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### Use of Vaginal Pessary in Geriatric Women



Colleen Mellen, MS, CNS, APRN
Hartford Healthcare Medical Group
Urogynecology Division
Hartford CT
colleen.mellen@hhchealth.org

#### **Disclosures**

▶ I have no relevant financial relationships to disclose

### **Objectives**

## Special considerations for use of pessary in the geriatric woman:

- Discuss counseling and preparation for trial of pessary
- Describe pessary fitting
- Describe routine pessary follow-up, surveillance exam
- Describe management of complications
- Discuss when to terminate use of pessary

#### Pessary fitting and Maintenance References

- Atnip,S & O'Dell,K, Vaginal support pessaries: Indications for use and fitting strategies; Pessary Care: Follow up and management of complications. Urol Nursing, 2012; 32(2):114-136, 145
- www.augs.org FPRMS Webinar. Oct 12, 2016. Pessary fitting, follow-up and management of complications. Speakers: Colleen Mellen, APRN; Katharine O'Dell, PhD, WHNP CNM
- ► Hooper G, Atnip S, O'Dell K,. Optimal Pessary Care: A modified Delphi consensus study. J Midwifery & ,Women's Health, 2017;62(4):452-462
- www.uptodate.com Vaginal pessary treatment of prolapse and incontinence. Author: Jeffrey Clemons, MD, FACOG. Literature review current through: June 2018, Topic last updated Feb 08, 2018
- Robert M, Schultz J, Harvey M et al, Technical update on pessary use. J Obstet Gynaecol Can. 2013; 35(7): 664-674
- www.ajog.org Miller K, Baraldi C, Expert Reviews, Geriatric gynecology: promoting health and avoiding harm. Nov 2012: Am J Ostet Gynecol, 355-367

#### **Geriatric Women-Definition?**

- No precise definition of when adults become geriatric. Age > 65 often used as starting point to define "geriatric" population
- By 2030, estimated > 20% of the U.S. population, or 1/5 people, will be 65 years of age or older [1]
- Adults often remain physically active, independent, do not require geriatric expertise for healthcare until age 70 to 75 or older. Women in the U.S. have a higher life expectancy than men [2,3]
- By 2020, projected > 50 million women in the U.S. will be postmenopausal [4]
- \*\*\*Women are expected to live about 40% of their lives after menopause

#### Pessary and Geriatric Women: ROL

- The percentage of women reporting at least one PFD increases with age: 9.7% age 20-39 to 49.7% age > 80 [6]
- ▶ Older women are more likely than younger women to choose pessary for treatment of POP, SUI [22,23,24]
- Women age >65 years, with severe comorbidities more likely to use pessary long-term compared with women≤ age 65. [13]
- One large scale retrospective review of CMS data for 34,782 women >65 years, with a diagnosis code of POP, and billing code for pessary fitting found only 4019 (11.6%) were treated with pessary [35]

# Natural history of pessary use in women aged 65-74 versus 75 years and older with pelvic organ prolapse: a 12-year study [49] Ramsay et al. 2015

- A retrospective cohort study of 304 women >65 undergoing pessary fitting at Urogynecology clinic in Quebec, Canada reported:
  - Women with hx of hysterectomy or pelvic reconstructive surgery were more likely to fail initial pessary fitting
  - ▶ Women aged 65-74 and women aged 75+ years continued pessary use 87.5% vs 80.8% at one year, 80.6% vs 70.9% at 2 years and 62.1% vs 37.8% at 5 years
  - ► Erosions occurred in 19.3% of long-term users (> 1 year)
  - Vaginal erosions were > 3 x's more likely to occur in women 75+ years

#### **Contraindications:**

- Non-adherence to follow-up maintenance schedule
  - ► Lack of transportation, family, or community support
  - ► Medical/ mobility problems
  - **▶** Dementia/ Cognitive impairment

#### Pessary complications:

#### Low Risk, but not No Risk [19]

#### Common:

- Vaginal discharge
- Odor
- Irritation

#### Less Common:

- pain
- Infection
- Erosions
- Vaginal bleeding
- Obstruction or urination or defecation

Rare: (usually associated with neglect)

- Incarcerated pessary
- Vesicovaginal or Rectovaginal fistula
- Small bowel incarceration
- Fecal impaction
- Cervical entrapment
- Pyelonephritis
- Hydronephrosis and urosepsis
- Vaginal or cervical cancer

# Factors related to major pessary complications in geriatric women [31]

- Prolonged Pessary use, years to decades
- Advanced vaginal atrophy
- Cognitive Impairment
- Change in healthcare provider: loss of information that pessary is in place
  - ▶ Use diagnosis code Vaginal pessary in situ Z92.89 in EHR or
  - ▶ Use diagnosis code Vaginal pessary present Z92.89 in EHR
- ➤ Transition of residence: home → rehabilitation center/assisted living → long-term care

### Pessary Fitting

- ► Patient Assessment
- ▶ Counseling
- Preparation
- **Fitting**
- **Education**

#### **Patient Assessment:**

- Dementia/ cognitive impairment
- Support system, Transportation for follow-up
- Mobility level
- Medical comorbidities
- Current medications/allergies
- Anticoagulants
- Incontinence products
- History of pelvic surgery, hysterectomy, previous prolapse or incontinence surgery, use of mesh
- Prescription drug coverage

#### **Patient Assessment:**

- ► Most bothersome symptom(s) [16]
  - ▶ Bulge, pressure, urinary leakage, nocturia...
- Address fears and concerns regarding pessary use
  - ▶ Will it hurt?
  - ▶ Will it fall out?
  - ▶ Will I get an infection?
  - ▶ Do I have to clean it?
  - ▶ What do I have to do? Do I have to touch it?
  - ▶ What are my activity restrictions? Shower? Swim?
  - ▶ Will everyone know that I am wearing pessary?
  - ▶ What about sex?

