Spring 4-25-2018

Pessary Therapy Compared to Pelvic Floor Muscle Training in Women with Pelvic Organ Prolapse

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Table of Contents

Abstract:

Background/Purpose: Women with pelvic organ prolapse (POP) report symptoms, which include urinary incontinence, discomfort in the pelvic floor, and difficulty voiding with bowel and bladder. These symptoms often affect the individual's ability to participate in physical activities, intimate relationships, and daily activities. Conservative treatments for prolapse include pessary therapy and pelvic floor muscle training (PFMT). Stress urinary incontinence (SUI) often coincides with POP and is treated with either pessary or PFMT as well. The purpose of this article analysis is to determine which treatment is more effective when treating women with POP.

Case Description: The patient described was a 42 year-old woman with a stage II POP. She had a history of two births with mild tearing and chronic constipation. She was experiencing vaginal heaviness sensations, difficulty voiding, and stress urinary incontinence. She was interested in conservative treatment and was hoping to avoid surgery. Her goal was to reduce symptoms and allow her to return to her previous level of physical activity.

Outcomes: In women with POP, pessary therapy was shown to make greater improvements in symptoms and quality of life (QOL) compared to PFMT. For women experiencing SUI, PFMT and behavioral therapy was found to improve SUI symptoms greater than pessary therapy.

Discussion: Pessary use leads to greater improvements of POP symptoms, however, only 60% of women continued their use so women need to be managed throughout their fittings to ensure they find a pessary type and size that works for them. For SUI, PFMT is the best treatment compared to pessary, however improvements only lasted 3 months. More research is needed to examine adherence issues and the mechanism causing SUI so the best treatment option can be selected.

Introduction:

Background and Purpose

Pelvic floor dysfunctions affect 25% of women in the US.[1] Of those, pelvic organ prolapse (POP) is a common pelvic floor dysfunction. Women have an 11% risk of receiving surgical intervention for pelvic organ prolapse in their lifetime.[2] Women with POP often report symptoms affecting their continence, intimate relationships, daily activities, physical exercise, and overall body image and confidence.[2] POP is often treated with surgical intervention however, the revision rate is 30%.[3]

Pelvic organ prolapse is the descent of the pelvic organs into the vaginal canal. Different types of common prolapses include: cystocele or the descent of the bladder, rectocele or the descent of the rectum, and uterine prolapse or the descent of the uterus into the vaginal canal.[4]

The internal organs often associated with pelvic prolapse are supported internally primarily by the levator ani pelvic floor muscular group and ligaments. Risk factors for POP include previous childbirth, increased age, obesity, history of hysterectomy, heavy lifting, and chronic constipation which disrupts the intraabdominal pressure.[2] The increase of intraabdominal pressure applies strain and pressure on the ligaments holding up the internal organs.

Prolapses are divided into stages to describe the severity of the translation of the pelvic organs. Stage I is a slight lengthening of the pelvic organ ligaments, demonstrating a small translation into the vaginal canal. Stage II prolapse descends to the hymen. When the organ translates beyond the hymen, the prolapse is a stage III. A stage IV prolapse is a complete protrusion of the organ out of the vaginal canal. Conservative interventions are considered the best treatment options for prolapses at stages I and II, while prolapses at stages III and IV are

considered candidates for surgery.[2] Medical providers such as a physician, a physician's assistant, or a nurse practitioner can stage a prolapse. It can also be staged by a skilled pelvic floor physical therapist.[2,3]

Symptoms of POP include a bulge and pressure in the vaginal area. The patient may also be experiencing additional symptoms such as difficulty voiding, incontinence, and sexual dysfunction. Stress urinary incontinence (SUI) has been found to often impact patients with a staged I or II prolapse due to loss of support in the anterior vaginal compartment. As the prolapse descends further, the urethra may kink which adds additional resistance to the stream of urine. This may reduce the amount of SUI occurrence, but may add symptoms such as a slow urine stream, incomplete emtpying.[2]

Treatment for pelvic organ prolapse includes conservative and surgical interventions. Conservative treatments include pelvic floor muscle training (PFMT), pessary therapy, and estrogen therapy. PFMT is the strengthening of the pelvic floor muscles often taught by a physical therapist trained in pelvic floor dysfunction. Behavioral training is often used along with PFMT, where education on voiding habits and ways to prevent further progression of prolapse is given.[3] A pessary is an intravaginal device that supports the organs and prevents them from descending into the vaginal canal (Fig. 1).[2]

Figure 1.

