Laparoendoscopic single-site surgery versus conventional multi-port laparoscopy in ovarian drilling: A Randomized Controlled Trial

Thesis

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List of Abbreviations

AES	:	Androgen Excess Society
ALVH	:	Assisted Laparoscopic Vaginal Hysterectomy
AMH	:	Anti-Mullerian Hormone
ART	:	Assisted Reproductive Technology
ASRM	:	American Society of Reproductive Medicine
AUB	:	Abnormal Uterine Bleeding
BMI	:	Body Mass Index
DHEAS	:	Dihydroepiandrosterone Sulfate
ESHRE	:	European Society of Human Reproduction and Embryology
FAI	:	Free Androgen Index
FSH	:	Follicle-Stimulating Hormone
GTT	:	Glucose Tolerance Test
Hb	:	Hemoglobin
IVF	:	In Vitro Fertilization
LESS	:	Laparoendoscopic Single Site Surgery
LESSCAR	:	Laparoscopic Single-Site Surgery Consortium for Assessment and Research
LH	:	Lutienizing Hormone
LOD	:	Laparoscopic Ovarian Drilling
MRCOG	:	Member/Fellow of the Royal College of Obstetricians and Gynecologists
NCCAH	:	Non Classic Congenital Adrenal Hyperplasia
NIH	:	National Institute of Health
NOTES	:	Natural Orifice Transluminal Endoscopic Surgery
NOTUS	:	Natural Orifice Transumbilical Surgery
OHSS	:	Ovarian Hyperstimulation Syndrome
OPUS	:	One-Port Umbilical Surgery
PCOS	:	Polycystic Ovary Syndrome
POD	:	Post Operative Day

List of Abbreviations (Cont.)

POSAS	:	Patient and Observer Scar Assessment Scale
SHBG	:	Sex Hormone Binding Globulin
SILS	:	Single Incision Laparoscopic Surgery
SIMPL	:	Single-Instrument Port Laparoscopic Surgery
SLAPP	:	Single Laparoscopic Port Procedure
SLIT	:	Single Laparoscopic Incision Transabdominal Surgery
SPA	:	Single Port Access Surgery
SPL	:	Single Port Laparoscopy
TLH	:	Total Laparoscopic Hysterectomy
TSH	:	Thyroid Stimulating Hormone
TUES	:	Transumbilical Endoscopic Surgery
UTI	:	Urinary Tract Infection
VAS	:	Visual Analogue Scale
WHO	:	World Health Organization

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Abstract

Study objective: To compare the efficacy and safety of Laparoendoscopic single site surgery (LESS) to conventional multiport laparoscopy (CML) for laparoscopic ovarian drilling (LOD) in polycystic ovary syndrome patients (PCOS).

Design: A randomized controlled trial.

Setting: University hospital.

Patients: Women with PCOS scheduled for LOD.

Interventions: 70 women were randomly assigned to either LESS or CML group (35 in each group) underwent LOD using straight laparoscopic instruments. Successful procedure was evaluated by the need of an additional port.

Measurements and Main Results: There was no significance difference in demographic characteristics between the groups. In addition, there were no differences in postoperative outcomes regarding operative time, estimated blood loss, postoperative pain, and length of hospital stay, between the two groups. LOD was successful in 94.3% of patients (33/35) in LESS group without the need of an additional port. Port insertion related morbidity were reported in the CML group in the form of extraperitoneal insufflation (2.9%), and wound hematoma (2.9%). While, surgical site infection was reported in the lESS group (5.7%). The mean score of the patient and Observer Scar Assessment Scale (POSAS) was significantly decrease from day 1 to 7 in both groups with LESS having lower score on day 7 compared to CML (12.6 vs 14, P= .001).

Conclusion: LESS is feasible, safe, and equally effective to CML with a better cosmetic satisfaction, and less port site related morbidity. However, it is associated with superficial wound infection.

Keywords: cosmetic outcome; Laparoendoscopic single site surgery; Laparoscopic ovarian drilling; Single port laparoscopy

PROTOCOL OF A THESIS FOR PARTIAL FULFILMENT OF M.D. DEGREE IN OBSTETRICS AND GYNECOLOGY

Title of the Protocol: Laparoendoscopic single-site surgery versus conventional multi-port laparoscopy in ovarian drilling: A Randomized Controlled Trial.