#### Patient Assessment:

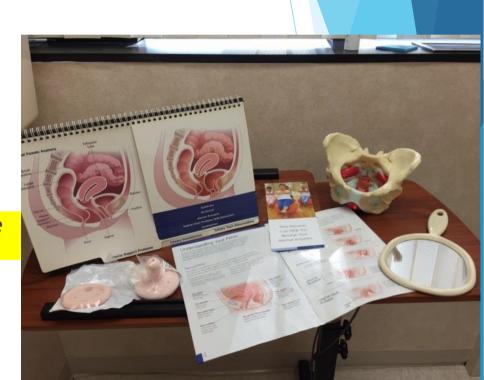
- Patient goals for use of pessary, personal and social factors [16]
  - Preference for non-surgical treatment- belief "too old"
  - ► Relief of symptoms:
    - a. Bulge, pressure
    - b. Incomplete bladder emptying, voiding dysfunction
    - c. Urinary incontinence: SUI, UUI, nocturia
    - d. Recurrent UTI's, vulvovaginal irritation
    - e. Constipation, defecatory dysfunction
    - f. Difficulty walking, low back pain, hip pain
    - g. Comfortable "going out" for social activities

ARE GOALS REALISTIC?

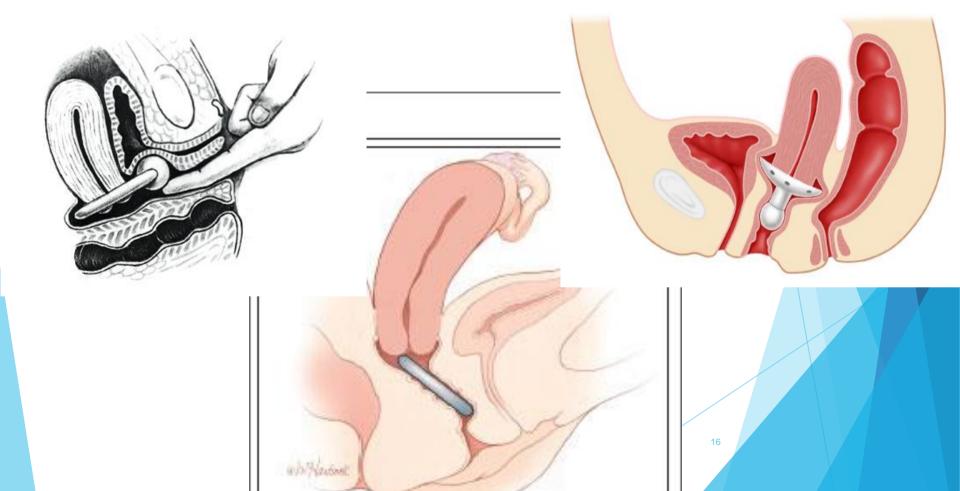
What can pessary do/ not do?

#### Counseling

- Review patients individual exam findings: use diagrams, look with mirror
- Patient preference for self-management
- Sexual Activity
- De novo SUI
- Pessary selection
- Pessary complications, warning signs
- Follow-Up schedule, patient responsibility
- May take more than one visit to determine best pessary size or type. [5] (May incur additional charges)



### Placement of pessary in vagina



### Counseling: Address safety issues

- Importance of keeping scheduled follow-up visits
- Review warning signs of pessary complications to notify provider for
- Informed consent
- Enlist family/ social support
- Suggest Medi-alert bracelet
- Provider appointment reminder system or follow-up log



### Informed Consent/ Patient Responsibility \*\*DRAFT\*\*

WOMEN'S HEALTH SERVICES
DIVISION OF UROGYNECOLOGY

PESSARY P	ATIENT	INFORM	ATION
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You have been fitted with a	l	Pessary
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#### **GENERAL INFORMATION**

Pessaries are used for non-surgical management of pelvic organ prolapse. Some pessaries can help manage urinary incontinence.

Normally causes no pain or discomfort.

Regular hygiene is all that is required.

If you are able to remove and clean your Pessary please remove and clean your Pessary at home every \_\_\_\_\_\_\_.

Use a mild soap, such as Dove bar soap or Cetaphil gentle liquid cleanser to clean your Pessary at home. AVOID antimicrobial soaps. No sterilization is required.

You are not required to care for your Pessary on your own if you do not wish to.

#### Informed Consent/ Patient Responsibility DRAFT

#### VAGINAL DISCHARGE

Some mucous-like discharge is normal.

Some vaginal odor is normal but it should not be foul smelling.

You should not experience any increased vaginal itching or burning.

There should not be unusually large amounts of vaginal discharge.

Please call the office if you have vaginal bleeding (pink, bright red to dark brown discharge).

CALL OFFICE 860-545-4338, press option #3 to speak with a nurse

#### USE OF VAGINAL CREAMS

The risks/ benefits/ alternatives of vaginal estrogen creams were discussed	
You have been prescribed This medication is to be used	
Vaginal estrogen creams are not needed if still menstruating.	
We sometimes recommend use of vaginal estrogen creams with pessary to maintain the health and strength of vaginal line	ng.

Vaginal lubricants and moisturizers can also be used but these preparations do not prevent vaginal sores or heal the vaginal lining.

You have been recommend to use \_\_\_\_\_

## Informed Consent/ Patient Responsibility Draft

COMPLICATIONS ASSOCIATED WITH PESSARY USE [MOST COMMON WITH NEGLECTED PESSARY]

Vaginal infections (bacterial/fungal)			
Vaginal bleeding.			
Vaginal erosion (open sore in vaginal lining)			
Vaginal fistula (hole between vagina and bladder or re	ctum)		
Pessary incarceration (Pessary that is "stuck" in the va	gina and may need a procedure to	o remove).	
I understand that failure to follow up with scheduled	l Pessary checkups can result in	vaginal wall erosions and other serious complica	itions
Please call the office at (860) 972-4338 if you experifalls out and you are unable to reinsert it, or if you ha	ence any pain, foul vaginal discha ve any further questions regarding	arge, bleeding, or if you are unable to urinate or pa g the care of your Pessary, don't hesitate to call.	ss bowel movement. If your Pessary
Please call the office at (860-972-4338) if you need to	o reschedule your Pessary checku	ıp appointment.	
I have read and understand these instructions. I am al extreme weight loss/gain, after vaginal surgery or wit finding the Pessary that will take care of my problem(	so aware that fitting pessaries is r nchanges in condition. I will be re s).	not a perfect science and that type and/or size ma esponsible (billed to insurance) for the cost of eac	ly need to be changed periodically with th additional Pessary which is used in
Patient Signature	Date		
Provider Signature	Date		20

