A Randomized Trial comparing the effect of vaginal cuff closure techniques at vaginal hysterectomy on vaginal length

Thesis
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Protocol of thesis

Introduction

A hysterectomy is the surgical removal of the uterus. Hysterectomy maybe total, (removing the fundus, body and cervix of the uterus) or subtotal (removing the uterine body but leaving the cervical stump). It is the most commonly performed gynecological surgical procedure. In ٢٠٠٣, over ٦٠٠،٠٠٠ hysterectomies were performed in United States alone, of which over ٩٠٪ were performed for benign conditions (**Wechter, ٢٠٠٧**).

Vaginal hysterectomy is an excellent operation when removal of the uterus is indicated in case of either benign disease or carcinoma in situ of the cervix. Removal of the uterus results in physiological changes that include cessation of menstrual flow and sterility. In addition, it eliminates any existing cervical or uterine disease (**Clifford, ١٩٩٧**).

Vaginal hysterectomy is usually performed for problems with the uterus itself or problems with the entire female reproductive complex. Some of the conditions treated by vaginal hysterectomy include *uterine prolapse, dysfunctional uterine bleeding, adenomyosis and fibroids* (uterus up to ١٢ weeks size) (**Roopnarinesingh, ٢٠٠٣**).

Gynecologists currently use both vertical (longitudinal) and horizontal (transverse) cuff closures at the time of vaginal hysterectomy. Surgical texts have historically suggested vertical closure could decrease the incidence of short post hysterectomy vagina (**Nichols, ١٩٩٦**). These arguments, however, have been based entirely on expert opinion and

not on any scientific method. Several studies have addressed various ways of managing the vaginal cuff at hysterectomy (**Cruikshank, ١٩٨٧. Gray, ١٩٧٥, ١٩٥٨. Rochowiak , ١٩٨٠. Swartz, ١٩٧٦. Poulsen, ١٩٨٤**). There are only two publications by one author based on a single study population, which attempted to address the question of what is the optimal method for vaginal cuff closure at vaginal hysterectomy with regard to its effect on vaginal length (**Cruikshank, ١٩٨٧, ١٩٨٨)**. The conclusion of these prior studies was that either vertical or horizontal closure of the cuff was acceptable.

There were shortcomings, however, within the methodology used in both of these protocols. The preoperative vaginal length in these previous studies was measured from the introitus to the anterior cervicovaginal fornix instead of the posterior vaginal fornix. As defined by the pelvic organ prolapse quantization (POP-Q) system, the proper way to measure total vaginal length (TVL) when the cervix is present is to document the distance from the hymenal ring to the posterior vaginal fornix (**Bump, ١٩٩٦**).

The current study is similar to previous trials but with one important change: preoperative measurement of the vaginal length from the introitus to the posterior vaginal fornix, a measurement that accurately reflects the total vaginal length. In doing so, we intend to more accurately determine whether a horizontal versus a vertical closure technique has any effect on postoperative vaginal length.

Aim of the work

The objective of the study was to compare the effect of the horizontal versus vertical closure of the vaginal cuff during vaginal hysterectomy on post operative vaginal length.

Patients and Methods

This a randomized controlled study will include ٤٨ with the inclusion criteria for vaginal hysterectomy who receive care at maternity hospital at Ain Shams University in the period starting from

Inclusion criteria:

- Uterine prolapse grade ١.
- Dysfunctional uterine bleeding.
- Fibroid uterus and adenomyosis provided that the size of the uterus is not more than ١٢ weeks pregnancy.

Exclusion criteria:

- Presence of suspected pelvic adhesion as in case of endometriosis and previous caesarean section.
- Size of the uterus more than ١٢ weeks of pregnancy.
- Malignant conditions.
- Unfavorable pelvic assessment.
- Uterine prolapsed grade ٢, ٣ & ٤.
- Short vagina.

