Pelvic Organ Prolapse – Evaluation, Management, Surgical Outcomes

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Disclosures

No relevant disclosures

Objectives

- Be familiar with evaluation and treatment options for women with pelvic organ prolapse
- Be familiar with anatomical considerations of pelvic floor support
- Be familiar with mechanisms of pelvic organ prolapse
- Be familiar with outcomes of surgical repair of prolapse
"kept standing by engineering design, not supported with brute strength or redundant protections"

"fracture critical - if a single, vital component of the bridge is compromised, it can crumple"

"some bridges deemed to be fine structurally can still be crippled if they are struck hard enough in the wrong spot"

Female Pelvic Floor

- Prevent incontinence, support pelvic organs
  - Elevations in abdominal pressure
  - Motions associated with daily activities
- Permit waste elimination
- Allow childbirth

Pelvic Organ Prolapse

ICS & IUGA 2009 update defining PFD’s
- POP - “descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix) or the apex of the vagina (vaginal vault or cuff scar after hysterectomy),” correlated with symptoms, assisted by any relevant imaging

Variability in est of prevalence & incidence due to variation in definitions - prevalence POP impacted by threshold definition
- Mild POP (any degree) practically universal in older women (98%) but may not have symptoms unless more severe

Nygard et al., Green Journal 2004
Pelvic Organ Prolapse - Increasing

- Cross-sectional study (nationally representative population of women in the US) ➔ prevalence of ≥1 PFD was 23.7%¹.
- Est. more than doubled in women 80 years or older
- 2006 – est direct annual cost ambulatory care for PFD’s in US was $412 million²
- Wu and colleagues used US Census Bureau population projections to estimate total # women who will undergo surgery for POP from 2010-2050 ➔ expected to increase by 48.2% over these 4 decades

1. Nygaard et al, JAMA 2008
2. Wu et al AJOG 2011

Anatomy - Pelvis

Bony pelvis 4 parts: Bil hip bones (ilium, ischium, pubis: fused at acetabulum), sacrum, coccyx

Ilium, ischium, & pubis are fused at the cup-shaped acetabulum

Anatomy - Pelvis

False Pelvis
- superior to iliopectineal line – form pelvic brim
True Pelvis
- below pelvic brim
- sacrotuberosous, sacrospinous ligaments - attach ischial tuberosities & ischial spines bilaterally ➔ sacrum = pelvic stability
Firm, Soft Tissue Support - Pelvic Diaphragm

- Levator Ani
- Coccygeus
- Iliococcygeus
- Pubococcygeus
- Puborectalis
- Pubococcygeus m.
  - Pubovaginalis
  - Puboperinealis
  - Puboanalis

Pelvis - Lateral Walls

- Obturator internus
- Piriformis

Levator Plate

- Connection between anus and coccyx
- Medial insertion of iliococcygeus m. on coccyx

Anococcygeal raphe
Ligamentous Support, Fascial Layers

- Parietal fascia
  - arcus tendineus levator ani (ATLA)
  - arcus tendineus fascia pelvis (ATFP)
  - arcus tendineus fascia rectovaginalis (ATFR)
- Visceral (endopelvic)
  - Cardinal,
  - Uterosacral
  - Pubocervical/pubovesical fascia
  - Rectovaginal

DeLancey – support in the pelvis

- Support of the bladder, vagina, uterus, and rectum
  - network of visceral connective tissue attachments
  - function as a continuous unit
  - contain distinct areas that provide separate defined levels of support along the pelvic floor

DeLancey – support in the pelvis
Apical Support

- Level I
  - Cervix
  - Proximal 1/3 vagina
- Suspend apex
  - Upper paracolpium
  - Cardinal, uterosacral ligaments

Integral Theory – Pericervical Ring

- Failure of cervical ring to support the bladder base → apical or middle compartment prolapse
  - Contributes to stress & urgency urinary symptoms

- Not shown
  3. pubocervical/vesical fascia (vesicovaginal space)
  4. rectovaginal (rectovaginal space)

Anterior Compartment

- Urethra
- Bladder
- Adjacent to anterior vaginal wall
- Separated from posterior
  - Vagina
  - Uterus
  - Endopelvic fascia
Anterior Compartment