### Prepare for pessary placement: Education & Treatment re genitourinary syndrome of menopause (GSM)

- GSM "constellation of signs and symptoms secondary to a decrease in estrogen and other sex steroids" [32]
- Physical signs symptoms: in the labia majora/minora, clitoris, vestibule/ introitus, vagina, urethra, and bladder" [32]
- GSM is directly related to a decrease in circulating estrogen after menopause, resulting in anatomic, physiologic and clinical changes to the genitourinary tract and sexual function. It is a progressive, but treatable condition. [32]
- GSM signs and symptoms may need to be addressed first or concurrent with pessary fitting



#### Prepare for pessary placement

- Treat signs & symptoms of advanced vulvovaginal atrophy (GSM)
- Sample regimens: expert opinion [5]
  - Estrogen cream 0.5-1.0 gm with applicator 2-3 nights per week for 2-4 weeks before trial of pessary
  - Fingertip application of cream to introitus Q HS prior to pessary fitting
- Treat constipation- may make pessary fitting difficult/ uncomfortable

# **Preparation:** Treat Incontinence associated dermatitis (IAD) and vulvar contact dermatitis

- Sensitive skin/ pH balanced cleanser for peri-care
- Use appropriate incontinence absorbent pads rather than menstrual pad or menstrual mini-pad (no preservatives, fibers that wick-away urine)
- Use barrier ointment to protect skin from acidic urine/ mechanical friction from pad
- Sensitive skin laundry detergent, no dryer sheets or fabric softener
  - Diane Newman, AWHONN Seattle, 2000

### Pessary Fitting: Two types of pessaries Both can be used in Geriatric Women

#### Support pessary

- ▶ 2-D fitting the long axis of the vagina
- ▶ Require introitus integrity to retain
- ▶ Easiest for patient to remove and insert
- Sexual intercourse may be possible with pessary in place
- ► Includes incontinence pessaries

#### Space-filling or self-retaining pessaries

- ▶ 3-D to fill vagina/ may have concave portions
- Used with Stage III or IV POP
- More difficult for women to remove on their own
- Sexual intercourse often not possible with pessary in place

### **Support Pessaries:**

All pessary photos courtesy of Cooper surgical, Pan Pac



# Self-Retaining/ Space Filling Pessaries:













Pessary fitting: patient comfort, positioning

and safety

- Assist with undressing if needed
- ▶ Use electronic, adjustable exam table
  - Assist on and off exam table
- Head elevated to accommodate breathing
- Adjust stirrups to accommodate hip/knee problems
- Limit number of postural changes to avoid lightheadedness, postural hypotension
- Position yourself so patient can see your face when speaking. Use assistive hearing devices
- Arrange office equipment to eliminate fall risks



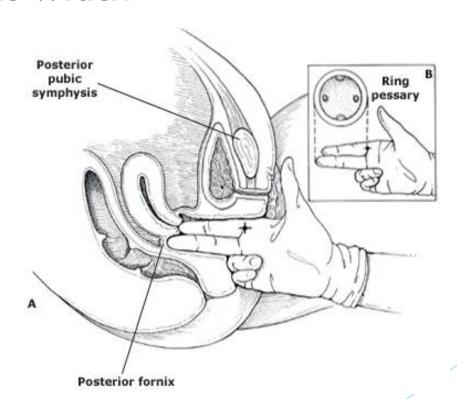
# Preparation: "Will it hurt?" lidocaine-prilocaine cream

- Some women experience pain, or have anxiety in anticipation of pain with pessary insertion and removal.
- One study compared lidocaine-prilocaine cream pretreatment with a placebo cream. 4 g lidocaine-prilocaine cream applied 5 minutes before pessary insertion or removal, reduced patient-reported pain [30]

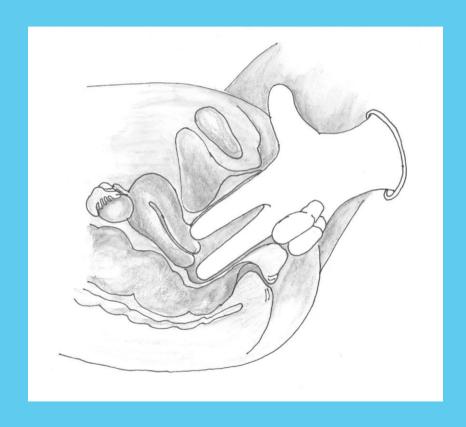
#### **Pessary Fitting Guidelines**

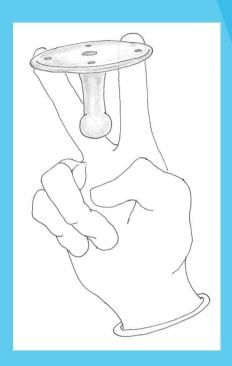
- Start small and work up
  - ▶ POP Q: Especially <u>TVL</u>, <u>GH</u>, leading compartment of prolapse
  - \*POP Q exam does not assess: introitus width, vaginal caliber, pelvic floor muscle atrophy, shape of pelvic bones which all influence pessary fit [5]
- The largest comfortable pessary should be used
- ► At the initial visit, approximately 85% of women with POP can be fitted with pessary [26]
- Several sizes often need to be tried. May take 2-3 visits to establish best pessary fit. [5]

## Pessary fitting: Vaginal length, Introitus width



#### Pessary fitting: vaginal caliber, vaginal vault





### Pessary fitting guidelines: sample [5]

- ▶ Try Ring pessary first
  - ▶ if vaginal introitus size is 1-2 fingerbreaths & POP is stage II-III
- ► Try Gellhorn pessary first
  - ▶ if vaginal introitus is 3-4 fingerbreaths and/or stage IV POP

#### Fitting/ Refitting decisions: sample

[K 'Dell, AUGS Pessary Webinar 2017]

- Adequate introital integrity Try ring with support
- 2. **Pessary falls out** Try self-retaining
- 3. **De novo SUI** Try incontinence device



Case 3: 74 yo female with urinary urgency, frequency, must reduce prolapse manually to void. Uncomfortable to sit.



