

Complications of Female Anti-incontinence Surgery

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October 10, 2007

SUI Epidemiology

- Estim. prevalence of female incontinence
 - 20-30% of young adults
 - 30-40% of middle aged
 - Up to 50% of elderly
- Type of incontinence
 - SUI 50%
 - Mixed 30%
 - UUI 20%

SUI Pathophysiology

- Intact neural and anatomic mechanisms
- Continenence requirements
 - Bladder
 - Compliant
 - Absence of instability
 - Normal sensation
 - Outlet
 - Closed at rest
 - Remains closed during rises in intra-abdominal pressure

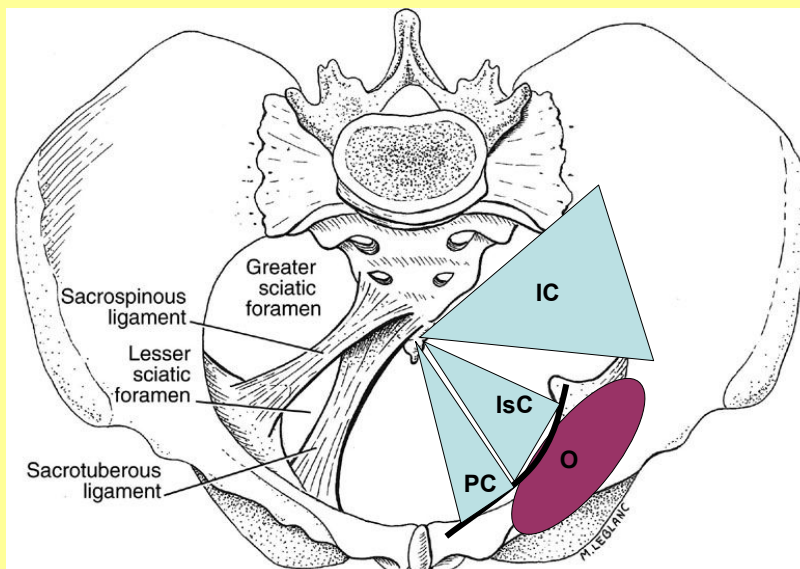
SUI Pathophysiology

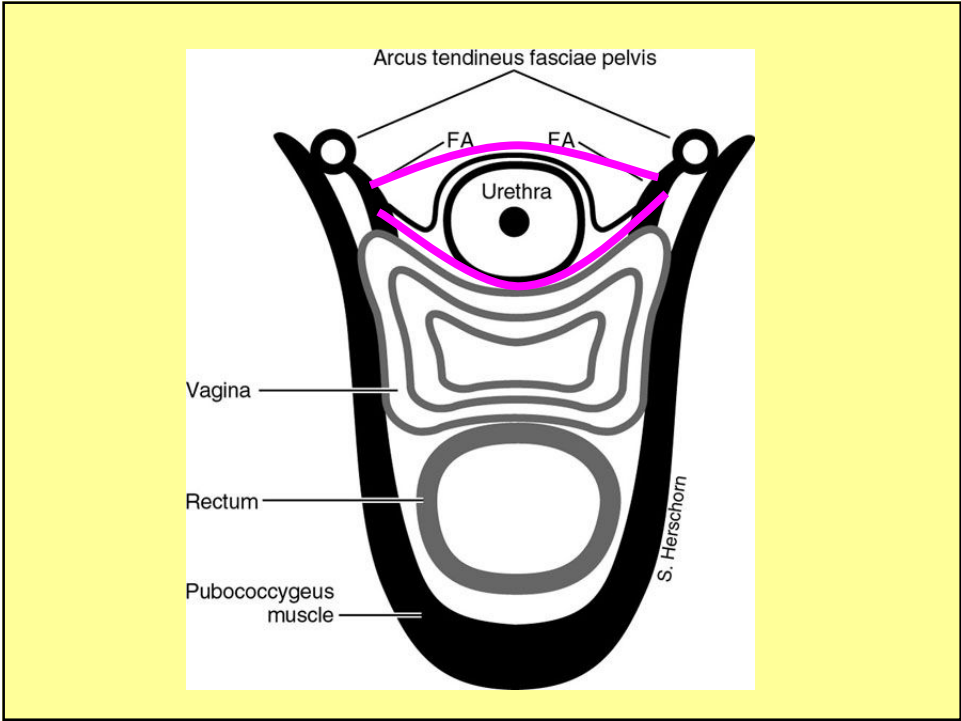
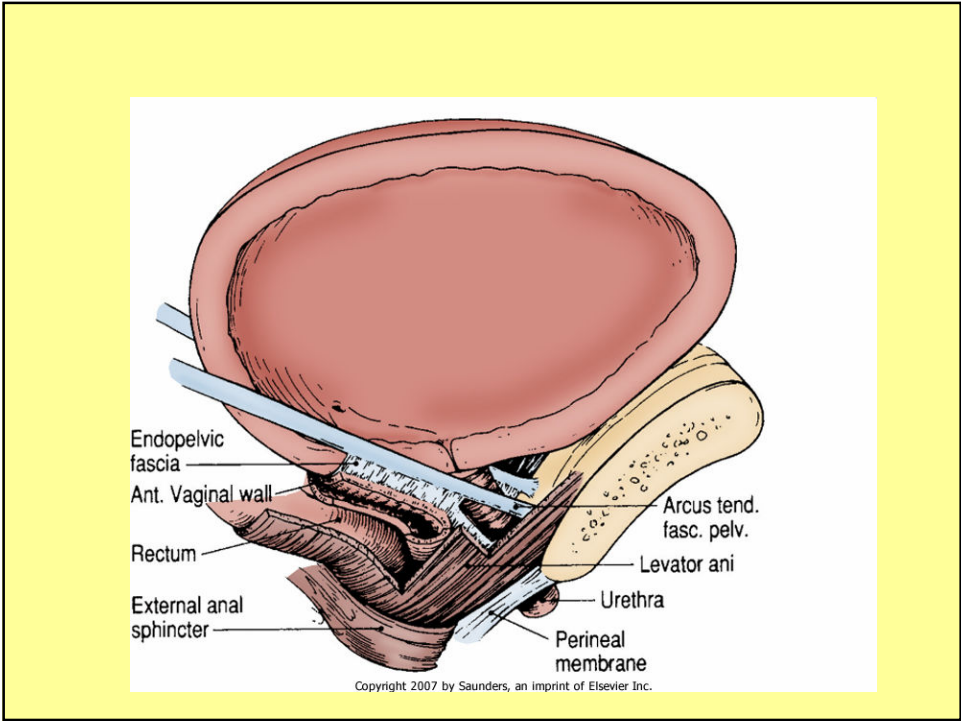
- | | |
|---|--|
| <ul style="list-style-type: none">• Bladder<ul style="list-style-type: none">• Compliant• Absence of instability• Normal sensation• Outlet<ul style="list-style-type: none">• Closed at rest• Closed during rises in IAP | <ul style="list-style-type: none">• Bladder<ul style="list-style-type: none">• Hypocompliance• DO• Sensory UI• Outlet<ul style="list-style-type: none">• ISD• Hypermobility |
|---|--|

Female Sphincter Mechanism

- Urethral Support
 - Muscle (levators)
 - Fascia (endopelvic, pubocervical, ATFP)
 - Ligaments (pubourethral, urethropelvic)

Pelvic Floor Musculature





Fascial Supports

- SANDWICH
 - Levators covered by fascia on both sides
 - Superior (internal) side: endopelvic
 - Inferior (external) side: periurethral/perivesical
 - Condense laterally to form “ligaments” attached to arcus or bony pelvis
 - Classified by organ they support

