## Does Extra Corporeal Shock Wave Lithotripsy Predispose Patients to Diabetes Mellitus? Prevalence of Diabetes Mellitus after ESWL in 15 Years Follow-up

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**Abstract: Background and Purpose** To investigate the hypothesis that extra corporeal shock wave lithotripsy (ESWL) increases the risk of new onset diabetes mellitus (DM) or significant changes in FBS. **Materials and Methods** A total number of 307 patients enrolled in this study. All of them had undergone ESWL for kidney stone from 1991 to 1994. In 2009, after 15-19 years, we invited patients to check their Blood Sugar. **Results** there were 307 patients, 19.8% female, and 80.1% male. Mean age of the patient were 44 for female and 42 years for males.47.5% had kidney stone in left side, 42.9% in right side and 9.4% bilateral. The mean FBS increasing was 11.86 g/dl. It was 14.54 g/dl for right side, 8.57 g/dl for left and 16.24 g/dl for bilateral ESWL. **Conclusions** The increasing of FBS is more significant in shock wave intensities higher than 15.5 KV. And there wasn't any significant relationship between age, sex, BMI and total number of shock waves with increasing of FBS. ESWL treatment might associate with increasing FBS without relation to age, sex and BMI.

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Key words: Extracorporeal shock wave lithotripsy (ESWL), Diabetes mellitus (DM), Fasting blood sugar (FBS)

### Introduction

Since 1982, ESWL changed dramatically management of stones but with its popularity new concerns have developed about the potential adverse effects associated with ESWL(Chaussy, Schmiedt et al. 1982) .In a retrospective study, Krambeck proposed that diabetes mellitus was a potential complication of ESWL related to number and intensity of shock waves (Krambeck, Gettman et al. 2006).In another research Makhlouf concluded that patients treated with ESWL don't develop DM at greater rate than does the general population at 6 years of follow-up (Makhlouf, DThornier et al. 2009).according to above finding the aim of this study was to investigate the prevalence of diabetes mellitus or significantly increasing FBS after 15 years of ESWL for managing urolithiasis.

## Materials and Methods

It was a cohort study of 307 patients who underwent ESWL at the hospital, since 1991 until 1994 for kidney stones by the Storz lithotripter (Lithostar-SIEMENS- 1990). An invitation was sent to 1400 consecutive patients.307 patients accepted our invitation and came back to ESWL department. We reviewed the documents of them at the time of ESWL, with specific notification to their medical history including D.M, hypertension and cardiac disorders and BMI. Their CBC, FBS, UREA, Cr, PT, PTT, U.A and U.C were checked. Stone burden, side and stone location, total number and intensity of shockwaves and amount of x-ray exposure were written .The patients' current height and weight, BMI and their FBS checked, and asked about history of DM, and date of onset or diagnosis of DM, family history of DM, and current medications. The operative records were reviewed to obtain data on stone burden, number of shockwaves, and laterality of treatment. Exclusion criteria for this study were previous history of diabetes mellitus. A statistical analysis was done with the version 17 SPSS statistical package. This study had approved by Ethical committee of university.

#### Results

The total number of 307 patients who have undergone ESWL for kidney and upper ureteral stone were selected. There were 61(19.8%) female patients and 246(80.13%) male patients. The mean age was 43.61 years (11-70) for females and 41.63 years (7-72) for males. There were 132(42.99%) patients with right side, 146(47.55%) with left side and 29(9.44%) with bilateral kidney stone. The mean stone size was 2.03 cm. Number of shockwaves was 1000 -50000 (divided in multiple sessions) and its intensity was 14-20 KV.The average increment of FBS was 11.86 g/dl. It was 16.24 g/dl in bilateral, 14.54 g/dl in right side and 8.57 g/dl in left side ESWL. The increasing of FBS (FBS f\_p=FBS follow up-FBS patient) was more significant in ESWL with intensities higher than 15.5 KV (figure 1). The prevalence of DM according to ADA (American Diabetes Association) criteria's for diagnosis of DM was about 8.1% after ESWL.There were no any correlations between age (figure 2) and BMI [BMI=wt (kg)/ht (m<sup>3</sup>] with increasing of FBS.There were no any correlations between total number of shock waves (figure 3) and increasing of FBS.

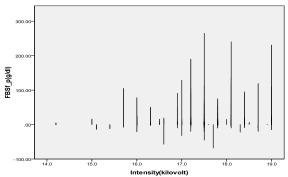


Figure 1-correlation between intensity of shockwaves and increment of FBS

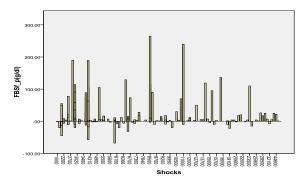


Figure 2-correlation between age and increment of FBS

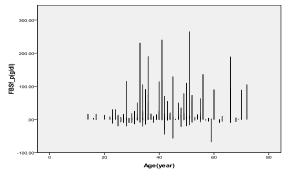


Figure3-Correlation between total number of shockwaves and increment of FB

### Discussions

The potential use of ESWL as a new modality for management of urolithiasis was proposed

in 1960 by Dornier. In 1980, it was used for the first time and the first successful clinical series using this modality reported in 1982 (Chaussy, Schmiedt et al. 1982).

Nowadays ESWL is a safe and non invasive procedure. More than 90% of stones in adults might be suitable for ESWL treatment. Majority of solitary kidney stones are less than 10mm. Thus they can treat successfully by ESWL. For stones between 10 to 20mm, often ESWL is first choice, because this modality is considered noninvasive and effective.

In children, ESWL is safe and effective method for treating renal and upper ureteral stones (Badawy, Saleem et al. 2012).