#### Satisfied Patient:



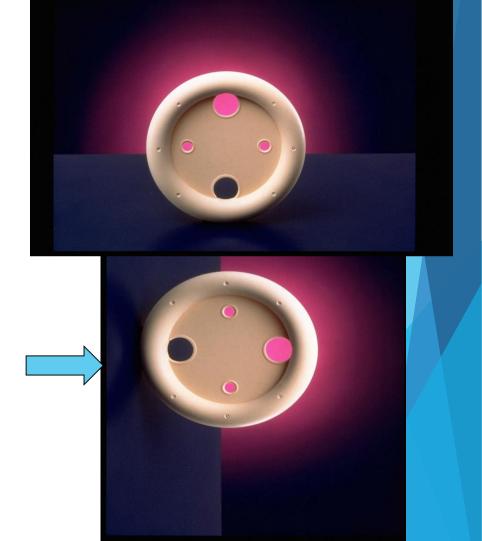
### Pessary Fitting: Trouble shooting

# Predictors for unsuccessful pessary fitting in geriatric women<sub>[20]</sub>

- Short vagina (< 6 cm)</p>
- Wide introitus (>4 fingerbreadths)
- Distal posterior wall prolapse (rectocele)
- Previous vaginal surgery (apical narrowing)
- Coexisting or new onset SUI

Problem:
Wide Genital Hiatus:
Pessary slips out
with straining

rotate pessary 1/4 turn- make rigid



# Problem: Narrow introitus, vaginal canal, apex Try oval pessary or small gellhorn





### **Complaint of Rectal Pressure**

► Try Shaatz pessary (thinner profile rim) instead of ring





# Problem: Shortened vaginal length use Gellhorn Pessary

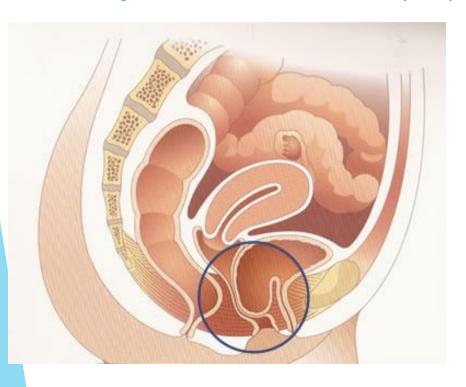
1" stem vs

2" stem



#### Problem: New onset SUI with pessary in place:

Unmasking of Occult SUI associated with prolapse







### Use Incontinence Pessary or Consider pessary plus urethral bulking

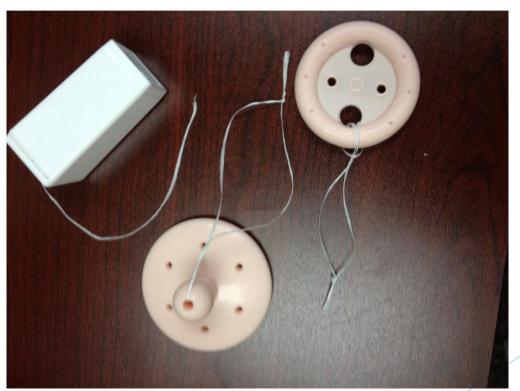
- Urinary Incontinence with prolapse
- Increases urethral closure pressure
- Stabilizes urethrovesical junction



Procidentia:
Cube pessary with drainage holes, Tandem cube or double pessary (ring + Gellhorn, donut + Gellhorn) [38]



### Patient can not remove pessary for self-care: Tip: Pessary removal with Dental floss/ dental tape



### All attempts at pessary fitting failed: Consider support undergarment, or pregnancy support belt [34]



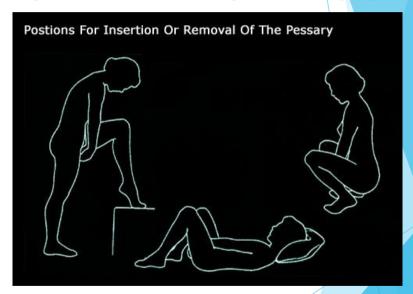




### Education: pessary self-care

Women to care for pessary themselves experience fewer complications [19]

- Demonstrate with patient participation
- ·Have patient practice insertion and removal
- •Give lots of positive reinforcement
- •Enlist the help of spouse, partner or family member to learn how to remove/ reinsert pessary
- Review wearing schedule, cleaning and maintenance
- Provide contact information for patient questions



#### Education: Vaginal Estrogen, Vaginal Moisturizers

- Discuss purpose, mechanism of action, risks/ benefits/ alternatives, dosing & schedule, application techniques
- Determine best type of product (cream, tablet, ring) for maximal adherence based on patient dexterity, time schedule, memory deficit
- Contact patient's Oncologist if concerns about patient history of breast cancer, gynecologic cancers for approval to use vaginal estrogen
- Demonstrate application of vaginal estrogen cream, tablet, ring or vaginal moisturizers with patient participation in drawing up dose (if cream or gel) and applying in vagina
- Demonstrate fingertip application of vaginal cream or moisturizers if using this method.



### Pessary Fitting Summary: Allow time

- Pre-treat with Lidocaine cream if indicated
- Digital exam to size
- Decide on pessary
- Insert pessary
- ► Have patient bear down, cough (supine & standing)
- > Stand, sit, walk, urinate, valsalva while on toilet before leaving
  - \*\*\*slow postural changes to avoid lightheadedness/ postural hypotension
- ▶ Re-examine patient in standing position to check if pessary "slips" with cough
- Discuss follow-up appointment
- Discuss use of vaginal moisturizers, topical estrogen- when indicated
  - Demonstrate application of topical estrogen with patient participation
- ▶ Provide contact information for patient questions

## Pessary maintenance follow-up & Surveillance exam

### Timing of Pessary Follow-up: How often?

- Initial follow-up visit:
  - No consensus on time interval for first pessary check, 1-3 days (manufacturers recommendation); 1-2 weeks [5], 2-4 months [33]
- On-going Follow-up maintenance visit:
  - Every 3 months (common practice in US, 70% of APP's Q 3 months ) [39]
  - Recommended Pessary Quality Care Indicator: Follow-up at least every 6 months: AUGS Expert Panel, Anger, JT et al, 2013
  - Individualize based on:
    - ▶ Type of pessary: support vs space filling
    - ► Tissue response: intact vs vaginal epithelial abnormality (VEA) [39]
- PAPER 37: Timing of Pessary Care study. Propst, K, Mellen, C, O'Sullivan, D, Tulikangas, P. AUGS 2018 First, randomized, controlled study comparing traditional 3 month follow-up (US) vs 6 month follow-up (European model) comparing epithelial abnormalities, unplanned visits, patient satisfaction.
- Return every 6 months to 1 year for patients managing pessary on their own [39]

