THE EFFECT OF TAMSULOSIN ON STONE FREE RATE AFTER SWL

(A Placebo Controlled Study)

Thesis

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بسم الله الرحمن الرحيم

قالوا

سبحانك لا علم لنا
إلا ما علمتنا إنك أنت
العليم الحكيم

صدق الله العظيم

سورة البقرة الآية: ٣٢

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Ahmed Samy Elsaid Abo Elatta

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List of Abbreviations

Abb.	Full term
AS	*Active surveillance*
BMI	*Body mass index*
BPH	*Benign prostatic hyperplasia*
CBC	*Complete blood count*
CT	*Computed tomography*
CTUT	*Computed tomography of urinary tract*
DJ	*Double-J*
ESWL	*Extracorporeal shock wave lithotripsy*
F1	*Focal point*
GA	*General anesthesia*
HU	*Hounessfield Units*
IL	*Infundibular length*
INR	*International normalization ratio*
IV	*Intravenous*
KUB	*Kidney ureter bladder X-ray*
LUTS	*Lower urinary tract symptoms*
MET	*Medical expulsive therapy*
MRI	*Magnetic resonance imaging*
NSAIDs	*Nonsteroidal anti-inflammatory drugs*
PCN	*Percutaneous nephrostomy*
PCS	*Pelvicalyceal system*
PNL	*Percutaneous nephrolithotomy*
RIRS	*Retrograde intrarenal surgery*
SSD	*Stone skin distance*
URS	*Ureteroscope*

INTRODUCTION

Extracorporeal shock wave lithotripsy (ESWL) is a noninvasive technique for the treatment of kidney stones. Most ESWL is carried out when the stone is present in the renal pelvis. ESWL involves the use of a lithotriptor machine to deliver externally applied, focused, high-intensity pulses of ultrasonic energy to cause fragmentation of a stone over a period of around 30–60 minutes.

It is agreed that the preferred approach for stones <1 cm is SWL, whereas for stones > 2 cm, it is PNL, but the management of stones of 1-2 cm is still controversial ***(Seitz et al., 2009)***.

The most important factors which affect the outcome of SWL are stone burden and stone location. Various studies have concluded that the results of SWL are satisfactory if the size of stone is <2 cm, especially in non lower pole location ***(Campschroer et al., 2014; Wang et al., 2016)***.

The highest clearance is achieved with calculi in the renal pelvis and at the pelvi ureteric junction ***(Galvin and Pearle, 2006)***.

The stone free rate for stones in the renal pelvis, lower, middle, and upper calices were 72.4, 56, 55.6, and 69%, respectively, whereas that for stones 1 cm, 1.1 to 2 cm, and >2 cm were 50.2, 39.6, and 10.2% respectively ***(Galvin and Pearle, 2006)***.

The use of medications to speed the spontaneous passage of stones in the ureter is referred as medical expulsive therapy (MET) ***(Saxby et al., 1997)***.

Several agents, including alpha adrenergic blockers (such as tamsulosin) and calcium channel blockers (such as nifedipine), have been found to be effective ***(Saxby et al., 1997)***.

Alpha blockers appear to lead to higher and faster stone clearance rates. alpha blockers only appear to be effective for stones over 4 mm but less than 10 mm in size ***(Rao et al., 2001)***.

Adding medication to SWL has been suggested to improve the success rate such as tamsulosin (alpha blocker) and nifedipine (calcium channel blocker). In addition to additional SWL or ureteroscpoe are the most adjunctive procedure for increasing the success rate of ESWL ***(Srivastava and Chipde, 2013)***.

AIM OF THE WORK

To evaluate the efficacy of alpha blocker (tamsulosin) to enhance stone fragments from urinary tract after ESWL on renal pelvic stones and increased stone free rate after ESWL compared to the placebo.

REVIEW OF LITERATURE

Incidence and prevalence of urolithiasis

Nephrolithiasis refers to stones within the kidney, while ureterolithiasis refers to stones within the ureter. Urolithiasis refers to stones within the kidneys, ureter, bladder, or urethra ***(Sakhaee et al., 2 012)***.

Humans have been affected by urinary stone diseases since at least the first identified case of Egyptian mummies dated to 4800 BC (Before Christian). At present, urinary stones affect 10–12% of the population in industrialized countries ***(Scales et al., 2007).***

Approximately 11–16% of men and 7–8% of women will experience symptoms from urolithiasis by age of 70 years. Over 70% of the population affected with urolithiasis is between 20 and 50 years ***(Shoag et al., 2015)*** with a recurrence rate approaching 50% over 10 **years** ***(Romero et al., 2010).***

Men experience stones in a 2:1 ratio when compared with female ***(Schissel and Johnson 2011)***.