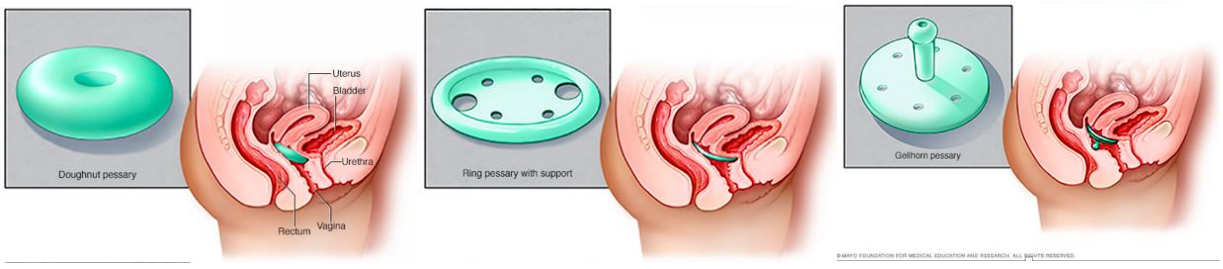

Image courtesy of Mayo Clinic

Figure 1: Three types of pessaries used to support organ prolapse. They come in different shapes and sizes in order to provide the best fit to the individual.[5]

Surgical interventions have been shown to be effective in older and younger women; however, younger women are more likely to have revisions.[6] Despite the increased risk to younger women for revisions, younger women receive surgical intervention more often and older women often prefer pessary therapy.[7]

Conservative treatments for POP are ideal for women who either prefer not to have surgery or who are not considered good surgical candidates. This article analysis will be examining the following PICO question: Is pessary therapy more effective at reducing discomfort and dysfunction from pelvic organ prolapse symptoms compared to pelvic floor muscle training?

Case Description:

The patient was a 42-year-old woman referred to outpatient physical therapy for symptoms related to pelvic organ prolapse. She reported symptoms of "heaviness" and "bulging" in her pelvic floor, difficulty with urinary voiding, and occasional stress urinary incontinence accompanying sneezing or running. She had a history of two vaginal births five and three years ago. Tearing was minimal with both deliveries and she reported there were no complications during pregnancy or postpartum. Symptoms of pelvic organ prolapse began shortly after her second child's birth, approximately five years ago. She reported a history of occasional constipation but not what she considered severe.

Employed as a psychiatrist, she spent much of her day sitting with patients. She was active outside of work, exercised 4-5 times per week and was in good overall health. She used to be a runner, but had not run in the last couple years due to increased symptoms. She reported

increased symptoms when she had been up and moving around all day and had reduced her physical activity since the symptoms began. The patient was diagnosed by her physician with a stage II cystocele a few weeks before the evaluation. She reported feeling great distress and experiencing poor body image after her diagnosis. She had a new partner and reported feeling self-conscience during sexual activity but not experiencing additional distressing symptoms during sexual activity.

At the time of her evaluation, she had an appointment for a pessary fitting with a local women's health clinic the following week. She was concerned about her outcomes and was worried about the prolapse worsening. She hoped to avoid surgery as she had read about the poor outcomes. Her goals were to be able to return to her daily activities without as many bothersome symptoms.

Evidence Based Analysis:

Methodology of Search:

A search was performed to answer the following PICO question: Is pessary therapy more effective at treating pelvic organ prolapse symptoms compared to pelvic floor muscle training? The databases used for article search included: Pubmed, CINAHL, PEDro, and Cochrane Search phrases included: "pelvic organ prolapse" AND "pessary", "pelvic organ prolapse" AND "pessary" AND "pelvic floor muscle training", "pessary" AND "pelvic floor muscle training" (Figure 2).

