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A single center experience with a lithotripsy machine "Modulith SLX-F2": Evaluation of dual focus system and clinical results

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Introduction

Since the introduction of Dornier HM-3, lithotripters have been improved and localization using both X-ray and US systems or larger shockwave source was introduced. At present, most of the lithotripters in the field were the 3rd generation systems. The focal size has been reduced and higher energy is distributed in a smaller area to improve disintegration and reduce complications. However, disintegration efficacy of these 3rd generation systems is not as good as that of HM-3 and complication rate has been increased. Small focus may not improve the treatment results due to unclear stone disintegration mechanism or respiratory movements. The dual focus system of the Modulith SLX-F2 was developed to improve the success rate using the two focal size.

Patients and Methods

From May 2005 through October 2006 we treated a total of 362 stones with Modulith SLX-F2. Among them, 293 stones could be followed up 3 months after and we analyzed the results using Mann-Whitney's U test. Staghorn stones were excluded.

Total energy of the 12mm focal area in one session is displayed as Storz Medical Lithotripsy Index (SMLI) value on the control panel of SLX-F2 and we evaluated the treatment results in relation with total shots, energy setting and SMLI value. SLX-F2 enables the operator to select either a standard focus (SF: 5 x 28 mm) or a large focus (LF: 9 x 50 mm), which can be changed even during the therapy session. We used the both focus during the treatment. Shockwave frequency was 1.5 to 2 Hz.

- Treatment method

The first period: From May 2005 through April 2006, we used mainly LF switching to SF only when disintegration was not satisfactory.

The second period: From May 2006 through November 2006 the patients were treated mainly with SF and LF was used only when the disintegration was not satisfactory and we had large fragment area.

It should be noted that this study is retrospective. Usually we change the focus during a

session depending on the disintegration process and treatment results were examined based on the focus mainly used during the session.

- Treatment details
  At the beginning we limited the total SMLI to 350 SMLI for renal stones and 500 SMLI for ureteral stones according to the European data. The limit for renal stones was lowered each time we had patient developed hematoma after SWL and the final limit became down to 200 SMLI.

- Sedation
  Diclofenac, Pnetazosine and Midazolam were used as sedation.
- Operator
  Only two operators treated the patients throughout the aforementioned period.
- Evaluation
  The stones were divided into five groups depending on the length of the longer axis: ≦ 4mm, 4< - ≦10mm, 10< - ≦20mm, 20< - ≦30mm and 30mm<. Evaluation of the treatment results was made by reading plain x-ray films, and when necessary from CT scans at three months after the session. The results were categorized into three: stone-free with no residual stone, success with residual stones less than 3 mm and failure with residual stones larger than 4 mm. The results were also analyzed using Efficiency Quotient, number of SWL sessions and success rates. Auxiliary procedures were TUL after SWL or using of stents.
- Renal hematoma
  We collected blood from all the patients before treatment, on the same day or the next day of SWL session. Renal echography was performed for all the patients with renal stones after SWL session.

Results

Table 1 shows the background of the patients of the first and the second periods. We treated 210 stones in 263 sessions in the first period and 151 stones in 178 sessions in the second period. Statistically here was no difference between the two groups.

Table 2 shows the details of SWL treatment. There was no significant difference in the total number of shockwaves, but the treatment level and SMLI showed significant differences. In the second period, the treatment level was lowred by -0.96 in the renal stones and -1.05 in the ureter stones compared with the first period. SMLI was also reduced down to 73.7% in the renal stones and 70.3 % in the ureter stones. In the first period, 85.4% of the kidney stones and 57.2% of ureter stones were treated mainly with the large focus and 35.7% and 21.4% in

the second period.

The treatment results are summarized in Table 3a, 3b: Table 3a shows treatment results by stone position: The stone-free rate of kidney stones in the second period was 57.1% which is the lowest but the success rate of the same stones was 90.5%. The stone-free rate of lower ureter stones was excellent and over 90%. Examining the results by stone position, stone-free rate and success rate were higher and number of auxiliary procedures was smaller for lower ureter stones. In the first period, the EQ was 0.603: 0.565 for kidney stones and 0.626 for ureter stones. In the second period, the EQ was 0.724: 0.553 for kidney stones and 0.798 for ureter stones. The EQ in the overall period was 0.646. Little difference was observed about kidney stones but treatment results of ureter stones in the second period were better than that of the first period.

As EQ value depends on stone size, we assessed the results by stone size (Fig. 3b). The number of patients may be too small to make a simple comparison, but we found the results of ureter stones in the second period was better than those in the first period in spite of smaller SMLI used in the second period. We compared the SMLI of the success group and that of the failure group. Although there was no significant difference, SMLI of the success group was smaller in both the first and the second periods (Feg.1). No correlation between SMLI to and the disintegration results was suggested.

For the kidney stones 4-10mm in size the treatment results in the first period were better. On the other hand, for those larger than 10mm the results in the second period were better.