Urethral ligaments

- Pubourethral Ligaments
 - Anchors mid-urethra to symphysis
- Urethropelvic Ligaments
 - Endopelvic fascia + periurethral fascia
 - Attach to arcus laterally
 - Supports proximal urethra and bladder neck to lateral pelvic sidewall

Hypermobility vs ISD

Definition	<ul style="list-style-type: none">• Subjective physical finding	<ul style="list-style-type: none">• Objective
Clinical Parameter	<ul style="list-style-type: none">• Q tip test	<ul style="list-style-type: none">• ALPP < 60
Pathophysiology	<ul style="list-style-type: none">• Anatomic support defects	<ul style="list-style-type: none">• Neurologic, injury
Repair	<ul style="list-style-type: none">• Retropubic suspension	<ul style="list-style-type: none">• Sling/tape, bulking

Hypermobility vs ISD

- Coexist in most incontinent women
- All patients with sphincteric incontinence have some degree of ISD

- Definitions controversial
- Use in guiding therapy controversial

SUI Risk Factors

- Age
- Menopause
- Parity
- Obesity
- Smoking/COPD
- Surgery

SUI Evaluation

- Basic Evaluation
 - Focused History
 - Questionnaires
 - Voiding diary
 - Physical Examination
 - Demonstrate incontinence
 - Urinalysis
 - PVR

SUI Evaluation

- Goals of basic evaluation
 - Confirm presence of incontinence
 - Identify reversible factors
 - Treat uncomplicated cases
 - Identify those that require further evaluation

Indications for Further Evaluation

- Diagnosis unclear
- Failure of initial treatment
- Plan for surgery
- Previous failed surgery
- Comorbid conditions
 - Neurogenic bladder
 - Suspected obstruction
 - Recurrent UTIs
 - Prolapse

Further Evaluation

- Urodynamics
 - Uroflow
 - CMG
 - LPPs
 - PFS
- Pad testing
- Radiology
 - Pelvic US
 - Pelvic MRI
 - VCUG
- Cystoscopy

SUI Conservative Management

- Behavior modification
 - Dietary changes
 - Timed voiding
 - Smoking cessation
 - Weight loss
- Pelvic floor muscle training
 - Kegels, biofeedback, E-stim
- Pharmacologic
 - A-agonists, Imipramine, Duloxetine
 - Estrogen not helpful

SUI Conservative Management

“proper to counsel women who might appropriately choose surgery that, although surgery is the single most effective treatment for SUI there is a **40% to 50% chance that they can avoid an operation** and be satisfied with the outcome by going through PFMT.”

CWU 9, p2142

Patients Who Benefit From Prompt Surgical Management

- Associated significant prolapse
- Severe SUI
- Already have good pelvic floor muscle tone and function
- Motivated to be completely dry

Indications for SUI Surgery

- Diagnosis confirmed
- Failure of conservative management
- Bothersome symptoms

Selection of Surgical Procedure

- Choices
 - Retropubic suspension
 - Pubovaginal sling
 - Trans-vaginal needle suspension
 - Trans-vaginal tape
 - Urethral injection

CUA Guidelines 2005

- Retropubic suspensions and PV slings are gold standard
- PV slings best for significant ISD or failed retropubic repair
- Tapes show good intermediate-term results
- Vaginal needle suspensions and colporrhaphy are less effective
- Urethral bulking is a good first option

SOGC Guidelines 2005

- Retropubic suspension has best durable cure (I-A)
- Tapes effective but long-term data lacking (I-A)
- Anterior repair or needle suspensions are inferior for isolated SUI (I-A)
- Urethral bulking associated with high failure rates (III-C)

What is Long-Term? What is Success?

- 5 yrs or more
 - Late failures
 - Delayed complications
- No standard definition
 - Subjective cure, QoL
 - Objective cure
- Difficult to compare studies...