Selection Criteria:

Articles were included if they were women with pelvic organ prolapse or stress urinary incontinence, publication date in the last 10 years, treatment involved pessary and/or pelvic floor muscle training. Exclusion criteria included articles that were not in English and RCT's that

compared pessary or PFMT to surgical or pharmaceutical intervention. Articles that met inclusion and exclusion criteria were read and analyzed. Article analysis tables are included in Appendix A.

Figure 2.

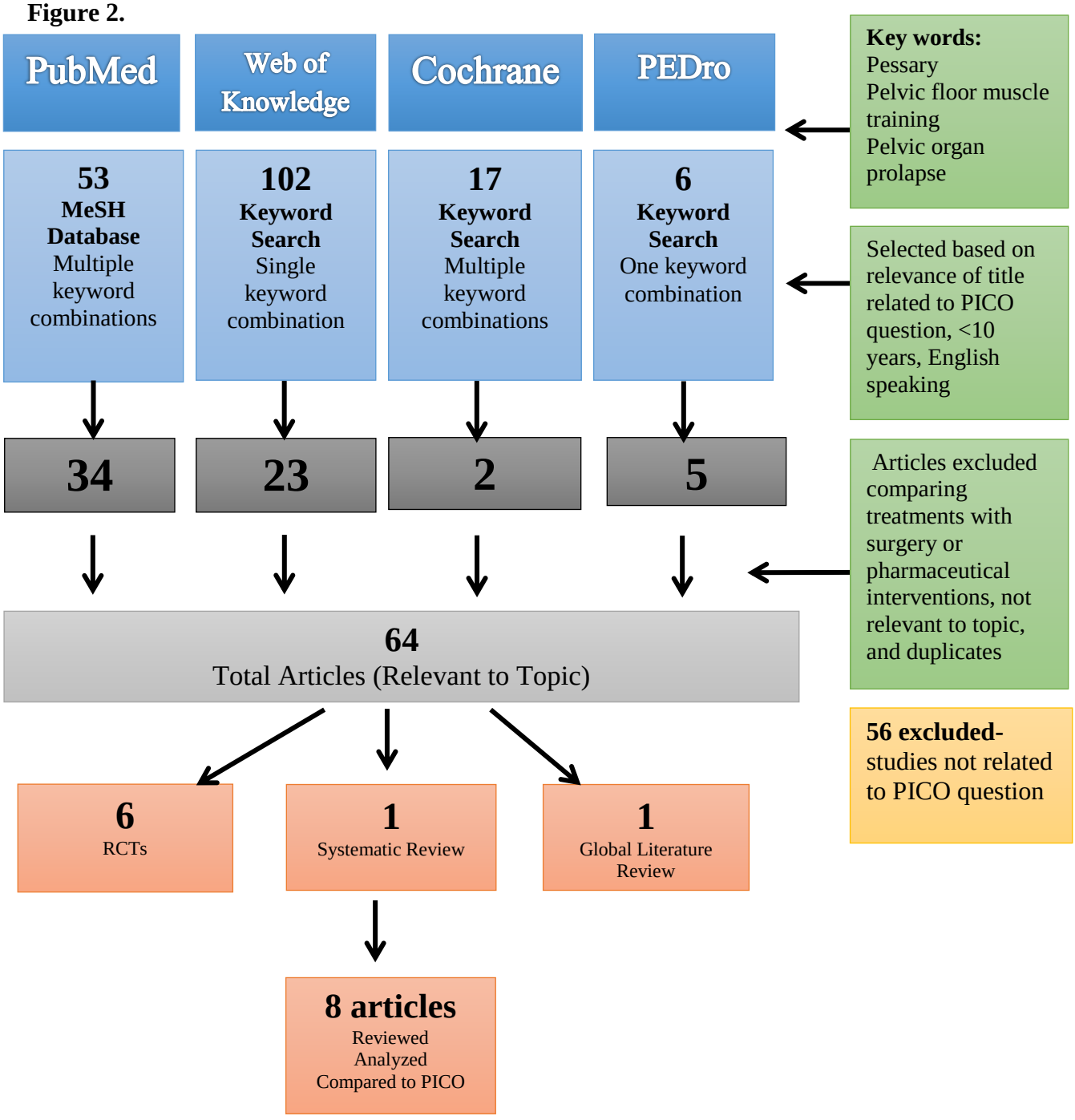

Figure 2: How articles were included, excluded, and selected for analysis.