Methods:

All patients were subjected to the following:

١) All of them will be informed about the aim of the work and tests during the study and written consent will be taken.
٢) Thorough history taking with emphasis on presence of the inclusion criteria and absence of exclusion criteria.
٣) General & pelvic examination as well as Pap smears.
٤) Preoperative assessment and postoperative assessment by POP-Q system which is characterized by six well-defined points on the vagina: two points in the anterior compartment, two points in the apical compartment and two points in the posterior compartment. This points (Aa, Ba, Ap, Bp, C and D). Point Aa is located in the midline of anterior vaginal wall ٣cm proximal to external urethral meatus. Point Ba represents the most distal position of any part of the upper anterior vaginal wall from the vaginal cuff or anterior vaginal fornix to point Aa. Point C represents either the most distal edge of the cervix or the leading edge of the vaginal cuff (hysterectomy scar) after total hysterectomy. Point D is only described if the cervix is present and represents the location of the posterior fornix (Douglas pouch) where

the sacrouterine ligaments are attached to the posterior side of the cervix. Point Bp represents the most distal position of any part of upper posterior vaginal wall from vaginal cuff or posterior fornix to point Ap. Point Ap is located in the middle of posterior vaginal wall ٣cm proximal to the hymen (**figure** ١). The hymen will be the fixed point of reference used throughout this system of quantitative prolapse description. The anatomic position of the six defined points for measurement should be centimeters below or distal to hymen (positive number) or centimeter above or proximal to the hymen (negative number). By definition, the range of position of the points Ap and Aa relative to the hymen is -٣cm to +٣cm. In addition, the length of the perineal body (pb), the genital hiatus (GH) and the vagina total vaginal length-TVL are measured. All the value can be documented by using a three-by-three grid (**figure** ٢). The degree of prolapse can also be quantified using a five stage ordinal system as summarized in (**table** ١). Stages are assigned according to the most sever portion of the prolapse (١٣).

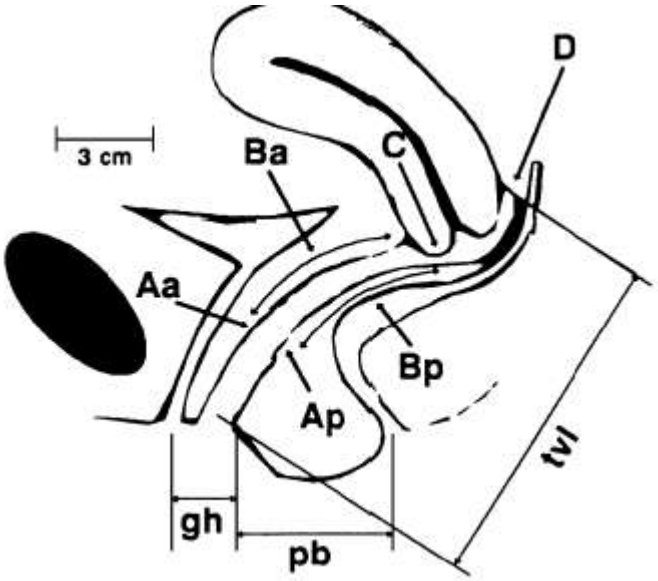

FIGURE ١ Drawing displays the anatomical landmarks used

during pelvic organ prolapse quantization (POP-Q)

Anterior wall Aa	Anterior wall Ba	Cervix or cuff C
Genital hiatus gh	Perineal body pb	Total vaginal length TVL
Posterior wall Ap	Posterior wall Bp	Posterior fornix D

FIGURE ٢ Grid system used for charting in pelvic organ prolapse quantization system (POP-Q).

Stage ٠	No prolapse is demonstrated. Points Aa, Ap, Ba and Bp are all at -٣ cm and either point C and D is between –TVL (total vaginal length) cm and –(TVL-٢) cm (i.e., the quantization value for point C and D is equal or less than –[TVL-٢] cm).
Stage١	The criteria for stage ٠ are not met, but the most distal portion of the prolapse is > ١ cm above the level of the hymen (i.e., its quantization value is < -١ cm).
Stage٢	The most distal portion of the prolapse is equal or less than ١ cm proximal to or distal to the plane of the hymen (i.e., its quantization value is equal or > -١ cm but equal or < +١ cm).
Stage٣	The most distal portion of the prolapse is > ١ cm below the plane of the hymen but protrudes no further than ٢ cm less than the TVL in centimeters

	(i.e., its quantization value is > +١ cm but < + [TVL-٢] cm).
Stage٤	Essentially, complete eversion of the total length of the lower genital tract is demonstrated. The distal portion of the prolapse protrudes to at least (TVL-٢) cm (i.e., its quantization value is equal or > + [TVL-٢] cm). In most instances, the leading edge of stage ٤ prolapse will be the cervix or vaginal cuff scar.