Reporting of Complications

- Lack of standardized definitions
- Differences in reporting
- Difficult to compare and summarize studies...
- Knowledge of potential complications important for **INFORMED CONSENT**

Retropubic Suspensions

Retropubic Suspension

- Indications
 - Surgeon preference
 - Significant hypermobility
 - Limited transvaginal access
 - Undergoing laparotomy for something else
 - Abdominal colposacropexy

Retropubic Suspension

- Contraindications
 - Lack of hypermobility, ie. Pure ISD
 - Inadequate vaginal length or mobility
 - Significant prolapse (need to address prolapse as well)

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Abdominal Sacrocolpopexy with Burch Colposuspension to Reduce Urinary Stress Incontinence

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for the Pelvic Floor Disorders Network*

- 322 women with no SUI and apical prolapse
- Grade 2-4 apical prolapse
- Randomized to Burch or no Burch

Table 2. Baseline Urinary Evaluation According to the Women's Responses to Two Questionnaires and Results of Stress Testing with and without Prolapse Reduction.*

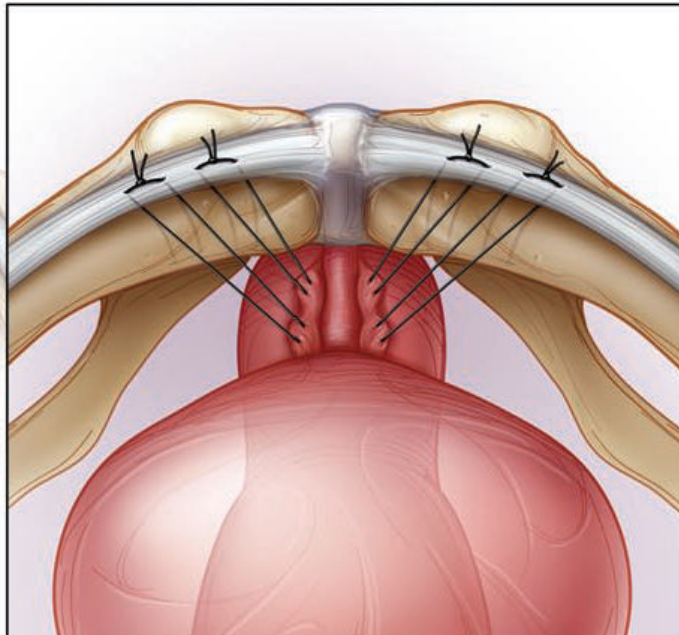
Variable	Burch Group (N=157)	Control Group (N=165)	P Value
PFDI questionnaire — no./total no. (%)			
Stress incontinence‡	30/152 (19.7)	30/160 (18.8)	0.67
Bothersome stress incontinence‡	15/144 (10.4)	15/149 (10.1)	0.95
Urge symptoms§	138/154 (89.6)	145/160 (90.6)	0.76
Urge incontinence¶	42/154 (27.3)	45/160 (28.1)	0.99
Bothersome urge incontinence‡	22/145 (15.2)	24/149 (16.1)	0.98
MESA questionnaire			
Stress incontinence	13.8±17.1	11.1±14.9	0.12
Urge symptoms	12.4±17.0	12.5±15.1	1.00
Positive stress test — no./total no. (%)**			
Without prolapse reduction	3/153 (2.0)	9/159 (5.7)	0.09
With prolapse reduction	55/154 (35.7)	58/162 (35.8)	1.00
Detrusor overactivity (with or without USI) — no./total no. (%)	19/157 (12.1)	17/163 (10.4)	0.24

3 month follow-up

- 25% subjective SUI if no Burch
- 6% subjective SUI with Burch
 - Maintained effect when pre-op SUI excluded
- Also a significant reduction in urge/UI
- No difference in adverse events

Procedures

- Open
 - MMK
 - Paraurethral tissue anchored to pubic periosteum
 - Burch
 - Anchored to Cooper's ligament
 - Paravaginal repairs
 - Anchored to ATFP
- Laparoscopic