### Return visit symptom review:

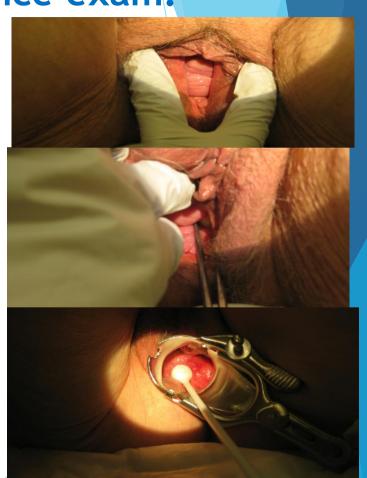
"My pessary is NOT working"

- Lower urinary symptoms
- Bowel status
- New onset SUI
- □ Abnormal discharge/ bleeding/ odor
- □ Pelvic pressure/ pain
- Bulging past pessary
- □ Sexuality/ QOL issues
- □ Current self-care habits
- ☐ Adherence to prescribed vaginal estrogen or topical gel

Pessary follow-up surveillance exam:

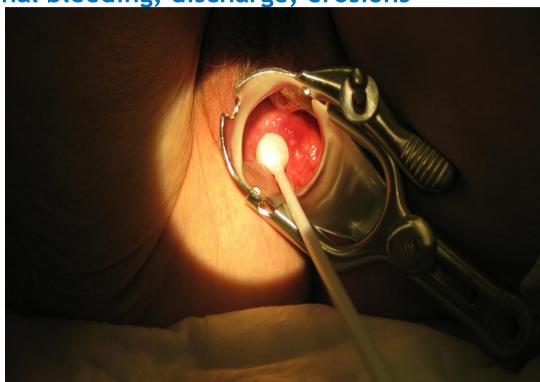
#### **Components**

- Pre-treat with Lidocaine cream if indicated
- Remove pessary, Clean pessary
- Visually inspect
- Vaginal epithelial abnormalities (VEA) [Tulikangas 2018] rule-out at each follow-up visit
- Vaginal exam/ speculum exam-careful evaluation of posterior fornices
- Rectovaginal exam, if thinning of tissues posterior fornix to evaluate for fistula
- Silver Nitrate if minor vaginal epithelial disruption/ granulation tissue [40]

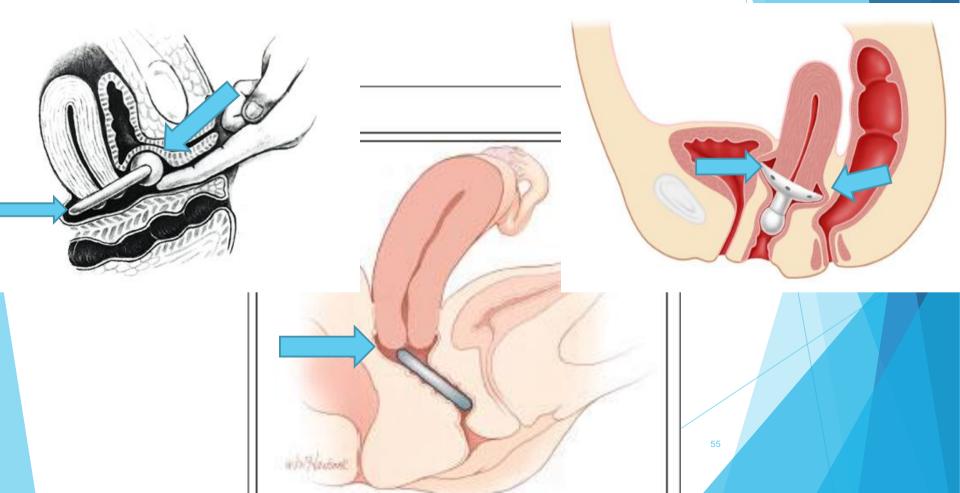


### Pessary follow-up: Surveillance

Vaginal bleeding, discharge, erosions

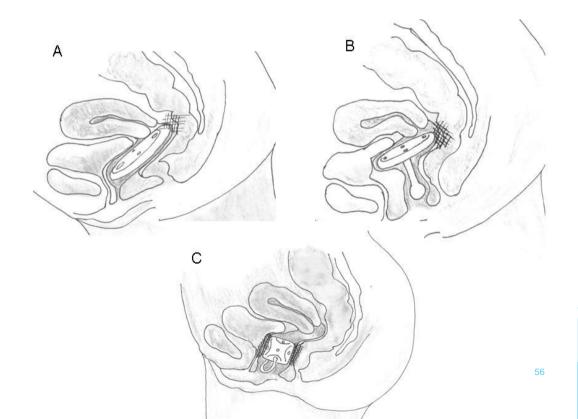


### Pressure points of pessary Apex is 2-4 mm thick post-hyst [46]



### Pressure points, Mechanical friction related to pessary

[K. O'Dell]



### Pessary follow-up exam: Equipment



### Pessary Follow-up: Decision making

#### Decision to:

- Treat minor vaginal epithelial disruptions in-office
  - ► Silver nitrate [40]
  - Topical estrogen applied
- Re-insert
- Refit-different size or type
- Remove -Leave out if erosions [pessary holiday]
- ► Continue or start treatment for vaginal atrophy with low-dose topical estrogen cream, tablet, ring. Demonstrate/ reassess use of local estrogen product

## Management of complications secondary to pessary use

### ► Etiology?

- ► Vaginal atrophy
- ► Mechanical injury
- ► Infection
- ► Inflammation

### Common Complications: Discharge, Odor- mechanical injury? Vaginal atrophy?

- □ R/O Erosion
- □ Refit using pessary with larger drainage holes or less occlusive
- More frequent pessary cleaning visits
- Prescribe
  - □ Vaginal moisturizer [41, 44]
  - Acidifier Hydroxyquinoline-based gel [42]
  - □ Estrogen [43]
- Temporary pessary holiday
- Change to alternate pessary manufacturer
  - expert opinion





#### Treatment of complications: Less Common but More Worry

#### Vaginal epithelial abnormalities (VEA)

- Vaginal bleeding, spotting, abnormal drainage
- ► Vaginal erosion aka Mechanical Pressure Ulcer
- ► Hypergranulation tissue