Article Summaries:

Article #1:

Wiegersma M, Panman CMCR, Berger MY, De Vet HCW, Kollen BJ, Dekker JH. Minimal important change in the pelvic floor distress inventory-20 among women opting for conservative prolapse treatment. *Am J Obstet Gynecol*. 2017;216(4):397.e1-397.e7. doi:10.1016/j.ajog.2016.10.010.

Level of Evidence: 2b

Purpose: The purpose of this study was to compare the effectiveness of PFMT and pessary interventions for women experiencing symptomatic pelvic floor organ prolapse. The authors defined effective as improving pelvic floor symptoms and cost effectiveness with each intervention.

Methods:

Participants included 162 women 55 years or older with a stage II or III prolapse. Participants were excluded if they had undergone prolapse treatment in the last year, or if they were currently receiving treatment for other urogynecological disorders or cognitive impairments. The women were randomized into either the pessary treatment or PFMT groups.

Within the pessary group, participants were fitted for the pessary by a trained research physician. The fitting was considered successful if the pessary was worn for 2 weeks without discomfort. If the pessary did not fit correctly, another type would be used. Three attempts were allowed to try a new pessary, after that the pessary fitting would be regarded as unsuccessful.

In the pelvic floor muscle training group, the women were referred to a pelvic floor physical therapist. They were trained to contract and relax their pelvic floor. Then they were instructed on a strengthening program at home and with their therapist. Women with hypertonic pelvic floors were taught exercises on how to relax rather than contract. This group was also given information on lifestyle and toileting habits.

Treatment groups were followed up at 3, 12, and 24 months. Questionnaires were given and the pelvic floor was assessed for POP measurement and pelvic floor muscle function. The Pelvic Floor Distress Inventory (PFDI) was the primary outcome measure. Pelvic Organ Prolapse Distress Inventory (POPDI) was also used. Costs of each treatment were examined on an individual basis.

Results: Pessary fitting was successful in 57% of women in the pessary group. The rest of the women did not receive a pessary due to unsuccessful fitting. There were no significant difference between groups for the PFDI questionnaire. However, there was a significant difference between groups for the POPDI outcome measure that showed greater improvements in the pessary group (P=0.047). Both groups showed improvements with their pelvic floor symptoms at 3 months, the pessary group maintained their improvements while the PFMT group went back to baseline at 24 months. Pessary treatment is less costly at an average of $309 compared per person compared to $437 for PFMT.

Bottom Line: After 24 months, the authors found a significantly greater improvement in the pessary group in change of pelvic floor symptoms compared to the PFMT group in women 55 years old or greater. Pessary treatment may be a preferred treatment but because of the difficulty with fittings and adverse effects, it is not appropriate for all women with symptomatic POP. Pessary treatment also appears to be affordable as shown in the Netherlands, this may not be

generalizable to the treatment in the United States since healthcare costs differ. Limitations of this study include the fact the authors exceeded their 15% pessary group attrition rate which lowered the pessary sample size that compromises the validity of the study.

Article #2:

Cheung RYK, Lee JHS, Lee LL, Chung TKH, Chan SSC. Vaginal Pessary in Women With Symptomatic Pelvic Organ Prolapse. *Obstet Gynecol*. 2016;128(1):73-80. doi:10.1097/AOG.0000000000001489.

Level of evidence: 1b

Purpose: The purpose of this study was to compare the effects of pessary treatment with PFMT against the effects of PFMT alone on pelvic floor symptoms, quality of life, and adverse effects in women with symptomatic POP.

