Single Incision Trans-obturator Tape Procedure *versus* The Standard Trans-obturator Tension-free Tape In The Management of Primary Urodynamic Stress Incontinence

Thesis

Submitted for Partial Fulfillment of MD Degree in **Obstetrics and Gynecology**

BY

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Acknowledgement

First of all, all gratitude is due to ***God*** *almighty for blessing this work, until it has reached its end, as a part of his generous help, throughout my life.*

Really I can hardly find the words to express my gratitude to ***Prof. Khaled Kamal Ali,*** *Professor of Obstetrics and Gynecology, faculty of medicine, Ain Shams University, for his supervision, continuous help, encouragement throughout this work and tremendous effort he has done in the meticulous revision of the whole work. It is a great honor to work under his guidance and supervision.*

I am eternally grateful to ***Prof. Hazem Mohamed Sammour*** *Professor of Obstetrics and Gynecology, faculty of medicine, Ain Shams University, for his help and keep support, without his help this work would have never been completed. I am deeply indebted to him for his comments and suggestion and his deep interest in the subject.*

I would like also to express my sincere appreciation and gratitude to ***Prof. Ahmed Mohamed Ibrahim,*** *Professor of Obstetrics and Gynecology, faculty of medicine, Ain Shams University, for his continuous directions and support throughout the whole work.*

Really I can hardly find the words to express my gratitude to ***Dr. Adel Shafik Salah El-Din,*** *Assistant Professor of Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University for his continuous directions and meticulous revision throughout the whole work. I really appreciate their patience and support.*

I would like to express my deepest gratitude to ***Dr. Ahmed Mohamed Mamdouh,*** *Lecturer in Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University, for his kind advice support and valuable supervision and his great effort throughout this work.*

Finally, I want to express my deepest gratitude to the staff of the urogynecology unit and to my patients.

Last but not least, I dedicate this work to my family, whom without their sincere emotional support, pushing me forward this work would not have ever been completed.

Maii Medhat Nawara Mohyi ElDin

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List of Abbreviations

ALPP	:	Abdominal leak point pressure
AMS	:	American medical systems
ATFP	:	Arcus tendineus fascia pelvis
BMI	:	Body mass index
CI	:	Confidence interval
CLPP	:	Cough leak point pressure
CT	:	Computed tomography
DM	:	Diabetes mellitus
DO	:	Detrusor overactivity
EGP	:	Egyptian pounds
EMG	:	Electromyography
ICIQ-UI-SF	:	International Consultation on Incontinence Questionnaire - Urinary Incontinence - Short Form
ISD	:	Intrinsic sphincter deficiency
MMK	:	Marshal, Marchetti and Krantz
MRI	:	Magnetic resonance imaging
MUCP	:	Maximum urethral closure pressure
MUI	:	Mixed urinary incontinence
MUS	:	Mid-urethral slings
NICE	:	National institute for health and clinical excellence
OAB	:	Overactive bladder
Pdet	:	Detrusor presuure
PFMT	:	Pelvic floor muscle training
PGI-I	:	Patient Global Impression of Improvement
POP	:	Pelvic organ prolapsed
POP-Q	:	Pelvic organ prolapse scoring system
PPV	:	Positive predictive value
Pura	:	Urethral pressure
Pves	:	Bladder pressure
Qave	:	Average flow rate
Qmax	:	Maximum flow rate

List of Abbreviations (Cont.)

RBCs	:	Red blood cells
RCT	:	Randomized controlled trial
SD	:	Standard deviation
SPARC	:	Supra-pubic arch sling system
SUI	:	Stress urinary incontinence
Tds	:	Three times daily
TOT	:	Transobturator tape
TVT	:	Tension-free vaginal tape
TVT-O	:	Transvaginal tape-obturator
UI	:	Urinary incontinence
UPP	:	Urethral pressure profile
UTI	:	Urinary tract infection
UUI	:	Urge urinary incontinence
VAS	:	Visual Analogue Score
VH	:	Vaginal hysterectomy
VLPP	:	Valsalva leak point pressure
vs	:	Versus
VV	:	Voided volume
WHI	:	Women Health Initiative

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A protocol of Thesis

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Introduction

Stress urinary incontinence (SUI) is defined by the international continence society (ICS) as involuntary loss of urine that creates a hygienic and social problem and affects the quality of life of the patient ***(Moreno et al., 2006).***

The prevalence of urinary incontinence in women, using the inclusive definition of any leakage at least once in the past year, ranges from 25 to 51 percent ***(Buckley et al., 2010; Markland et al., 2011)***.

SUI is associated with significant social and financial costs. The social costs include personal embarrassment and curtailment of daily activities that may cause urine leakage. SUI is associated with depression, particularly in the elderly**.** The cost of incontinence pads and undergarments are borne directly by patients as they are usually not covered by health insurance plans ***(Viktrup et al., 2005)***.

Over 200 surgical procedures to treat SUI have been described in the medical literature ***(Farrell et al., 2003).*** An early procedure for treating female SUI, developed by Kelly in 1911, involved anterior colporrhaphy with plication of the urethra ***(Kelly and Dumm, 1914 cited in Berek et al., 2007)***.