- Middle 1/3 - Level II support via the lower paracolpium:
  - mid-vagina, anterior wall
  - endopelvic fascial attachments to the ATFP
  - supportive layer beneath the bladder, (pubocervical fascia)

- Arcus tendineus fasciae pelvis (ATFP) - condensation of the fascia over the medial obturator internus & levator ani mm.
  - lateral attachment of anterior vaginal wall to pelvic sidewall

Anterior Compartment

- Distal 1/3 - Level III support:
  - Fusion pubocervical fascia to the perineal membrane, perineal body, and levator ani muscles

Posterior Compartment

rectum & anus – separated from the anterior by vagina & uterus & endopelvic attachments to the pelvic sidewalls

Level I support shared anterior (cardinal and uterosacral ligaments) - proximally, ant & post vaginal walls abut → flattened appearance on transverse cross section
Posterior Compartment

- Middle 1/3
  - Level II support, lateral → arcus tendineus fascia rectus (ATFR)
- ATFR
  - Lateral attachments of "rectovaginal fascia" → pelvic sidewall

Posterior Compartment

- Distal 1/3 Level III support → fusion "RV fascia" to perineal membrane, perineal body, & levator ani mm.
Evaluation

• Women with symptoms, should undergo pelvic examination
• Assessment should be done with the patient resting & straining, supine & standing
  – Define the extent of the prolapse
  – Establish the segments of the vagina affected (anterior, posterior, or apical)

• Goal: reproduce maximum extent of prolapse in daily life

Evaluation - Anterior

Anterior wall
• assessed by placing either a Sim’s speculum or the posterior blade of a bivalve speculum in the vagina to retract the posterior wall
woman asked to strain
• extent of anterior vaginal prolapse noted

Evaluation - Posterior

The blade is then placed to retract the anterior vaginal wall - strains again to reveal any posterior prolapse
Evaluation - Posterior

Rectovaginal exam can be useful to identify presence of a rectocele and establish the integrity of the perineal body.

Evaluation - Apical

- Bivalve speculum is inserted & the cervix or vaginal cuff is identified to assess apical vaginal support.
- While the patient strains, speculum is slowly withdrawn & the descent of the vaginal apex is noted.
- Women with prolapse that protrudes beyond the hymen for a long duration, the vagina, cervix, or both can become hypertrophied and develop erosions.

POP-Q

- Only system with international acceptance.
- Defines prolapse by measuring anterior, posterior, & apical segments of vaginal wall in cm relative to vaginal hymen.
- Highly reliable and reproducible staging system.
Management Options

• Expectant
• Pelvic floor muscle training
• Pessary
• Surgical

Success of Surgery for Prolapse

• Varies widely depending on definition
• 30 - 65% of women without symptoms (WWE)– POP-Q stage 2 with strain, 3 - 6% prolapse beyond hymen
• Strict anatomic criteria not appropriate
• More clinically relevant criteria
  – No prolapse beyond hymen
• Success 82-94%

Defining Surgical Success

• Barber and colleagues tested 18 “success” permutations
  – Renalyzed CARE trial (colpopexy and Urinary Reduction Efforts)
  – POP-Q, PFDI, PGII
• Absence of vaginal bulge symptoms postop has a significant relationship with a patient’s assessment of overall improvement & improvement in QOL after surgery, whereas anatomic success alone does not
• Subjective cure after native tissue repair high (82-96%)
• Reoperations for recurrent prolapse less than 10%
Apical Support – Surgical Procedures

- Transvaginal
  - Uterosacral ligament colposuspension
  - McCall culdoplasty
  - Sacrospinous ligament colposuspension
    - Synthetic mesh kits
  - Iliococcygeus (prespinous) fascia suspension

- Transabdominal / Laparoscopic
  - Sacrocolpopexy (synthetic graft/mesh)
  - Uterosacral ligament colposuspension

Vaginal apex – Native Tissue

- McCall’s culdoplasty
- Iliococcygeus fixation (ICS)
- Sacrospinous ligament fixation (SSLF)
- Uterosacral ligament suspension