Table ١ the pelvic organ prolapsed quantization (POP-Q) staging system

of pelvic organ support.

٥) Operative technique of vaginal hysterectomy :

- After adequate general or regional anesthesia is administered, the patient is placed in a standard dorsal lithotomy position. The vagina is surgically prepped, and a Foley catheter is placed. A right-angle or suitable retractor is placed along the anterior vaginal wall, whereas a weighted vaginal speculum is placed posteriorly.
- *Vaginal wall incision.* A Volsellum is used to grasp both the anterior and posterior cervical lips and close them together. The margin of the bladder is identified as a crease in the overlying vaginal epithelium. This margin can be accentuated by in-and-out displacement of the cervix. The vaginal wall above the cervix then is circumcised. To avoid dissection into the cervix, this incision is kept at a depth superficial to pubocervical fascia.
- *Anterior peritoneal entry.* The anterior vaginal wall grasped and elevated with an Allis clamp. Additional, tension is created by outward traction on the Volsellum. This traction will reveal fibrous bands connecting the bladder and cervix. With surgical gauze covering the index finger, the surgeon pushes downward and cephalad against the cervix to bluntly dissect through these fibers and move the bladder anteriorly. This motion is continued until the vesicouterine fold is reached. In patient in whom these cervicovesical fibrous bands dense, sharp dissection may be required to avoid blunt cystotomy by surgeon’s finger. The vesicouterine fold can be seen as a transverse white line across the anterior cervix. Palpation

reveal two thin smooth layers of peritoneum slipping against one another. The vesicouterine fold is grasped and elevated to place this peritoneal layer on tension. The peritoneum then is incised. An index finger explores the opening to confirm peritoneal entry and palpate any unanticipated pathology. The anterior retractor then is repositioned with its distal blade entering the peritoneal cavity and elevating the bladder.

- *Posterior entry.* The Volsellum and cervix are lifted anteriorly to expose the posterior vaginal vault, and an Allis clamp is placed on the incised edge of the posterior vaginal wall. The Allis clamp is pulled downward to create tension across the exposed posterior peritoneum. The posterior vaginal wall is cut with curved Mayo scissors, and the Douglas cul-de-sac is entered. The posterior peritoneum is affixed centrally to the posterior vaginal wall incision with a single stitch of delayed absorbable suture. This approximation will assist with closure of the peritoneum at the procedure's end. The short, weighted vaginal speculum is placed by one with a longer blade, which enters the cul-de-sac.
- *Transaction of uterosacral and cardinal ligaments.* Outward traction on the Volsellum pulls the supporting uterine ligaments into view. Such traction on the cervix aids in preventing ureteral injury. The uterosacral ligament is identified, clamped with a curved Heaney clamp, transected and ligated with ·-gauge delayed-absorbable suture using transfixing stitch. After ligation of uterosacral ligament, the cardinal ligament similarly are clamped, cut, and sutured. When the anterior jaw of the Heaney peritoneal edge is pulled downward and incorporated around the pedicle. The uterosacral and cardinal ligament are isolated, clamped, and ligated individually or in combination depending on the size of each. Once the knots of these pedicles are secured, the suture ends are not cut but rather are held by hemostats. These will be suture later to the vaginal cuff to aid in long-term vaginal support.
- *Uterine arteries .*The uterine arteries are identified a serially clamped with two curved Heaney clamps. A simple suture is placed behind the proximal clamp and is secured as this clamp is removed. A second suture is then behind the distal clamp.