Complications

- Early
 - Bleeding (<5% transfusion)
 - Organ injury (<2%)
 - Wound complications
 - Osteitis Pubis - MMK (1-3%)
- Late
 - OAB
 - Voiding dysfunction/Retention
 - Prolapse

Leach 1997

OAB

- Urgency or DO present in up to 30% pre-op
- Most resolve after repair
- 36% persistent urgency
- 11% de novo urgency
- **May be associated with obstruction**

Voiding Dysfunction

- Retention lasting > 4 wks (5%)
- Permanent retention (<5%)
- Require CIC or revision
- Risk factors:
 - pre-operative voiding dysfunction/retention
 - re-do surgeries

Prolapse

- Lateral vaginal wall tension may aggravate posterior weakness → enterocele
- 10-38% incidence
- most are asymptomatic
- < 5% require surgery

Pubovaginal Sling

Pubovaginal Sling

- Indications
 - Loss of proximal urethral closure (ISD)
 - Neurogenic
 - Iatrogenic
 - Surgery
 - Radiation
 - Trauma
 - Proximal urethral defects/loss requiring surgery
 - Fistula
 - Diverticulum
 - Chronic catheterization
- Contraindications
 - Hypocompliant detrusor

Sling Materials

	Pros	Cons
<ul style="list-style-type: none">• Autologous fascia (Rectus/Fascia lata)	<ul style="list-style-type: none">• Erosion rare• Strong	<ul style="list-style-type: none">• Harvest morbidity
<ul style="list-style-type: none">• Allografts (cadaveric)• Xenografts• Synthetics	<ul style="list-style-type: none">• Avoid harvest• Abundant	<ul style="list-style-type: none">• Processing weakens• Infection• Erosions

Specific Complications

- Retention relatively common
- Harvest site pain
- Erosion very rare (autologous sling)
- Sling failure

Retention

- Reported incidence varies widely
 - Groen & Bosch, 2004:
 - 42% require CIC at 3 months
 - 18% at 6 months
 - Leach et al. 2007:
 - 8% beyond 4 wks
- Predictors of??

ORIGINAL ARTICLE

Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence

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Table 2. Adverse Events.*

Event	Burch Procedure (N = 329)	Sling Procedure (N = 326)	P Value†
	no. (%)		
Serious adverse events‡			
Patients with event	32 (10)	42 (13)	0.20
Total events	39	47	
Genitourinary	22	30	0.12
Ureteral injury	2	0	
Ureterovaginal fistula	1	0	
Incidental vaginotomy	1	0	
Incidental cystotomy	10	2	
Erosion of suture into bladder	1	0	
Recurrent cystitis, leading to diagnostic cystoscopy	5	6	
Pyelonephritis	1	1	
Catheter complication	1	1	
Voiding dysfunction leading to surgical revision	0	20	
Pelvic pain	0	2	0.25
Bleeding	3	1	0.62
Wound complication requiring surgical intervention	13	11	0.83
Gastrointestinal	1	1	1.00
Respiratory distress requiring intubation	0	1	0.50
Laryngospasm requiring reintubation	0	1	0.50

Sling too tight...

- Presentation variable (Webster, 2003)
 - Obstructive LUTS, CIC dependence
 - Urge, urge incontinence (most common)
 - Recurrent UTIs
- Evaluation
 - Hx, Px, Voiding diary, cysto, VUDS
 - Only 33% had urodynamic evidence of obstruction
 - Thus, clinical diagnosis in most

Sling too tight...

