Vaginal Surgery Without Mesh

How Are We Doing?

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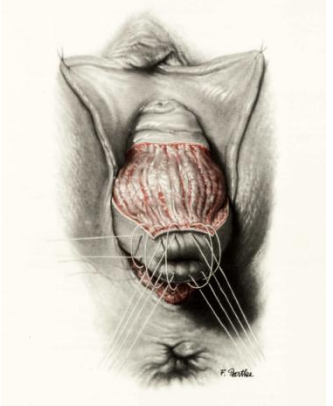
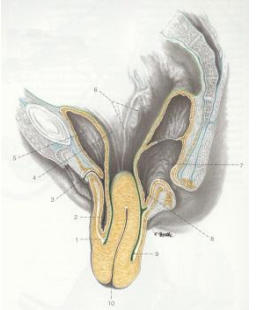
No Disclosures

UFK GYN GRAZ





How Are We Doing?

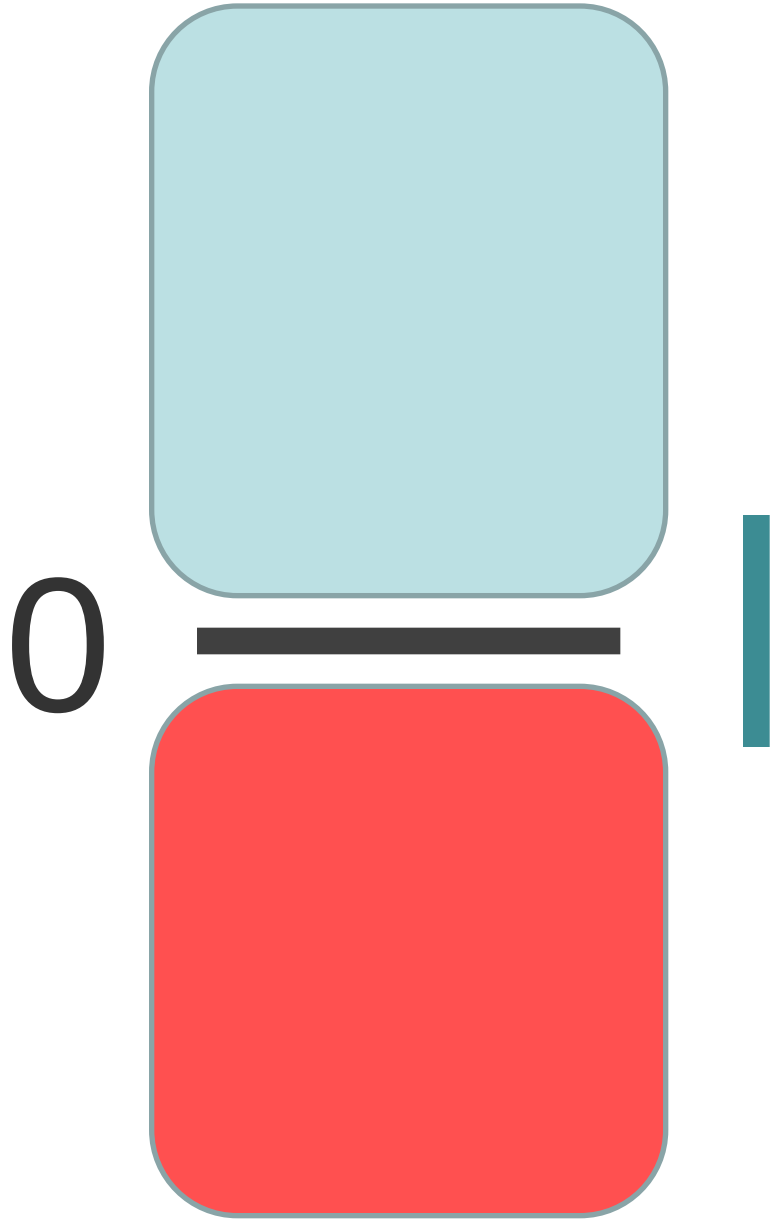
- Definitions
- Failure/Recurrence common problem?
- New look at older studies

What is Recurrence?

- St.p. simple hysterectomy?
- Same compartment?
- Other (non operated) compartment?
- Incontinence after prolpase surgery?

Is This Recurrence?

- 50 yo nurse with „Descensus“ 5 y after vag. HE
- 72 yo former sports teacher with „recurrent CC“
  - St.p. vag. HE at 45 y for bleeding problems
- 76 yo mit „recurrent rectocele“
  - St.p. abd. HE at 41 yrs for myomas
  - St.p. Colpoperineoplasty at 68 y for RC elsewhere



Stage 0: no prolapse

Stage 1: >-1

Stage 2: -1 to +1

Stage 3: >+1

Stage 4

Definitions matter

Definitions matter

I did not have sex …

Failure big problem?