Vaginal Apex - Native Tissue
McCall's & ICS limited to observational studies

- Maher et al 2001 retrospective case-control study:
  - ICS (n=50) v SSLF (n=78)
  - Subjective & objective success similar (91 vs 94%, 85.4 vs 67%, respectively)
  - Stage IV VVP independently predicted POP recurrence

- McCall’s culdoplasty limited to retrospective series
  - Reoperation rates for POP 0% to 14%
Vaginal Apex - Native Tissue
High Uterosacral Ligament

Vaginal Apex - Native Tissue
Sacraspinous Ligament Fixation

Comparison of 2 Transvaginal Surgical Approaches and Perioperative Behavioral Therapy for Apical Vaginal Prolapse (OPTIMAL)

- Largest prospective, multicenter, multisurgeon trial - 374 women, undergoing apical prolapse surgery
- 1st outcome surgical: composite surgical success
  - no apical descent > 1/3 into the vaginal canal or anterior or posterior vaginal wall beyond the hymen
  - no bothersome vaginal bulge symptoms
  - no retreatment for prolapse at 24 months
- Surgical success not different - 64.5% (USLS 100 of 155) v. 63.1% SSLF (94 of 149) (adjusted OR, 1.1, 95% CI
- 18% of women (55 of 305) - bothersome vaginal bulge symptoms
- 14.6% (45 of 308) had anterior or posterior or both beyond the hymen
- 5.1% (16 of 316) underwent retreatment either with a pessary or surgery.
OPTIMAL, Cont

• Randomly assigned to periop behavioral tx with pelvic floor muscle training (BPMT)
  - No difference in BPMT’s usual care for 6- and 24-month outcomes (composite success)
• Anterior vagina - most likely to prolapse beyond the hymen (BPMT = usual care; 12.1% vs 13.8%)
• Usual care → USLS were less likely to have apical descent than those with SSLF (4.9% vs 15.6%; adjusted OR, 0.3; 95% CI, 0.1–0.8)
• BPMT, no difference in apical descent (USLS 16.2% vs SSLF 12.0%; adjusted OR, 1.4; 95% CI, 0.6–3.7)
• USLS & SSLF safe procedures: < 5% of serious AE’s over 2-year follow-up
• Adverse events
  - ureteral obstruction - 3.7% (3.2% [n = 5] diagnosed intraop v 0.5% [n = 1] was diagnosed postop (all in USLS group)
  - acute neurologic pain (buttock pain), possibly as a result of gluteal nerve entrapment, was 4.3% with persistent pain beyond 6 weeks. (all SSLF)
• neither USLS nor SLPF were superior (anatomic, function, or AE)
• perioperative BPMT did not improve prolapse outcomes at 2 years.

Native tissue -Anterior Compartment

Weber et al
• prospective, RCT - 114 patients - standard anterior colporrhaphy (midline plication) v ultralateral native tissue (dissection to pubic rami) v standard colporrhaphy + polyglactin mesh graft
• 1º outcome - anatomic success (optimal cure = stage 0, satisfactory = stage I anterior)
• independent observer - f/u exam with pre/postop questionnaire at 6, 12, and 24 months after surgery
• cure rate - 38% (strict anatomic criteria, median f/u 23 months)
• high rate of symptomatic
• No advantage of one suturing technique v another for anterior repair
  Addition of absorbable mesh to traditional repair did not substantially improve cure rates

Native tissue -Anterior Compartment

Chmielewski et al - reanalyzed the data from Weber trial
• Redefined success
  – (1) no prolapse beyond the hymen
  – (2) no bothersome bulge symptoms
  – (3) no retreatment (repeat surgery or pessary)
• 88% success – no differences between groups
Posterior - Paraiso et al

- Anatomic & functional outcomes 3 surgical techniques for rectocele repair - (1) posterior colporrhaphy, (2) site-specific repair, and (3) porcine-derived, graft-augmented, site-specific repair.
  - ≥ Stage 2 posterior vaginal prolapse, wanted surgery
  - 12 month outcome - anatomic cure: Bp ≤ -1 cmH2O one year after surgery
- Anatomic cure - standard (86%) & site-specific (78%) were significantly > than graft augmentation (54%; P = .02)
- all with functional outcome improvements
- worse colorectal & prolapse symptoms 1 yr post op (16% standard v 12% site-specific v 21% graft augment)
- posterior colporrhaphy and site-specific rectocele repair result in similar anatomic and functional outcomes