- Most recommend urethrolisis if urethra appears hypersuspended
- Most recommend intervening if retention lasts > 5-6 wks

CWU 9, p 2245

Method of Urethrolisis

- Webster 2003
 - Anterior vaginal wall approach
 - Localize sling and incise in midline
 - Dissect sling laterally into retropubic space as needed

 - Fill bladder and perform Crede manœuvre
 - Endpoint is good urinary stream

Urethrolysis Results

- Webster, 2003. Series of 32 patients.
 - 93% re-established efficient voiding
 - 67% improved urge
 - 10% recurrent SUI

Persistent Incontinence

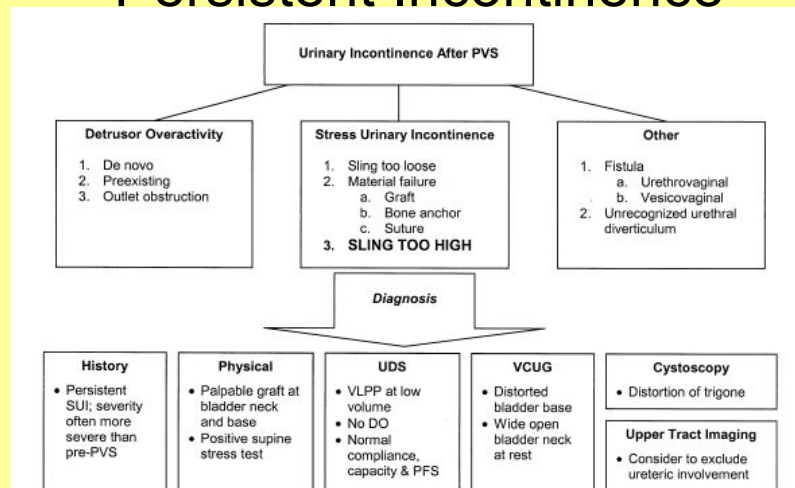
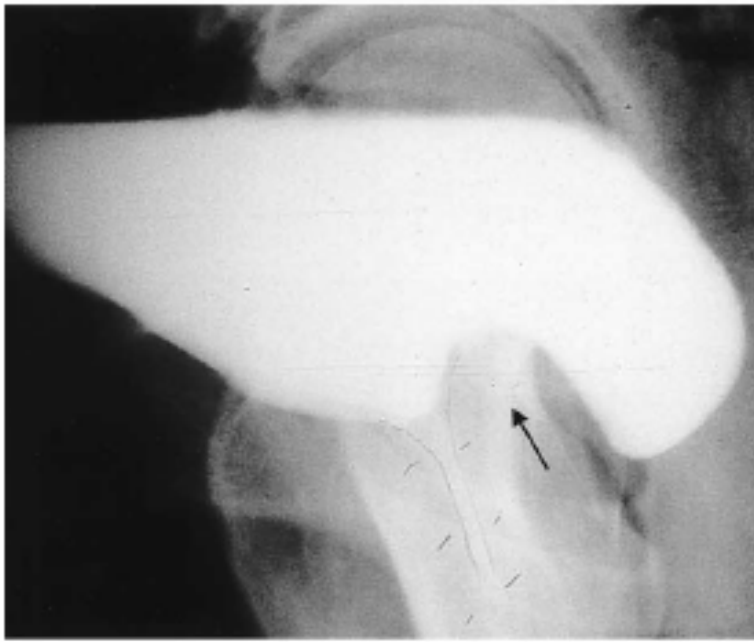


FIGURE 3. Diagnostic algorithm for persistent or recurrent incontinence after PVS. UDS = urodynamic studies; VLPP = Valsalva leak point pressure; DO = detrusor overactivity; PFS = pressure-flow study; VCUG = voiding cystourethrogram (lateral views).