### Terminology: Erosions-no consensus

- Erosion- size, depth? Any break in the epithelium?
- Vaginal Epithelial Abnormality (Hartford FPMRS definition)
  - ► Granulation tissue > 1 cm, Break in epithelium > 1cm [15]
- Mucosal pressure ulcer
  - Due to medical device in a moist lining of body cavity communicating with exterior (GI, tongue, nasal passages, GU, vagina)
  - -document location, surface circumference, friability
- Hypergranulation tissue
  - -abnormal build-up of mucosal granulation tissue due to chronic friction (ie pessary in vagina), in a process that impedes normal healing
  - ▶ Document location, size, friability [14]

### Risk factors for vaginal erosion: [48]

- Erosion rate for this study sample retrospective chart review, 119 subjects
  - ► Average 16.8% erosion rate over 13 years
    - ▶ 1<sup>st</sup> year: 1.68%, by 13<sup>th</sup> year 50%
- Factors identified that increased the rate of erosion
  - Increase
    - ▶ Daily ASA use
      - ► Alone p < 0.001
      - ▶ When controlled for all variables
      - ► HR 2.794 (1.480 5.275), p=0.002
    - **▶** Greater Parity
      - ▶ Chance of erosion increases 27% with each additional child
      - ► HR 1.268 (95% CI: 1.036-1.553)
      - Theorize that greater parity may be associated with larger prolapse and need for larger pessary?

### Risk factors for vaginal erosions secondary to pessary use: [48]

- ▶ Factors identified that decreased the rate of erosion
  - ► Use of Estrogen cream p = 0.022
    - ► ERT sub-analysis
      - ► Hysterectomy p=0.048, HR: 0.459 (0.212 0.995)
      - ► This finding is not consistent with other reports in ROL which state presence of cervix is protective against vaginal erosions.

# Propsed Terminology: Mucosal pressure ulcer vs vaginal erosion [47]

#### Mucosal Pressure Ulcer:

- ▶ Due to medical device; moist lining of body cavity communicating with exterior (GI, tongue, nasal passages, GU, vagina)
- Injury→ inflammation/ bleeding →soft clot/ coagulum→ easily shed (not slough)

#### Problems with identification/ staging:

- Initial shallow open ulcer difficult to see (background)
- Tenderness/ edema don't occur
- Coagulum and slough are both yellow/ shiny

#### Healing:

- Similar to skin but no scar
  - ▶ [47[National Pressure Ulcer Advisory Panel, 2010

### Mucosal Pressure Ulcer: erosion

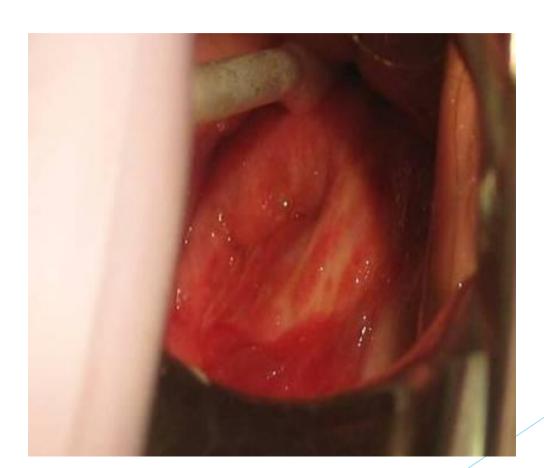


#### Treatment options: mucosal pressure ulcers

- First Line: temporary removal
  - > 2-4 weeks
- Vaginal estrogen
  - ▶ Nightly or twice a week while out
  - ▶ Widely used with little evidentiary support
- Consider refit—change size or style
- Apply cream under the pessary
- Learn more about mucosal ulceration from other disciplines (GI, dentistry)

### Hypergranulation tissue:

another abnormal epithelial membrane response to mechanical injury



#### Treatment: Friable Hypergranulation Tissue

- Removal for 4 to 6 wks or longer± topical estrogen
- Change size/ shape of pessary ± topical estrogen
- Chemical cautery to remove abnormal granulation tissue/ promote re-healing
  - Silver nitrate
  - Ferric sulfate (Monsel's) [40]

### Options for treatment of vaginal atrophy [ACOG 2014] [Rahn, 2014]

Treatment	Dosage	Evidence of Benefit*	FDA Approved
	Hormonal		
Estrogen			
Systemic			
• Standard Dose	Conjugated estrogen 0.625 mg/d	Yes	Yes
	Micronized estradiol-17β 1 mg/d	Yes	Yes
	Transdermal estradiol-17β 0.0375–0.05 mg/d	Yes	Yes
• Low Dose	Conjugated estrogen 0.3-0.45 mg/d	Yes	Yes
	Micronized estradiol-17β 0.5 mg/d	Yes	Yes
	Transdermal estradiol-17β 0.025 mg/d	Yes	Yes
• Ultra-Low Dose	Micronized estradiol-17β 0.25 mg/d	Mixed	No
	Transdermal estradiol-17β 0.014 mg/d	Mixed	No
Vaginal/Local	Estradiol-17β ring 7.5 micrograms/d	Yes	Yes
	Estradiol vaginal tablet 25 micrograms/d	Yes	Yes
	Estradiol ring 0.05 mg/d	Yes	
	Estradiol-17β cream 2 g/d	Yes	
	Conjugated estrogen cream 0.5–2 g/d	Yes	
	Nonhormona	l	
Estrogen agonists–antagoni	ists		
<ul> <li>Raloxifene and tamoxife</li> </ul>	en	No	No
<ul> <li>Ospemifene</li> </ul>	60 mg/d	Yes	Yes
Vaginal lubricants		Yes	No
Vaginal moisturizers		Yes	No
Herbal remedies and soy products		No	No

### Estrogen use and pessaries What is the evidence?

- Vaginal Estrogen use associated with:
  - lower pessary discontinuation rates [30.6 % vs 58.5 %, P < 0.001]
  - Less vaginal discharge
  - But did NOT decrease in vaginal erosions or vaginal bleeding
    - ▶ Retrospective chart review by billing code
    - ▶ Non-randomized; with > 6 months f/u [43]
- Estrogen users showed no significant differences in:
  - ▶ Level of comfort with removal/ insertion
  - Adverse effects: discharge, bleeding, infection.
    - ▶ Prospective, non-randomized (n=120) [45]