Posterior – Sung et al

RCT (2 sites) 160 women, ≥ stage 2 posterior wall prolapse

- NTR (standard or site-specific – surgeon pref) v. porcine graft augment; VVS allowed, no levator plication
- No difference graft (n=67) v. no-graft (n=70)
  - Anatomic failure (12% vs 9%; P = .5)
  - Vaginal bulge symptom failure (3% vs 7%; P = .4)
  - Defecatory symptom failure (44% vs 45%; P = .9)
- Subintestinal submucosal graft augmentation was not superior to NTR

Posterior – Nieminen et al

- RCT: transanal v. transvaginal rectocele repair
  - 30 women with symptomatic rectocele
  - transanal rectoceleplasty (n = 15) v posterior colporrhaphy (n = 15)
- 93% (14/15) transvaginal & 73% (11 of 15) transanal group reported improvement in symptoms
- 1 (7%) vs 4 (27%) in transanal had to splint postop
- Recurrence - 7% transvaginal (1 of 15) v. 40% (6 of 15) transanal
  - symptoms significantly alleviated by both techniques
  - transanal technique associated with more clinically diagnosed recurrences
Posterior - Farid et al

RCT transperineal + levatorplasty, v. transperineal no levatorplasty, v. transanal repair, multiparous women, rectocele > 2cm, ≥ one symptoms (need to splint, sense of incomplete evacuation, excessive straining)
- outcome - size of rectocele (defecography), emptying, symptomatic improvement, & postop sexual function.
- Transperineal approaches, 6 months postop –
  - Reduction in µ anal resting pressure, max reflex volume, urge-to-defecate volume
  - Incomplete emptying & straining → significantly improved
- Levatorplasty v transperineal alone - improved overall functional score, but increased incidence of dyspareunia
- Transperineal v transanal repair → superior in structural & functional outcomes
- Levatorplasty improves functional outcome but increases the rates of dyspareunia

Uterine Preservation

Review by Ridgeway et al, “uterine-sparing procedures require more research but remain an acceptable option for most patients with UVP after a balanced and unbiased discussion reviewing the advantages and disadvantages of this approach”

Hysteropexy v. TVH with Native Tissue Reconstruction – Dietz et al

Multicenter multisurgeon RCT 66 women, stage 2 - 4 UVP, TVH + USLS v. sacrospinous hysteropexy (SSH) ; with anterior repair, posterior repair, or both
- 1° outcome, return to work → shorter after SSH (43 v 66 days; P = .02)
- Recurrent ≥ stage 2 apical POP 1 year postop: 27% SSH group (reop rate 11%, 4/35) v. 3% TVH (reop rate 7%, 2/31)
- no differences in QOL 1 year postop
- Complications rare (1 ureteral obstruction TVH v 0 SSH group)
- SSH for UVP → associated w/ earlier recovery time but more recurrent prolapse, no difference in functional outcome or QOL
Hysteropexy v. TVH with Native Tissue Reconstruction – Detollenaere et al

Multicenter RCT, noninferiority, 208 women ≥ stage 2 UVP, no prior pelvic floor surgery, concomitant A&P repairs & anti-incontinence procedures allowed
• 1st outcome - recurrent apical prolapse, bothersome bulge, or retreatment at 1 year
• Surgical failure rate 0% SSH v. 4% TVH, anatomic outcomes of ANY compartment ≥ stage 2 50% SSH v. 44% in the TVH USLS
• anterior wall recurrence no difference (47/101 SSH v 33/99 TVH), posterior wall higher recurrence TVH USLS 14% v. 4% SSH
• buttock pain SSH, 8/9 symptom resolution 6 weeks postop
• OR time shorter SSH v. TVH (59±13 v 72±21 mins)
• SSH is noninferior to TVH with USLS for composite surgical success in management of apical UVP