Poon & Zimmern, 2004



Tension-Free Tapes

Rise of the Tape

- TVT first introduced in 1996 (Ulmsten)
- Despite lack of long-term data, tapes have gained popularity
 - “minimally invasive”
 - Day surgery
 - Excellent short-term results
- Over 1,000,000 tape procedures world-wide (Raz, 2007)

Rise of the Tape

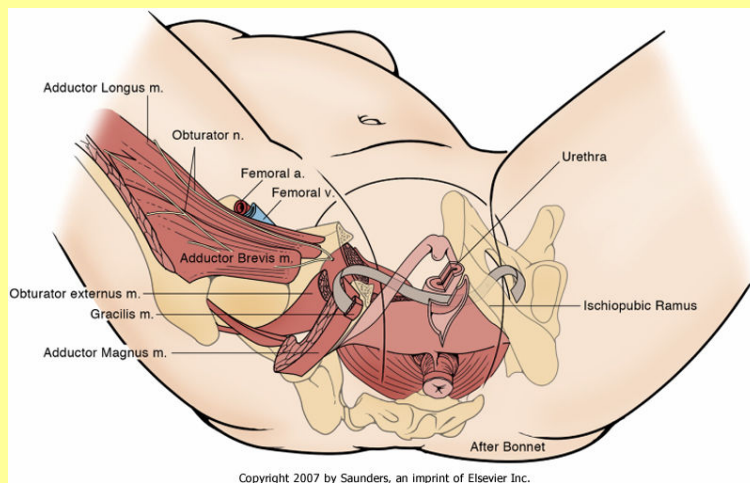
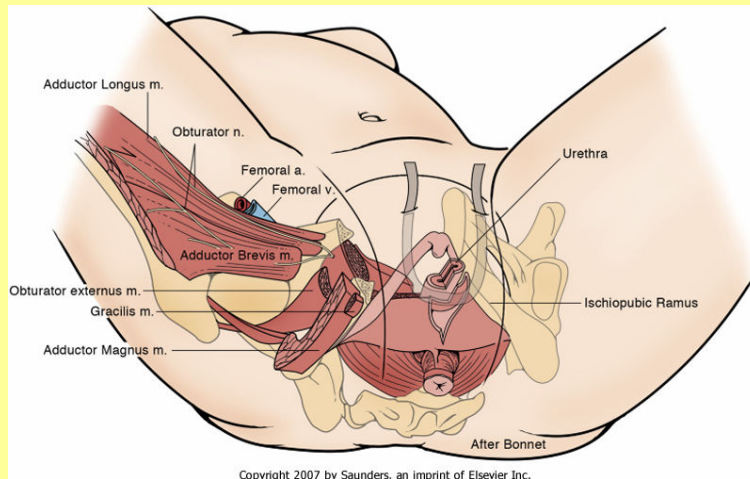
- In Europe (de Tayrac, 2005)
 - 84% of all incontinence procedures
 - 2/3 TVT, 1/3 TOT
- In North America, Canada, B.C.?

Trans-Vaginal Tape Procedures

- Principles
 - Mid-urethra placement
 - Monofilament polypropylene mesh
 - Tension-free
 - General or Spinal anesthetic
 - Day surgery

Approaches

- Retropubic
 - Ascending (TVT)
 - Descending (SPARC)
- Trans-obturator (TOT)
 - In-out
 - Out-in



Large TVT Series

Author (Year)	N	Follow-up
Nilsson (2004)	90	7yr
Kuuva (2002)	1455	-
Ward (2002)	344	2 yr
Aboussaly (2004)	241	-
Tamussino (2001)	2795	-
Schrafford (2005)	809	2 yr

Complication	Frequency
Peri-operative	
Hemorrhage	0.6-2.5%
Bladder injury	2.7-13.8%
Urethral injury	0-0.1%
Vascular injury (Iliac)	0.1-0.6%
Post-operative	
Pelvic hematoma	0.7-3.4%
Urinary retention	2.3-19.7%
Urinary tract infection	0.7-22.3%
De novo urgency	0.2-15%
Vaginal erosion	0.5-1.3%
Bladder/Urethral erosion	0.02%



Presentation and Management of Major Complications of Midurethral Slings: Are Complications Under-reported?

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Under-Reporting?