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What is already known on this subject? AND What does this study add?

Laparoscopic surgery is a better alternative to traditional open abdominal surgery because it involves a shorter operative time with less morbidity and faster recovery. However, the superiority of LESS surgery over conventional laparoscopy is the lower incidences of port infection, bleeding, and subcutaneous emphysema, resulting in faster recovery, lower morbidity, less postoperative pain, and a nearly completely hidden scar than those achieved with conventional laparoscopy.

1. INTRODUCTION/ REVIEW

Laparoscopic surgery has become the standard of care for many abdominal and pelvic surgeries. Several studies have proved that the laparoscopic approach to various benign and malignant conditions has resulted in decreased morbidity, shorter hospital stay, improved surgical outcomes, and improved quality of life when compared with conventional surgeries ***(Walker et al., 2009).***

Although laparoscopy has decreased the morbidity directly related to a surgical approach, each working port carries an inherent risk of bleeding, infection, concomitant organ damage, hernia formation, and decreased cosmetic outcome. Advances in surgical instrumentation and design have allowed minimal access surgery to become even more minimal ***(Rao, 2004).***

One of the more recent advances in the field of minimally invasive surgery is the increasing use of single incision laparoscopic surgery (SILS) in various gynecologic procedures. SILS allows laparoscopic surgery through a single incision in the umbilicus ***(Romanelli and Roshek, 2010).***

SILS has been described in the literature using many acronyms such as SPA (single port access surgery), LESS (laparoendoscopic single site surgery), SLIT (single laparoscopic incision transabdominal surgery), and SPL (single port laparoscopy). In 2008, an international consortium of minimally invasive experts (the Laparoscopic Single-Site Surgery Consortium for Assessment and Research—LESSCAR) made a consensus to use the term laparoendoscopic single site surgery (LESS) to include all procedures performed in a minimally invasive manner through a single incision ***(Gill et al., 2010).***

The potential drawbacks of the single-port approach are a

larger umbilical incision and the proximity of the instruments resulting in a technical challenge; the extracorporeal interaction of the instruments and camera (known as sword fighting) especially for advanced surgery (***Fanfani et al., 2012).***

Initially, during the 1960s and 1970s, the application of laparoscopic surgery in gynecology was restricted to diagnostic cases and tubal procedures such as sterilization ***(Yoon et al., 2010).***

Pelosi first described utilizing this technique for more complex gynecological surgery**;** who performed a single incision laparoscopic hysterectomy with bilateral salpingo-oophorectomy in 1991. This method, however, was not popularized for another 15 years due to numerous procedural obstacles ***(Pelosi, 1991).***

The interest in this surgical approach has grown exponentially. Several publications in the gynecology literature have demonstrated preliminary feasibility, safety and reproducibility of LESS in the treatment of both benign and gynecological oncology conditions ***(Fader and Escobar, 2009).***

The SILS ™ Port Multiple Instrument Access Port (Covidien®) is a multi-instrument access port that allows up to three laparoscopic instruments (three 5-mm cannulas or two 5-mm and one 12-mm cannula) to be used simultaneously through separate flexible channels. This port allows for adjustment of the cannula positions within the flexible port, and there is a separate channel for CO_2 insufflation with out leak. The port must be inserted through an open access technique **(*Rettenmaier, 2009).***

LESS performed using conventional laparoscopic instruments for appendectomy and cholecystectomy has been reported (***Akgür et al., 2010; Colon et al., 2011)***. However, the combined use of the SILS port (Covidien®) and the conventional laparoscopic instruments has only been reported in the gynecology literature in a report describing the use of conventional straight laparoscopic instruments with SILS port on 14 patients with adnexal masses ***(Dursun et al., 2013).***

The hypothesis is that single incision technique might offer advantages over the standard multi-port laparoscopy as potentially leading to less postoperative pain and improved cosmoses from a relatively hidden umbilical scar, as well as risk reduction of postoperative wound infection, hernia formation and elimination of multiple trocar site closures. ***(Mencaglia et al., 2013).***