- *Utero-ovarian and round ligaments.* If the uterus is small and descensus adequate, two curved Heaney clamps may be placed in tendem across the utero-ovarian and round ligaments and fallopian tubes. Each pedicle is doubly ligated with a simple suture first placed medially. A transfixing syich is then placed distally and held by hemostat. Alternatively, if the uterus is lager, the uterine corpus may be delivered either the anterior or posterior colpotomy incision to expose these ligaments. To deliver the fundus, either fingers or a tenaculum can be used to pull the fundus into the vagina.
- *Oophorectomy.* If removal of the ovaries is desired, the adnexa is grasped with a babock clamp and gently pulled toward the incision. An index finger wrapped around the infundibulopelvic (IP) ligament to isolate him from surrounding structures. The IP ligament is clamped and ligated similarly to the utero-ovarian hemostat.
- *Evaluation of hemostasis.* Following removal of the uterus, the surgical pedicles are inspected for bleeding. Electrosurgical coagulation or individual figure-of eight sutures will control bleeding. If hemostasis is adequate, sutures to IP ligament are cut. At this juncture, if an enterocele repair is planned, it is performed (١٤).
- *Vaginal cuff closure.* During this study, we will do ٢ cuff closure methods: **Vertical** (closing the vagina side to side, leaving a vertical scar) or **Horizontal** (closing the vagina anterior to posterior, leaving a horizontal scar).

٦) Vaginal length measurements were undertaken in a standardized fashion. Once the patient was anesthetized and placed in lithotomy position, the vaginal length was measured in centimeters from the hymenal ring to the posterior vaginal fornix. Care was taken not to stretch the vagina during this measurement. This was accomplished by placing the distal end of ring forceps into the posterior fornix under direct visualization and then applying gentle pressure to be certain the instrument remained in the proper position. The weighted speculum was then removed and the pressure on the forceps released. The point at which the instrument crossed the hymenal ring was then marked and the distance measured. The same measurement was repeated postoperatively utilizing the same technique, the only difference being that the distal end of the forceps was placed at the vaginal cuff.

٧) Randomization will be by a closed envelope technique.

Statistical methods:

Assumptions:

Alpha = ٠,٠٥٠٠ (two-sided)

Power = ٠,٨٠٠٠

According to (Brett J. Vassallo et al, ٢٠٠٦)

Estimated required sample sizes:

n١ = ٢٤

n٢ = ٢٤

Data Management and Analysis:

The collected data will be revised, coded, tabulated and introduced to a PC using Statistical package for Social Science (SPSS ١٥,٠,١ for windows; SPSS Inc, Chicago, IL, ٢٠٠١). Data will be presented and suitable analysis will be done according to the type of data obtained for each parameter.

i. *Descriptive statistics:*

١. Mean.
٢. Standard deviation (± SD).
٣. Minimum and maximum values (range) for numerical data.
٤. Frequency and percentage of non-numerical data.

ii. *Analytical statistics:*

١. **Independent-Samples T** Test will be used to assess the statistical significance of the difference between two study group means.

٢. Paired t-test will be used to assess the statistical significance of the difference between two means of one quantitative variable measured twice for the same study group.

- P- value: level of significance
  -P>٠,٠٥: Non significant (NS)

  -P< ٠,٠٥: Significant (S).

  -P<٠,٠١: Highly significant (HS).

Results:

The results will be tabulated and statistically analyzed.

Conclusion:

Recommendation:

*First and foremost, I thank **God** who gave me the strength to follow this project through to completion.*

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*I am deeply grateful to **my Family** who directed and encouraged me during the preparation of this work.*

Mohamed Ahmed Desoky

List of Contents

List of abbreviations

BSO	Bilateral salpingo-oophorectomy.
CX	Cervix.
DP	Douglus pouch.
EXT.OS	External Os.
GH	Genital hiatus.
IMI	Intramuscular injection.
INT.OS	Internal Os.
IP	Infundibulopelvic ligament.
IVI	Intravenous injection.
MRI	Three-dimensional magnetic resonance imaging.
P	Parity.
Pb	Perineal body.
PID	Pelvic inflammatory disease.
POP-Q	Pelvic organ prolapse quantization system.
SD	Standard deviation.
SPSS	Statistical package for social science.
TVL	Total vaginal length.

List of figures