Or are studies misinterpreted?

Background

- 11% lifetime risk of surgery for prolapse or IC
- 29% → 2nd operation
- Established OPs inadequate?
- Contrary to our impression

Epidemiology of Surgically Managed Pelvic Organ Prolapse and Urinary Incontinence

AMBRE L. OLSEN, MD, VIRGINIA J. SMITH, MD, JOHN O. BERGSTROM, MD, JOYCE C. COLLING, RN, PhD, AND AMANDA L. CLARK, MD

***Objective*: To determine the incidence of surgically managed pelvic organ prolapse and urinary incontinence in a population-based cohort, and to describe their clinical characteristics.**

***Methods*: Our retrospective cohort study included all patients undergoing surgical treatment for prolapse and incontinence during 1995; all were members of Kaiser Permanente Northwest, which included 149,554 women age 20 or older. A standardized data-collection form was used to review all inpatient and outpatient charts of the 395 women identified. Variables examined included age, ethnicity, height, weight, vaginal parity, smoking history, medical history, and surgical history, including the preoperative evaluation, procedure performed, and details of all prior procedures. Analysis included calculation of age-specific and cumulative incidences and determination of the number of primary operations compared with repeat operations performed for prolapse or incontinence.**

***Results*: The age-specific incidence increased with advancing age. The lifetime risk of undergoing a single operation for prolapse or incontinence by age 80 was 11.1%. Most patients were older, postmenopausal, parous, and overweight. Nearly half were current or former smokers and one-fifth had chronic lung disease. Reoperation was common (29.2% of cases), and the time intervals between repeat procedures decreased with each successive repair.**

***Conclusion*: Pelvic floor dysfunction is a major health issue for older women, as shown by the 11.1% lifetime risk of undergoing a single operation for pelvic organ prolapse and urinary incontinence, as well as the large proportion of reoperations. Our results warrant further epidemiologic research in order to determine the etiology, natural history, and long-term treatment outcomes of these conditions. (Obstet Gynecol 1997;89:501–6.**

It is estimated that 50% of parous women lose pelvic floor support, resulting in prolapse; of these women, 10–20% seek medical care for their symptoms.[1] The prevalence of all causes of urinary incontinence is reported to be 10–25% in women age 15–64 years[2] and 15–37.7% in community-dwelling women over the age of 60.[3] However, the true incidence (new cases) of these conditions is unknown.

Treatment for pelvic organ prolapse and stress urinary incontinence involves surgical repair of site-specific defects in pelvic floor support. The National Center for Health Statistics reports that nearly 400,000 operations are performed annually for these conditions.[4] Although surgically managed cases represent only a subset of symptomatic patients, they are an identifiable group, and their care is costly.

A review of the English-language literature for the last 10 years reveals few published studies on the epidemiology of pelvic organ prolapse and urinary incontinence. Cited risk factors for the development of stress incontinence include advancing age, white race,[5] obesity,[6] vaginal delivery,[7] estrogen deficiency, activities or conditions associated with chronically increased intra-abdominal pressure, cigarette smoking,[8,9] underlying connective tissue disease, neuropathy, and prior hysterectomy. The purpose of this study was to determine the incidence of surgically managed pelvic organ prolapse and urinary incontinence in a cohort of women representative of the general population, and to describe their clinical characteristics.

Materials and Methods

Kaiser Permanente Northwest is a large health maintenance organization with nearly 393,000 members; it draws from an estimated service area of more than 2 million people. Members of Kaiser Permanente Northwest were chosen as our study group because their health histories are recorded in a uniform fashion, medical records are maintained in a centralized location, and membership demographics are representative

From the Departments of Obstetrics and Gynecology, Oregon Health Sciences University and Kaiser Permanente Northwest, Portland, Oregon.

