, pain itself is a very subjective phenomenon. For the same type of intervention, the degree of pain experienced varies from patient to patient and, can be affected by many factors such as age, personality, education, social status, patient's knowledge.

Although, our study has a large study population including 378 cases, some subgroups related to moon phases have relatively small sample size. Future studies with randomization may give more conclusive data.

In conclusion, to the best of our knowledge, our study is the first, that investigated the effect of lunar phases on post-SWL related pain outcome. SWL procedure performed in first quarter of the lunar phase may become less painful. However, pain perception during SWL procedure were not affected from patient age, gender, BMI and stone characteristics (side, location and burden).

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