The prevalence of urolithiasis in 1994 was 5.2%, which has more than doubled in 2017. This increase in prevalence is associated with over one million ER (emergency room) visits annually, with over 40,000 surgical interventions. Annual costs approach $5 billion, which will likely continue to increase.

Recurrence is also common, occurring in 15% of patients during the first year and 30–50% within 10 years ***(Ingimarsson et al., 2016)***.

Increasing rates of obesity, diabetes mellitus, and metabolic syndrome have resulted in an increasing rate of nephrolithiasis among women ***(Scales et al., 2007)***.

Diagnosis of urinary stone

Plain KUB: the majority of calcium-containing stones are visible on x-ray, certain stone compositions (eg, cystine and uric acid stones) are radiolucent and not identifiable on x-rays ***(Türk et al., 2016b)***.

Additionally, overlying bowel gas, patient body habitus, and extra-renal calcifications can further limit the diagnostic ability of x-rays ***(Dhar and Denstedt, 2009).***

As a result, the sensitivity and specificity have been reported as low as 59% and 71%, respectively ***(Dhar and Denstedt, 2009).***

Computed tomography (CT): Consequently, non-contrast CT has become the gold standard imaging modality for most patients with acute urolithiasis. CT is able to detect and measure ureteral stones with a sensitivity and specificity of 98 to 100% regardless of size or stone composition ***(Heidenreich et al., 2002).*** Additionally, CT can help to determine the type of stone and the anticipated difficulty with lithotripsy ***(Johri et al., 2010).***

However, CT imaging exposes patients to radiation and several studies have already highlighted the significant radiation exposure that occurs between the initial presentation and follow-up imaging among patients presenting with urolithiasis ***(Kaynar et al., 2015).***

This has led many to advocate for the use of low-dose CT imaging for renal stones ***(Sierzenski et al., 2014).***

Using the low-dose parameters has been demonstrated to reduce radiation exposure, while maintaining similar diagnostic accuracy in most patients.

However, this modality was less accurate for detecting small stones (ie, < 3 mm) and when performed on patients with a body-mass index (BMI) > 30 kg/m^2 ***(Poletti et al., 2007).***

This may be partially counteracted by increasing the radiation dose in proportion to BMI, while still maintaining lower overall radiation exposure than standard-dose CT ***(Moore et al., 2015).***

Advances in technology have led to the recent development of ultra-low-dose CT, with radiation exposure levels approaching that of x-rays. While further studies are needed, this shows significant promise in early literature ***(McLaughlin et al., 2013).***

It is often recommended to avoid intravenous contrast when performing a CT to evaluate for urolithiasis due to concern regarding stone detection. However, intravenous contrast may be needed for the concomitant evaluation of alternate etiologies for the patient's symptoms. Two studies have demonstrated that CT with intravenous contrast is able to reliably detect stones ≥ 3 mm with 97–100% accuracy ***(Dym et al., 2014).***

Ultrasound: Ultrasound offers the advantage of not exposing the patient to ionizing radiation, as well as the ability to be performed rapidly at the bedside. The presence of a stone is often indirectly assessed by evaluating for hydronephrosis ***(Noble and Brown, 2004)***.

Stones can also be directly visualized on ultrasound, appearing as hyperechoic lines with distal shadowing. Adding color Doppler will often demonstrate the "twinkling sign", which is the appearance of alternating colors located deep to the stone (ie, where the shadowing is typically seen on gray scale imaging). The "twinkling sign" has been suggested to be highly specific for the presence of a stone ***(Abdel-Gawad et al., 2016).***

Ultrasound is 54–57% sensitive and 91–98% specific for the diagnosis of urolithiasis ***(Ganesan et al., 2017)***.

Of note, while ultrasound was a less expensive individual test, the overall healthcare costs were not significantly different between both groups ***(Ziemba and Matlaga, 2015).***

Ultrasound is the imaging modality of choice for pregnant and pediatric patients, but may also be particularly valuable to support the diagnosis when there is a moderate or high clinical suspicion of urolithiasis ***(Türk et al., 2016b).***

MRI is useful for the identification of urolithiasis in pregnant patients when MRI has been suggested to be 93% accurate ***(Hernandez and Pais, 2016)*** and similar to ultrasound, does not require any ionizing radiation ***(Pedersen et al., 2011).***

Management of Urinary Stones

A-Management of Incidentally Discovered Urinary Stones (Non-obstructive and Asymptomatic)

1. **Renal or ureteral stone ≤5 mm**: Active surveillance (AS) is the best and the most cost-effective way to manage these stones as long as they remain asymptomatic, due to their likelihood to pass spontaneously.
2. **Renal stones 5–10 mm**: (ESWL) Extracorporeal shock wave lithotripsy is the first-line treatment ***(Türk et al., 2016a; Assimos et al., 2016).***