Native Tissue Repair Summary
• High-quality evidence to support use of reconstructive NTR as surgical tx of bothersome symptomatic POP of all compartments
• With use clinically relevant definitions of success NTR have high rates of success (subj & obj), low rates of reop, & low rates of AE’s
• Both USLSs and SSLFs effective tx apical POP & provide similar outcomes in anatomy & function w/ few AE’s
• ~18% of women will have bothersome vaginal bulge symptoms, 15% will have anterior, posterior, or both beyond the hymen, & 5% will undergo retreatment (pessary or surgery) 2 years after surgery

Vaginal & Laparoscopic Mesh
• In an effort to reduce failure rates, graft materials were introduced to augment reconstructive repairs
• 1970’s synthetic grafts introduced (based of groin hernia data)
  – placed abdominally for POP
• Preferred mesh- light-weight, large-pore polypropylene (monofilament fibers)
  – Promote integration into host
• Biologic grafts shown to be inferior to synthetic
Level 1 Evidence for Sacrocolpopexy

- RCT CARE trial (Colpopexy and Urinary Reduction Efforts) → that 71% to 76% of women had symptomatic relief of POP with abdominal SCP
  - only 5% re-treatment @ 7 years

Level 1 Evidence for Sacrocolpopexy

- 2013 Cochrane Review, 56 RCT’s
  - SCP associated with a lower rate of recurrent vault prolapse & lower reoperation rates than native tissue or transvaginal mesh (TVM) repairs
  - 3 trials → no significant difference between the abdominal subjective outcomes SCP vs SSLF, recurrent vault prolapse was higher in the vaginal group

Level 1 Evidence Laparoscopic Sacrocolpopexy – Freeman et al

- 2013 1st RCT open SCP to LSCP multicenter equivalence trial,
  - ≥ grade 2 (Baden-Walker) vaginal vault prolapse
- 27 open SCP v. 26 LSCP patients at 1 year
  - Equivalent anatomic success (point “C” on the POP-Q
  - Both groups subjective improvement QOL score
- LSCP → equivalent outcomes to open SCP, with advantage of reduced blood loss and shorter hospital stay
Evidence for Minimally Invasive Approach Sacrocolpopexy – Nosti et al

Multicenter retrospective cohort - open abdominal SCP, LSCP, & robotic sacral colpopexy (RSCP)

- open SCP group - longer hospitalizations, greater overall complication rates v. minimally invasive techniques
- anatomic outcomes (POP-Q) similar ~ 8-mo follow-up

Level 1 evidence - robotic v laparoscopic sacrocolpopexy – Paraiso et al

- RCT women with stage 2 to 4 vault prolapse
  - LSCP (38 patients) v. RSCP (40 patients)
- Both groups → significant improvement 1 year postop in vaginal support & functional outcomes
- No difference in POP-Q measurements or subjective validated questionnaires between groups at 1-year
- RSCP - significantly longer (~1 hour), & patients had significantly more pain at rest and with activity in early postop period (disappeared by the 6-week postop)
- No difference in complication rates (intra or postop)

Level 1 evidence - robotic v laparoscopic sacrocolpopexy – Anger et al

RCT 78 women ≥ stage 2 prolapse, LSCP (38) v RSCP (40)

- Surgical outcomes equivalent at 6 mo f/u (POP-Q & symptom bother)
- RSCP
  - longer OR times (202.8 minutes v. 178.4 minutes LSCP, P = .03)
  - higher pain scores 1 wk postop (disappeared 2-wk postop)
- no differences intraoperative complications
- surgeons had to have completed only 10 cases in OR technique used, training-level surgeons participated
Transvaginal mesh

- 2004 1st TVM- intent to improve anatomic cure rates of native tissue vaginal repairs
- Transvaginal - into the vesicovaginal/rectovaginal space, trocars, fixation tips
- Case series – high cure, low complications
- 2010 – 25% all POP surgeries