# Other potential vaginal treatments for vaginal epithelial abnormalities (VEA) secondary to pessary use:

- Estrogen agonist/ antagonist-Ospemiphene
- Hyaluronic acid sodium salt-ovule
- DHEA vaginal insert
- Dehydroepiandrosterone intravaginal
- Moisturizers/ lubricants
- Fractional CO2 Laser

No evidence to determine if these products have a role in improving risk of VEA's secondary to pesary (related to mechanical irritation in background of vaginal atrophy)

# Other etiologies: Infection Bacterial Vaginosis?

## Post menopausal microenvironment unchanged before and after pessary use

- Pessary use increases bothersome discharge in some women
  - ▶ New users vs established (>3 mos use): 2% v 30% p<0.001)
- Prevalent organisms were the same in women who had never worn a pessary and those who had worn pessary for >3 months. 100 pessary uses with follow-up at 2 weeks, 3 months, 6 months. No change in organisms over time. No vaginal estrogen use (IRB requirement)
  - ► Cornybacteria, S. viridans, lactobacilli, E.coli, Bacteroides
- WBC per HPF increased within 2 weeks of pessary use, indicating inflammatory changes
- Based on these findings, current definitions and diagnostic criteria for BV do not adequately describe the normal post-menopausal vaginal microenvironment. [37]

## Other etiologies: Inflammation? New study

- "Inflammatory response in women with vaginal epithelial abnormalities after pessary use"
- Aim: to compare the profiles of women who develop VEA with pessary with women who do not develop VEA with pessary. Specifically assess concentrations of 2 pro-inflammatory cytokines to determine if they are associated with VEA.

Dr Aparna Ramaseshan

Dr Christopher Nold

Dr Paul Tulikangas

Colleen Mellen, APRN

David O'Sullivan PhD

# Case 1: 84 yo, G1P1 women with procidentia, has worn Ring/ support pessary x 10 years

- Presented at age 74. Her presenting symptoms were vaginal bulge and pressure, sensation of incomplete bladder emptying, urinary urgency/ frequency.
- All symptoms resolved with size 5 ring with support
- After 2 years erythema/ thin appearing epithelium noted on exam at posterior fornix where rim of pessary rests. Pt prescribed estrogen cream, 1 g vaginally, twice weekly at HS, pt self-applied vaginal cream
- After 5 years, pt dx'd with early dementia, poor short term memory. Pt started Aricept. Her husband prompted her to use estrogen vaginal cream and to do timed voids during waking hours (c/o urge UI after "sitting all day"
- After 8 years, pt developed persistent granulation tissue at posterior fornix, husband noted occ bleeding/ spotting on her pad. Bx showed inflammation. Pt could not apply own estrogen cream, husband was not aware. Husband taught how to apply vaginal estrogen (fingertip method) for his wife
- After 10 years, pt is combative when husband tries to apply estrogen cream. She has superficial vaginal erosions, vaginal bleeding/ tan drainage. She is very uncomfortable with pessary removal and insertion. Pt and husband have met with Urogynecologist x 2 to discuss obliterative surgery to address prolapse. Husband is fearful that pt will not be able to tolerate 1 night hospital stay. Arrangements made for him to be with his wife pre-op and post-op to provider support.
- Husband hesitant to consent for his wife to have prolapse surgery. Their son volunteers to stay with them one month post-op. Husband declines surgery. Pessary holiday x 2 to allow for healing of vaginal erosions. Pt had "constant urinary urgency/ frequency " when pessary out. Estring (vendor sample) placed along with ring pessary. Patient seen frequently to assess vaginal lining.

# Case 2: 75 yo female seen in ED for acute urinary retention



## When to terminate use of pessary?

# Terminate use of pessary in Geriatric woman:

- ▶ Patient desire for surgery
- Patient request for trial of pessary removal
- Vaginal epithelial disruptions cannot be managed with standard treatment (risk of bleeding/deep tissue ulceration/ fistula)
- ► Risks outweigh benefits of pessary

## Terminate Pessary in Geriatric Woman

- Patient can no longer be transported to office for pessary follow-up and surveillance
- No trained provider at long-term care facility for pessary maintenance
- Patient is no longer ambulatory
- Patient/ family choice when making end-of-life decisions (when patient comfort outweighs risk of urinary retention/ defecatory dysfunction/ vaginal excoriation related to prolapse)

# Use of Vaginal Pessary in the Geriatric Woman: Summary

## Advantages of Pessary for Geriatric Women

- Minimally invasive
- Avoids surgical risk & post-op complications [27]
- Accepted by patients, (42-100% with provider encouragement) [20,21,22]
- Provides effective, immediate, relief of prolapse, urinary and bowel symptoms [11,12,13,1,4]
- Improves body image and QOL [17,18]
- Achieve personal goal attainment [16]
- May be self-managed by patient
- May allow for continued sexual activity

## Advantages of Pessary for Geriatric Women [5]

- ► Genital hiatus may decrease in size with pessary use, allowing a smaller or different shape pessary over time [28, 36]
- Made of medical-grade silicone (non-allergic, do not absorb odors, can be autoclaved)
- ► Contraindications, risks and complications are low [27]
- Minor complications (vaginal discharge, odor, bleeding, erosions) can be successfully treated [29]
- In the absence of major complications, pessary use can be continued for life [5]
- Pessaries have been a viable treatment for POP for centuries; still no clear guidelines for pessary fitting, follow-up, or management exist to date[35]

Recent new PFD risk factor to my extended family



# Resources: Patient Information

## Pessary Care Guideline Sample [33]

SOGC TECHNICAL UPDATE

#### APPENDIX. SAMPLE PATIENT CARE GUIDELINE AND INFORMATION

Courtesy: Pelvic Floor Clinic, Calgary
Pessary Care Guidelines and Follow-Up

Date: \_\_\_\_\_\_ Size: \_\_\_\_\_ Type: \_\_\_\_\_

After your pessary fitting, book a follow-up appointment in weeks.

- . This visit is to see if the pessary is helping you, and to examine your vagina to make sure it remains healthy looking.
- Further follow-up appointments are very important. When you are comfortable with caring for your pessary, the follow-up appointments
  will be less often.
- You may learn to care for your pessary yourself. If you can remove and insert your pessary yourself, then you should remove your pessary overnight at least once a week and clean it with warm water. Book regular follow-up visits to check on the health of your vaginal tissue.