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PII S0029-7844(97)00058-6

Anterior colporrhaphy: A randomized trial of three surgical techniques

Anne M. Weber, MD, Mark D. Walters, MD, Marion R. Piedmonte, MA, and Lester A. Ballard, MD
Cleveland, Ohio

- N = 114
- Standard CR / ultralateral CR / CR + Vicryl mesh
- „Cure“: POP-Q stage 0/I

→ „Cure“ (23 mo): 30%, 42%, 46%

Weber et al. AJOG 2001;185:1299

Original Article

The Standardization of Terminology for Researchers in Female Pelvic Floor Disorders

A. M. Weber[1], P. Abrams[2], L. Brubaker[3], G. Cundiff[4], G. Davis[5], R. R. Dmochowski[6], J. Fischer[7], T. Hull[8], I. Nygaard[9] and A. C. Weidner[10]

In general, prolapse is defined as descent of stage I or greater. An optimal anatomic outcome (cure) after intervention is defined as stage 0, or no prolapse. A satisfactory anatomic outcome (improvement) after intervention is defined as stage I. An unsatisfactory anatomic outcome (persistence or recurrence, failed treatment) after intervention is defined as stage II or greater, or no change or worsening from the pre-

2001




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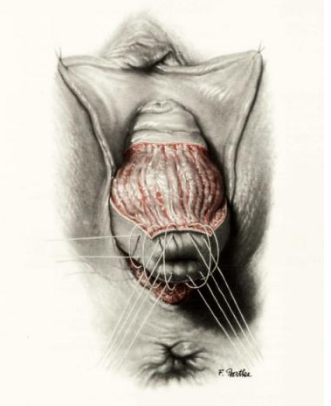

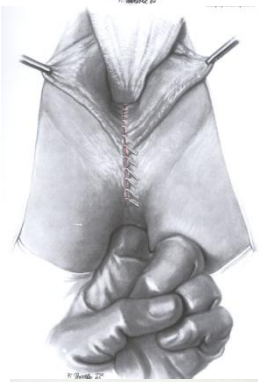
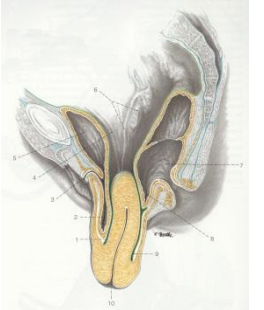

How Often Do Our Operations for Prolapse Fail?

P.T. Gotthart, K. Tamussino, Th. Aigmüller, P.F.J. Lang, G. Ralph

Medical University of Graz, KH der Barmherzigen Brüder Graz,
LKH Leoben /Bruck a.d. Mur
Austria

Objective

- Determine reoperation rate for recurrent prolapse 10 years after primary surgery for prolapse

Gotthart et al. IUJ 2012;23:1221-4

Methods

- Identify all patients undergoing primary surgery for POP at 3 large regional centers 1997-98
- Search hospital databases for reoperations through 2008
- IRB approval

Gotthart et al. IUJ 2012;23:1221-4

Results

- 456 patients identified
- Mean age, 62 yrs (31-93)
- Primary surgery, vag. HE + colporrhaphy, 89%

Gotthart et al. IUJ 2012;23:1221-4

Reoperations

- 13/456 (2.9%) reoperations identified
- Interval, 5.5 yrs (1.5-10)
- Age at initial surgery, 50 yrs

Gotthart et al. IUJ 2012;23:1221-4

Limitations

- Reoperation rate only a partial indicator of success/failure
- Underestimate
- No data on recurrences treated w/o surgery or untreated
- No data on patients reoperated elsewhere

Gotthart et al. IUJ 2012;23:1221-4

What do other studies (really) say?

- 11% lifetime risk of surgery for prolapse or IC
- 29% 2nd operation

→ Can´t separate reops. for prolapse from incontinence

→ Reoperation for prolapse???

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Reanalysis of randomized trial of three surgical techniques of anterior colporrhaphy

- N = 114, 3 techniques, FU 23 months
- „Cure“: POP-Q stage 0 or I
- Results: Cure: 30%, 42%, 46%

- 90% no prolapse beyond hymen, 95% without prolpase symptoms at 1 yr
- 1% reoperation rate

Barber et al. IUGA/ICS, Toronto 2010
Weber et al. AJOG 2001;185:1299

Defining Success of Prolapse Surgery

- CARE trial, 18 definitions of „success“
- Anatomic „success“: 19%-97%
- 94% no prolapse beyond hymen;
  2.8% retreatment

Barber et al (PFDN). Obstet Gynecol 2009;114:600

Complication and Reoperation Rates After Apical Vaginal Prolapse Surgical Repair

A Systematic Review

Gouri B. Diwadkar, MD, Matthew D. Barber, MD, MHS, Benjamin Feiner, MD, Christopher Maher, MD, and J. Eric Jelovsek, MD

OBJECTIVE: To compare postoperative complication and reoperation rates for surgical procedures correcting apical vaginal prolapse.

DATA SOURCES: Eligible studies were selected through an electronic literature search covering January 1985 to January 2008 using PubMed, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, and the Database of Abstracts of Reviews and Effects.