There are many negative factors that affect on outcome of ESWL, some of them are related to stone (size>20mm), certain compositions like cystine, calcium oxalate monohydrate, brushite and Hounsfield more than 1000 or related to kidney (obstruction, stone in lower pole) and related to patient (obesity, body habits)(Miller and Lingeman 2007). There are several contraindications for using of ESWL including: pregnancy, bleeding diathesis (Streem 1997), uncontrolled urinarv tract infections. skeletal malformations, severe obesity, arterial aneurysm (Carey and Streem 1992) and obstruction distal to stone.

The possible complications of the ESWL can be related to Stone fragments: Steinstrass, re-growth of residual fragments, renal colic, Infectious: bactriuria in non-infection stones, sepsis or to Tissue effect: renal Hematoma(Navarro, López et al. 2009). symptomatic and asymptomatic(Apostolos, Labanaris et al. 2007), cardiovascular dysrhythmia, morbid cardiac events .gastrointestinal bowel perforation (Kurz, Klein et al. 2009)liver, spleen hematoma and spinal cord epidural hematoma(Lee, Lee et al. 2012). There are unusual complications after many ESWL: Hypertension(Lingeman, Woods et al. 1990; Janetschek, Frauscher et al. 1997), that maybe is a sequel of perinephric hematoma (page kidney). Another complication is diabetes mellitus. The prevalence of diabetes for all age-groups worldwide was estimated to be 2.8% in 2000 and 4.4% in 2030(Wild, Roglic et al. 2004).In our study according to ADA (American Diabetes Association) criteria's for diagnosis of DM the prevalence of DM was about 8.1% after ESWL.

In a study by Krambeck AE and co-workers, at 19 years of follow up ESWL for kidney and upper ureteral stones was associated with a slightly higher likelihood of occurring Hypertension and Diabetes than other patients who underwent other therapies for kidney stone. In that study, 630 patients who were treated with ESWL 19 years prior, compared with a control group who treated conservatively for kidney stones at the same time. They found that in first group (ESWL) Hypertension and Diabetes Mellitus are higher than control group. Their explanation was injury of islet cells of pancreas due to shockwaves(Krambeck, Gettman et al. 2006). After that, a comparison of 772 patients treated with SWL for renal stones to 505 patients treated with SWL for ureteral stones by Sato showed no significant difference in new onset of DM, suggesting that, SWL treatment for renal stones might not be associated with new-onset DM(Sato, Tanda et al. 2008).

In recent investigation by Chew and coworkers in 2012, they didn't find any correlation between ESWL and D.M(Cógán, Krambeck et al. 2012).

Makhlouf and co-worker, after a 6 years follow-up study, examined a cohort of almost 2000 patients who treated by ESWL between 1999 and 2002. They had a control group consisted of matched persons. They concluded that patients treated with ESWL; don't develop D.M greater than control group (Makhlouf, DThornier et al. 2009).

Based on these studies, the correlation between ESWL and the development of diabetes mellitus is unknown.

We have some facts about these investigations:

In older studies, ESWL have done by older versions of shock waves systems with wider focal area than new systems. In first study of Krambeck, follow-up is done for 19 years(Krambeck, Gettman et al. 2006), but in newest studies, follow-up period is shorter (Sato, Tanda et al. 2008; Makhlouf, DThornier et al. 2009). New onset diabetes after ESWL may need long time after procedure.

In our study, we have a shock wave system that has made in 1990, and we followed patients for about 15 years and average increment of FBS is 11.86g/dl. These rises of FBS are 14.54 g/dl for right side, 8.57 for left side and 16.24 for bilateral ESWL. We use the ADA (American Diabetes Association) criteria's for diagnosis of DM(Reboldi and Perriello 2004). According these criteria's prevalence of diabetes mellitus is found in 8.15% of patients.

There are not any correlation between FBS rising and age, sex and BMI. We couldn't find any regular relationship between total numbers of shock waves and FBS rising. But there is a strong relation between FBS rising and intensities of shock waves, especially in intensities above 15.5 KV.

According to findings of first study of Krambeck and our study, that in both, the older versions of shock wave system are used, this hypothesis is formed that Old versions(generations) of shock wave systems because of their wide focal area can damage other organs like pancreas(Wendt-Nordahl, Krombach et al. 2007).

Insulin is produced by the beta cells of

pancreatic islets (Standl 2007). Majority of these cells are located in head of pancreas, which is nearby the right kidney. There are three important facts in our study:

1-Our shock wave system is from old generation (Lithostar-1990).

2-prevalence of new onset DM is highest in bilateral ESWL, follows by right side and least in left side ESWL. In bilateral procedure, damage to beta cells is extensive, in right side ESWL head of pancreas (main location of beta cells) is damaged and in left side, tail of pancreas is hurt.

3-The main damaging factor in our study is intensity of shock waves, especially above than 15.5 KV.

As conclusion in a 15 years follow-up of ESWL for kidney and upper ureteral stones, prevalence of new onset of DM is raised about 8.15%.FBS increment is highest in bilateral ESWL, following by right side and left side ESWL. Another important finding is direct affect of intensity of shock waves on rise of FBS, especially intensities above 15.5 KV.

According to these findings, we have some recommendations for managing of kidney and upper ureteral stones by ESWL:

1-shock waves with intensity less than 15.5 KV, is relatively safe. Use high total number-weak intensity shock waves.

2-Using of shock wave systems with small focal area is reasonable.

3-There are higher risks for occurring DM in bilateral and right side ESWL, in these cases, fine adjustment of focal point of system on stone is necessary.

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