#### Occasional Problems and Suggestions

Problem	Suggestions			
Pessary falls out	Reinsert your pessary if you are able to. Go to your scheduled appointment, and bring your pessary with you.			
You have pelvic pain	If you feel that your pessary is the cause of the pain, remove it and bring it with you to your new appointment. If you are unable to remove your pessary, contact the clinic.			
Vaginal odour and/or discharge	Some odour and discharge is normal. If the odour is very foul, remove the pessary if you can, and go to your scheduled appointment. If you are unable to remove your pessary, contact the clinic.			
Vaginal bleeding	This may be a sign that the pessary is irritating your vaginal lining. Remove the pessary if yo can, and go to your scheduled appointment. If you are unable to remove your pessary, conte the clinic.			
Leaking urine	If you feel that the pessary is making your leakage worse, remove it. Go to your scheduled appointment. If you are unable to remove your pessary, contact the clinic.			

#### If you are having urgent problems, phone the Pessary Clinic at: \_\_\_\_

This material is designed for information purposes only. It should not be used in place of medical advice, instruction, and/or treatment. If you have specific questions, please consult your doctor or appropriate health care professional.

#### Discharge and Odour

Some women find that they have an increased vaginal discharge, with or without an odour, when using a pessary. Usually this is normal, it is the body's reaction to wearing a foreign body inside of you. This can be controlled with various creams or gets—speak to a doctor or nurse about it.

#### Insertion and Removal

Most women are able to insert and remove the pessary on their own. The clinic nurse will teach you some way to do this, but you may find a way that works best for you over time.

We suggest that you should try to remove your pessary at least once each week. Leave it out overnight to give your bissues a break. Some women remove it nightly and others leave it out longer. Everyone's vaginal tissues have a different tolerance level for the pessary, in the same way that everyone's skin varies in its sensitivity. How often you remove your pessary also depends on whether you are on hormones, and the type of pessary you wear.

Some women are unable to remove or insert the pessary due to arthritis or for other reasons. The clinic nurse can help you work out what works best for you, along with helping you find a schedule that works best for you.

#### Insertion of Your Pessary

Fold the pessary and insert it through the vaginal opening, aiming down towards your tailbone, and pushing down on the back of the vaginal wall.

Using your forefinger, guide the pessary as far back as you can, then push the pessary up and behind the public bone.

#### \$10 . JULY JOGC JUILLET 2013

## Patient Information

AUGS Voices for PFD information sheet

## Vaginal Pessaries



A vaginal pessary is a silicone device, similar to a vaginal contraceptive diaphragm, that is used to treat urinary incontinence or prolapse.

#### **About Vaginal Pessaries**

A vaginal pessary is inserted into the vagina to support dropped pelvic organs and apply compression to the urethra during activities that can cause urine leakage. For many women, pessaries are a low risk treatment option for pelvic organ prolapse (POP) or urinary incontinence. They allow you to be comfortable and active without surgery. About 85 percent of women can be successfully fit with a pessary regardless of age, medical history, or extent of prolapsed pelvic organs.

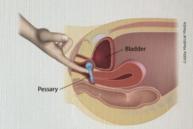
#### IS A PESSARY A GOOD OPTION FOR YOU? Consider wearing a pessary if you:

- Need temporary or long-term help with urine leakage during exercise.
- Have bothersome stress urinary incontinence (SUI) or POP symptoms and want a non-surgical treatment. Some women want to delay surgery and others want to avoid it completely—a pessary can help in both cases
- Have health problems that make the risks of surgery too great.
- Are considering pregnancy in the future and need to postpone surgery until after you have completed your family.
- Take the time to remove, clean, and reinsert the pessary on a regular basis. This can be done by you at home or through regular visits to your health care provider.

#### LEARN THE TERMS

Vaginal pessary: A device usually made of medical-grade silicone inserted into the vagina to correct vaginal prolapse or treat urinary incontinence.

Pelvic organ prolapse (POP): Dropping of the pelvic organs, such as the bladder, uterus and rectum, caused by a loss of vaccinal support.



Not all women are able to wear a pessary. Vaginal scarring, vaginal dryness, a surgically narrowed or shortened vagina, widened vaginal opening or very weak pelvic floor muscles are some reasons pessaries can fall out or be uncomfortable. Some of these problems can be treated to allow for pessary use

Pessaries require ongoing care to avoid problems with vaginal discharge, odor, bleeding or ulceration. Often, you can easily do this after receiving teaching from your health care provider. A forgotten pessary can cause problems. For example, you can develop erosions through the vaginal wall into the bladder or rectum. About 50 to 80 percent of women successfully fitted with a pessary, use it on a long-term basis.

#### Wearing a Pessary

Pessaries require fitting. This fitting is easily done during an office visit, allowing you to leave

## Resources: Professional practice

## Coding and Billing



1100 Wayne Avenue, Suite 825 Silver Spring, MD 20910 301.273.0570 • Fax 301-273-0778 info@augs.org • www.augs.org

#### Coding for Fitting and Insertion of a Pessary

A pessary is a device worn in the vagina for the treatment of pelvic organ prolapse or stress urinary incontinence. The pessary provides support of the vaginal walls or uterus when they have prolapsed by repositioning these organs to their original position. Some pessaries are specifically designed to stabilize the urethra for stress urinary incontinence. Pessaries can be used for short term or long-term treatment. They require long term surveillance for fit and for the health of the vaginal walls. Pessaries can also be used as a diagnostic tool to determine if symptoms are related to prolapse found on examination and to aide in therapeutic decision making.

#### Current CPT Codes for Reporting the Fitting and Insertion of a Pessary or Maintenance Procedures:

57160: Fitting and insertion of pessary or other intra-vaginal support device
57150: Irrigation of vagina and/or application of medicament for treatment of bacterial, parasitic,
or fungoid disease

#### **HCPCS Codes for Pessaries:**

A4561: Pessary, rubber A4562: Pessary, non-rubber

A4320: Irrigation tray with bulb or piston syringe, any purpose

#### CPT codes and RVU Table:

СРТ	Description	2018 Total RVU Non- facility	2018 Total RVU Facility	2018 DME fee
57160	Fitting and insertion of pessary or other intravaginal support device	2.15	1.33	
57150	Irrigation of vagina and/or application of medicament for treatment of bacterial, parasitic, or fungoid disease	1.28	0.82	

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