Transvaginal mesh

- Increase in use, inadequate studies → increase in AE’s, 2008 FDA public health notification
- 2011 FDA Safety Communication – TVM not found to be more effective than NTR & may expose patients to greater risk
- 2011 ACOG/AUGS Committee Opinion use of TVM
  - Restricted to high risk patient, adequate informed consent
  - Device specific training to experienced reconstructive pelvic surgeons
  - Need for continued surveillance of existing products, rigorous comparative trials between TVM and NTR
- FDA proposed to reclassify TVM for POP from a class II (low to moderate-risk) to a class III (high-risk) device

Complications of TVM for POP (2005 – 2013) as reported to the MHRA
Transvaginal mesh for anterior wall support – 2013 Cochrane Review

10 trials: native tissue v. nonabsorbable synthetic TVM in anterior wall
- largest RCTs comparing native tissue anterior repair with TVM, (Altman et al) → TVM superior to native tissue in anatomic and subjective cure at 1 year with composite success rates of 60.8% in the TVM compared with 34.5% in the native tissue group (95% confidence interval [CI] 15.6–37.0).
- NTRs were associated with more recurrent anatomic prolapse than TVM repairs (relative risk [RR] 1.15, 95% CI 1.20–3.96).
- women who underwent NTR of the anterior wall noted increased awareness of prolapse v. polypropylene mesh (28% vs 18%, RR 1.57, 95% CI 1.18–2.07).
- Reoperation rates for anterior wall prolapse were statistically similar between NTR (3%) and anterior polypropylene mesh repair (1.3%; RR 2.18, 95% CI 0.93–5.10).

Transvaginal mesh for anterior wall support- Jonsson Funk at al

Using adjudicated health care claims of women who underwent traditional anterior colporrhaphy v. TVM 2005 - 2010
- 5-year cumulative risk of any repeat surgery to be significantly higher for TVM versus native tissue (15.2% vs 9.8%, P < 0.001)
- 5-year risk of mesh revision/removal was 5.9%
- Risk of surgery for recurrent prolapse similar between groups (10.4% vs 9.3%, P = .70) → analysis indicated the higher reoperation rate seen in the TVM group, due to surgery for mesh complications (not recurrent prolapse).

Transvaginal mesh for posterior prolapse

- Evidence does not support the use of grafts at the time of posterior vaginal repair
- Similar recurrence rate
- Porcine grafts no consistent advantage over native tissue posterior repair
TVM for Apical & Multicompartment Prolapse – Gutman et al

Double-blind multicenter RCT TVM for POP repair
- 3-year outcomes published 2013
- stage 2 to 4 POP, traditional NTR (n=32, A & P repair, + vaginal colpopexy as indicated) v. TVM (n=33, anterior prolift or total prolift), women with a uterus underwent TVH
- prematurely halted ⇒ mesh exposure rate 15.6%
- various definitions of cure no difference (Composite (hymen) 63% mesh v. 57, anatomic cure - no prolapse beyond hymen - 85% mesh v. 71% no mesh)
- Symptomatic cure 92% mesh v. 81% no mesh, & satisfaction (88% mesh vs 81% no mesh) were high for both
- underpowered

TVM for Apical & Multicompartment Prolapse – Maher et al

RCT laparoscopic SCP v TVM for apical prolapse,
- objective & subjective success 2 yrs postop
- objective success rates 77% LSCP (41/53) v 43% TVM (23/55), P <.001
- significantly higher reop rate associated with TVM surgery 22% (12/55) v. 5% LSCP of 3 of 53 (5%), P = .006

TVM for Apical & Multicompartment Prolapse – Higher Reoperation Rate

Diwadkar et al
- review of complications & reoperation after apical repairs, TVM = higher reoperation rate (8.5%) v vaginal NTR (3.2%), mostly due to mesh-related complications
- reoperation rate after TVM repair (11%) was higher v. after NTR (3.7%; RR 3.1, 95% CI 1.3–7.3).
Summary for TVM

- TVM improves anatomic outcomes & sensation of bulge when used for repairs in the anterior compartment compared with NTR
- Despite anatomic benefit in the anterior wall, TVM has not been shown to significantly improve quality of life.
- Because of the known complications associated with TVM use (dyspareunia, mesh exposure or erosion), TVM prolapse repairs may best be used on-protocol.
- There is currently no evidence for use of TVM in apical, posterior, or multicompartment POP.