In 1949, Marshal, Marchetti and Krantz described a retropubic procedure (MMK), in which the rectus fascia was divided to allow access to the supportive tissue at the bladder neck, which is then fixed to the periosteum of the pubic bone. In 1961, Burch described a similar operation, in which these supporting tissues were anchored laterally to Cooper's ligament instead of the pubic bone, obviating the risk of osteitis pubis, an

uncommon but debilitating complication associated with the MMK procedure ***(Burch, 1961 cited in Berek et al., 2007)***. These procedures involved suspending and stabilizing the bladder neck and proximal urethra in a high retropubic position, thereby preventing their descent during times of increased intra-abdominal pressure. These techniques were effective, with mean 3-7-year continence rate of 77% ***(Walters M and Daneshgari, 2004)***.

Previously, the Burch procedure was offered to patients with SUI as the gold standard primary procedure. When compared with the outpatient minimally invasive procedures, the Burch has the drawbacks of an abdominal incision and a hospital stay. Laparoscopic Burch repair has demonstrated high subjective cure rates, but objective cure varies. Success with laparoscopic Burch repair is dependent upon the surgeon's experience and surgical technique ***(Jenkins et al., 2007)***.

More recently, suburethral pubovaginal sling operations have become popular amongst urologists and gynecologists. In 1942, Aldridge developed the first suburethral sling using rectus fascia. This avoided the need for a laparotomy, therefore decreasing morbidity, but a second incision was still required either abdominally (to harvest rectus fascia) or on the inner thigh (for fascia lata) ***(Aldridge, 1942 cited in Roger et al., 2011)***.

Published studies show long-term cure rates to be similar to Burch procedure, with sustained continence in about 85% of patients. In an attempt to obviate the need for a second incision to harvest fascia, many have evaluated the efficacy of cadaveric fascia, xenografts and synthetic materials e.g. Mersilene, Gortex, silicone and polypropylene, as the sling material ***(Walter and Daneshgari, 2004)***.

Normal urethral closure is maintained by a combination of intrinsic and extrinsic factors. The extrinsic factors include the levator ani muscles, the endopelvic fascia and their attachments to the pelvic sidewalls and urethra. These structures form a hammock beneath the urethra that responds to increases in intra-abdominal pressure by tensing, allowing the urethra to be closed against the posterior supporting shelf. For many women, the loss of this supporting mechanism is severe enough to cause loss of urethral closure during periods of increased intra-abdominal pressure, resulting in stress incontinence ***(Delancey, 1994).***

Modern surgical therapy of female SUI is no longer focused on the proximal urethra and bladder neck, but on providing additional support at the mid-urethra to restore continence. This has lead to introduction of mid-urethral sling procedures. Tension-free vaginal tape (TVT) is a standard minimally invasive procedure used to treat SUI since 1995 when it was first described by ***Ulmsten et al. (1995)***.

The TVT procedure used a "bottom-up" retropubic route of sling passage, and was soon followed by suprapubic arch (SPARC) sling system, using similar methods via a "top-down" approach through the retropubic space toward the midurethra. TVT has shown to have similar effectiveness to colposuspension but with fewer complications ***(Cody et al., 2003)***.

The efficacy, simplicity and minimal invasiveness of these procedures led to other procedures such as the transobturator tape (TOT) technique, and more recently prepubic TVT. All of these procedures keep the same principles of mid-urethral, tension-free placement of a synthetic sling material ***(Shindel and Klutke, 2005)***.

The latest in the logical progression of synthetic slings used in the minimally invasive treatment of SUI is the mini-

sling. However, the next step toward a less invasive, tension-free, mid-urethral sling was to develop a system that could be placed through one small vaginal incision. The TVT-Secur™ device uses a single vaginal incision to place a suburethral macroporous polypropylene mesh tape without exit wounds. The product can be placed either in a Ushape, similar to the transobturator tape position, or a V-shape, similar to the retropubic tape position ***(Salz et al., 2007)***.

The latest mini-sling is the MiniArc™ Single-Incision Sling from American Medical Systems. The product obtained U.S. Food and Drug Administration (FDA) approval for market distribution in March 2007, and the MiniArc™ Sling involves a minimally invasive procedure similar to the TVT-Secur™ product. The MiniArc™ sling has several modifications over the currently available minislings on the market that intend to make it easier to place and achieve immediate fixation for mid-urethral placement of the mesh tape sling ***(Moore and Miklos, 2008)***.

Although success of vaginal tension-free techniques ranges from 84 to 95%, complications described, related to passage of needles include bladder, bowel, and major blood vessel injuries, as well as postoperative voiding difficulties and *de novo* urgency and urge incontinence***(de Tayrac et al., 2004).***

With objective to simplify the previous techniques and minimize the complication rates related to the pass of needles, a new technique has been developed maintaining the principle of a tension-free sling and introducing the concept of application of the sling without needles through a suburethral single vaginal incision ***(Navazo et al., 2009).***