Six patients treated in the first period developed renal heamatoma. Table 4 shows the details. The mean age was 49.8 (36 – 46). Four patients had stones in renal pelvis, and two in UPJ junction. Three had stones in right kidney and three in left. Hemoglobin reduced by 0.85+/-0.76 g/dl on the average after SWL. While blood was collected on outpatient basis before treatment, after SWL blood collection was performed during intravenous drips, which may have resulted in different hemoconcentration. For the patients with renal heamatoma hemoglobin reduction was 0.8 – 5.6 g/dl and for two cases it was lower than the average. For the case 5 and 6, 3.3 and 5.6 g/dl hemoglobin were lost. Three patients were asymptomatic or complained of little pain or discomfort, but one patient complained of nausea, vomit and severe flank pain immediately after SWL session. Mean hospitalization period was 5.17 (1 – 14) days and extended by 3.17 (0 – 11) days on the average. One outpatient developed asymptomatic heamatoma which was found by CT scan later.

Three patients were suffering from hypertension, one was taking aspirin and one had had pyelonephritis. The patients with hypertension showed higher blood pressure during the SWL session. The other two patients who had no previous disease were thin and small women with BMI 17.8 – 19.1.

All patients were treated conservatively with rest or IV and no transfusion was given.
The rate of heamatoma occurrence was 2.28% (6/263) in the first period and 0% (0/178) in the second period: 1.36 % in the whole period.
To determine risk factors of severe heamatoma, we performed univariate analysis on sex, focal size, number of shots, SMLI, age, BMI and hypertension (previous disease and during the session). Table 5 shows the results and significant difference was observed only on SMLI.
There was no correlation between the severity of heamatoma and SMLI (Fig. 2).

Discussion

We investigated 1) shockwave energy setting, 2) risk factor for hematoma and 3) treatment results of Modulith SLX-F2 and combination usage of dual focus: SF and LF.
Proper energy should cause good disintegration results with low occurrence of serious side effects. As SLMI, accumulated shockwave energy applied, of Modulith SLX-F2 seems to be a good index, we examined the results not by number of shocks nor energy level but by SLMI. In the first period, the large focus was mainly used and a certain SMLI was applied based on European experience. SMLI was reduced every time a kidney hematoma was developed and finally 200 SMLI was determined as an upper limit. We performed treatment based on this setting in the second period to experience no hematoma. The treatment results were not deteriorated with lower energy applied. The difference between the small focus and the large focus still remains uncertain but 200 SMLI seems to be appropriate to treat kidney stones using both focal sizes. As SMLI should be adjusted according to the patients' physical size, the above setting can be applied only for the Japanese patients. Few side effects of SWL for ureteral stones make the discussion on proper energy difficult. Comparing the SMLI of effective cases with that of failure, SMLI of effective cases is lower both in first and second periods. SMLI for hard stones is usually higher but it is considered higher SMLI does not always bring good disintegration results as far as stone composition and location (impacted or not) also play important role in disintegration resistance.
Authors observed development of hematoma in six patients including asymptomatic ones. All the patients received ultrasound examination after SWL, which made the occurrence higher than other reports. Analyzing risk factors, only SMLI showed significant difference and was thought to be more important factor than number of shocks or energy intensity. Until now, hypertension is thought to be a major risk factor for kidney hematoma. Diabetes, urinary tract infection, usage of anti coagulant drugs, atrophic kidney and obesity are also pointed to be risk factors. In our study, three patients out of six were suffering from hypertension. They showed higher blood pressure during SWL treatment and blood pressure monitoring during

treatment seems to be important. It is also considered smaller SMLI should be applied for these risk patients. Two thin and small female patients with no risk factor developed hematoma, which suggested excessive energy was applied in the first period. As Japanese patients are smaller in stature than American and European ones, the primary setting based on European experience may have been too high. While obesity is usually considered as a risk factor for hematoma, thin and small body can be a risk factor when excessive energy is applied. All the patients with hematoma were treated with the large focus, we found no significant difference between the small and large focus and SMLI seems to be more important. Rasmus et al. reported no significant difference in hematoma development between the small and the large focus in ex vivo study. We also found no correlation between SMLI applied and Hb reduction in the patients with hematoma. Therefore, it is considered excessive energy may cause damage in kidney but the degree of severity of hematoma depends on other factors including the patients' condition.

Treatment results with Modulith SLX-F2 were comparable or better than those with Modulith SLX. Especially, the results of ureteral stones in the second period was remarkable. While EQ of the third generation lithotripters was reported to be 0.36 – 0.67, Teichman et al. reported EQ of HM3 was 0.64 – 0.67 and better than them. In this study, the authors compared the lithotripters in vivo and HM-3, Modulith SLX and Lithostar C showed excellent results. EQ from our study was 0.646, which could not catch up to that of HM-3(0.64-0.67) or Modulith SLX (0.57-0.67). However, if we take only the results of ureteral stones in the second period, EQ was 0.798. Generally, Ureteral stones have less respiratory movement and are smaller in size than kidney stones. Thus focusing is easier and we could take the advantage of the small focus at its best. We assume the excellent results were achieved using the large focus to cover the shortcomings of the small focus if necessary.

SWL also shows good success rate for kidney stones but stone free rate is lower. For large kidney stones, it is considered other methods like f-tul should be used more positively to improve the treatment results.

Conclusion

We examined the treatment results with Modulith SLX-F2. For ureteral stones, it is suggested usage of the small focus switching to the large focus properly may improve the treatment results. "Thin and small stature" is considered to be a risk factor for kidney hematoma when relatively high SMLI is applied. Although excessive SMLI may be involved in developing hematoma, we consider the degree of its severity is determined by other factors.