- Literature review:
 - 14 studies met criteria (TVT, SPARC, TVTO, TOT)
 - 11,806 patients
 - 86 major complications (0.7%)
- FDA MAUDE database (voluntary reporting of device complications)
 - 161 major complications, 10 deaths
 - No denominator (ie. No national registry)

TABLE IV. Comparison of the Distribution of Major Complications (Major/Total Complications) of Retropubic and Transobturator Approach in Published Literature versus FDA MAUDE Database

	Literature	FDA database
TVT/SPARC	78/1497 (5.2%)	154/766 (20%) → 8 deaths
TO	8/233 (3.4%)	7/162 (4%) → 2 deaths
Total	86/1730 (4.6%)	161/928 (17%)

FDA, food and drug administration; MAUDE, manufacturer and user facility device experience.

Bleeding (0.6-2.5%)

- Most define as >200-500mL blood loss
- Few require intervention
- Laceration of named arteries rare (0.1%)
- Post-op pelvic hematoma more common than intra-op hemorrhage
- Rarely requires intervention/transfusion

Bladder Perforation (2.7-13.8%)

- More common early in the learning curve
- Higher risk if previous incontinence surgery
- Conflicting evidence for other risk factors:
 - Previous hysterectomy
 - Obesity
 - Prolapse
 - Type of anesthesia

Value of Cystoscopy

- Duckett, 2007:
 - 5 bladder perforations picked up in 100 consecutive patients with routine cystoscopy
- LeSala, 2006:
 - No difference in subjective cure rates in patients with bladder perforation recognized at surgery

Voiding Dysfunction (2.3-19.7%)

- Most define as prolonged need for catheterization
- May also present with
 - Urgency
 - Recurrent UTIs
- Risk factors not well delineated
- Optimal evaluation and management not defined

Post-TVT Voiding Patterns

- Cohort studies have shown urodynamic changes consistent with obstruction
- **Gateau et al. 2003.**
- 112 patients. 86% cured. 99% improved.
- Compared pre and post-TVT UDS
 - Decreased Qmax
 - Increased PdetQmax
 - PVR > 100 cc in 10%

Post-TVT Voiding Patterns

- **Gateau et al.** cont'd
- Of interest:
 - 12% de novo urgency
 - No de novo detrusor overactivity
 - 24% had urodynamic obstruction pre-op

Urethrolisis

- Several studies showing effectiveness in restoring efficient voiding
 - Klutke, 2001: 17/600 patients in retention
 - All 17 urethrolisis at mean 64 days post-op
 - All had obstruction relieved, only 1 recurrent SUI
- No established predictors of who will benefit
- No optimal timing established

Vaginal Erosion (0.5-1.3%)

- Most present b/w 3wk and 3mo
 - Vaginal discharge
 - Dyspareunia
 - Palpable mesh
 - LUTS
- Optimal management controversial
 - Conservative (Kobashi and Govier, 2003)
 - Vaginal flap reapproximation
 - Tape excision

Vaginal Erosion

- Kuuva, 2002. Finnish National Registry.
- 10 erosions identified.
- 3 managed conservatively.
- 6 re-operated.
- All resolved and continence maintained.

Vaginal Erosion

- Conservative management plausible in asymptomatic small erosions
- Good results with reapproximation of vaginal mucosa for small erosions
- Tape excision reserved for severe symptoms or failure of above
- Continence usually maintained after tape excision

Urethral Erosion

- Rare
- Conservative therapy not an option
- Typically require tape excision and urethral reconstruction
- Martius flap may be used to bolster repair
- Autologous fascial sling placement has been described

Other

- Chronic Pelvic Pain
- Dyspareunia
- Leg Pain
- Obturator hematoma
- Obturator abscess

Conclusion

- Each procedure has a unique side effect profile
- Important in gaining informed consent
- Minimally invasive procedures not to be taken lightly
- Complication reporting is not standardized