METHODS OF STUDY SELECTION: Only clinical trials and observational studies addressing apical prolapse repair and recurrence or complication rates were included. The search was restricted to original articles published in English with 50 or more participants and a follow-up period of 3 months or longer. Oral platform and poster presentations from the American Urogynecological Society, the Society for Gynecologic Surgeons, the International Urogynecological Association, and the International Continence Society from January 2005 to December 2007 were hand searched to determine whether they were eligible for inclusion.

TABULATION, INTEGRATION, AND RESULTS: Procedures were separated into three groups: traditional vaginal surgery, sacral colpopexy, and vaginal mesh kits. Complications were classified using the Dindo grading system. Weighted averages were calculated for each Dindo grade, complication, and reoperation. Dindo grade IIIa (433/3,425 women) and IIIb (245/3,425) rates were highest in the mesh kit group owing to higher rates of mesh erosion (198/3,425) and fistulae (8/3,425). Reoperation rates for prolapse recurrence were highest in the traditional vaginal surgery group (308/7,827). The total reoperation rate was greatest in the mesh kit group (291/3, 425, 8.5%).

CONCLUSION: The rate of complications requiring reoperation and the total reoperation rate was highest for vaginal mesh kits despite a lower reoperation rate for prolapse recurrence and shorter overall follow-up.

(Obstet Gynecol 2009;113:367–73)

From the Cleveland Clinic, Cleveland, Ohio; and Wesley Hospital, Brisbane, Queensland, Australia.

Presented at the American Urogynecologic Society 29th Annual Scientific Meeting, September 4–6, 2008, Chicago, Illinois.

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Pelvic organ prolapse often involves a combination of support defects involving the anterior, posterior, and apical vaginal segments. There is growing recognition that adequate support for the vaginal apex is an essential component of a durable surgical repair for women with advanced prolapse.[1–3] The Surgery for Pelvic Organ Prolapse Committee of the 3rd International Consultation on Incontinence noted that "the apex is the keystone of pelvic organ support . . . the best surgical correction of the anterior and posterior walls is doomed to failure unless the apex is adequately supported."[1] Restoring the anatomy of the vaginal apex by apical suspension can be achieved by several techniques, with the "gold standard" being sacral colpopexy.[4] Traditional vaginal approaches include sacrospinous ligament fixation, uterosacral ligament suspension, iliococcygeus muscle suspension, and McCall's culdoplasty. More recently, commercially available vaginal mesh kits that use trocars to place permanent mesh transvaginally have gained in popularity.[5] However, none of these techniques is without risks for complications or prolapse recurrence.

Data are lacking that compare complication and recurrence rates of traditional procedures with vaginal mesh kits. We hypothesize the following: 1) sacral

Table 2. Weighted Averages and Confidence Intervals of Complications, Dindo Grades, Prolapse Reoperation Rates, and Total Reoperation Rates

	Traditional Vaginal Repair*	Sacral Colpopexy	Mesh Kits
Number of studies†	48	52	24
Number of patients	7,827	5,639	3,425
Mean follow-up (mo±SD)	32.6±19.8	26.5±20.1	17.1±13.8
Reoperation for prolapse recurrence	3.9 (3.5–4.4), 0–29.1	2.3 (1.9–2.7), 0–31.3	1.3 (1.0–1.7), 0–16.0
Total reoperation rate¶	5.8 (5.3–6.3), 0–29.2	7.1 (6.4–7.8), 0–26.2	8.5 (7.6–9.4), 0–30.0

Diwadkar et al. Obstet Gynecol 2009;113:367

	N	Follow-up	„Recurrence“	Reoperated for prolapse
CARE 2009	322	2 yrs	19-97%	2.8%*
Kapoor 2010	207	4 yrs	.	3.4%
Crafoord 2008	542	6 yrs	-	5.3%
Olsen 1997	395	Lifetime	--	?
Denman 2008	374	10 yrs	--	?**
Fialkow	142	10 yrs	25%	4%
Graz 2012	456	10 yrs	?	3%

*retreatment
**17% reoperation for prolapse and incontinence

Risk Factors
for Repeat Prolapse Surgery

- Age <60 years (OR 2.4)
- Stage III/IV (vs. Stage I/I, OR 2.7)
- Weight >65 kg

Diez-Itza et al. IUGJ 2007;18:1317
Salvatore et al. Neurourol Urodyn 2009;28:301
Whiteside et al. AJOG 2004;185:1533

Conclusions

- Definitions matter
- Recurrent prolapse not a uniform entity
- Misinterpreted studies
- Reoperations for prolapse after OPs without mesh appear modest (<5%)
- No need for paradigm shift
- But …

Treatment Individualized According to

- Compartment
- Risk factors (age, stage)
- Function
- Previous surgery
- Risks/Benefits

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