Methods: 276 women with symptomatic POP staged I-III were included who had not received previous treatment. Women with increased complications related to prolapse, cognitive impairment, and impaired mobility were excluded. The women were randomized to either the pelvic floor exercise group (control) or the pelvic floor exercise with pessary group.

The pessaries were fitted by a specialized physician and could be replaced with a different size up to three times before being declared an unsuccessful fitting. The pelvic floor exercise group were trained by registered nurses specialized in continence. Follow ups were performed at 6 and 12 months. Symptoms and quality of life were assessed by the PFDI, Pelvic Floor Impact Questionnaire (PFIQ), and Visual Analog Scale (VAS).

Results: 60% of the women in the pessary group were successfully fitted and still wearing the pessary at 12 months. The pessary group had a significantly higher improvement in the PFDI and

PFIQ compared to the exercise only group. The median VAS scores (P=.001) decreased in the pessary group significantly but not in the control. More women in the pessary group reported significantly more stress urinary incontinence. Some adverse effects of pessary use were abnormal vaginal bleeding, vaginal discharge, incontinence, and voiding difficulty.

Bottom Line: Pessary therapy combined with PFMT shows to be useful for treating POP over PFMT alone. However, adverse effects should be watched carefully and followed in women treated with a pessary to make sure they have better outcomes with reduced adverse effects.

Article #3: Richter HE, Burgio KL, Brubaker L, et al. Continence pessary compared with behavioral therapy or combined therapy for stress incontinence: a randomized controlled trial. *Obstet Gynecol*. 2010;115(3):609-617. doi:10.1097/AOG.0b013e3181d055d4.

Level of Evidence: 2b

Purpose: This study's purpose was to examine the effectiveness of a pessary compared to behavioral therapy and combined therapy in women with stress urinary incontinence.

Methods: 446 women 18 years or older with SUI or mixed urinary incontinence were selected. They were randomized into one of three groups: pessary treatment, behavioral therapy, or a combination of both. Behavioral therapy included in-person instruction for pelvic floor muscle training and a home program. Pessary treatment included a fitting that allowed for three re-fittings in order to allow for appropriate fit. Participants were followed up at 3, 6, and 12 months. The two primary outcome measures were the Patient Global Impression of Improvement (PGI-I) and the Pelvic Floor Distress Inventory (PFDI). A 7-day bladder diary was also performed and a 75% reduction in frequency of incontinence was considered successful.

Results: At 3 months, 46% of the participants reported they were "much better" on the PGI-I among the three groups, with no significant differences between the pessary and behavioral

groups (pessary 40%, behavioral 49%, combination 53%) The combination group was significantly higher than the pessary only group (p=0.02). The PFDI showed a significantly greater improvement in the behavioral group compared to the pessary group. The combined group showed an improvement that was greater than the pessary group but not the behavioral group. At 12 months, there was a decline in treatment success with 32% of participants reporting they were "much better." There were no significant differences between groups at 12 months.

Bottom Line: Overall, women in the behavioral group reported greater improvement in SUI symptoms and increased satisfaction at 3 months compared to the pessary treatment group. The combination group was shown to be just as effective as the behavioral therapy alone group. Differences between groups did not remain at 12 months, likely to due to lack of adherence. This study could be related to the PICO question but not directly since it was not an inclusion criterion that the women have a POP. They were only excluded if they had a POP of III or greater.

Article #4:

Handa VL, Whitcomb E, Weidner AC, et al. Sexual function before and after non-surgical treatment for stress urinary incontinence. *Female Pelvic Med Reconstr Surg*. 2011;17(1):30-35. doi:10.1097/SPV.0b013e318205e263.

Level of Evidence: 2b

Purpose: The purpose of this study was to examine the improvements of sexual activity and function in women with stress urinary incontinence (SUI) by comparing pessary treatment, behavioral therapy, and combined treatment.

Methods: 445 women 18 years old or older with symptoms of SUI were randomized into either a pessary, behavioral therapy, or combined groups. Women with a stage III or greater POP were excluded from the study. The women were identified as having true SUI or mixed incontinence. Women in the behavioral and combination groups participated in 4 treatment sessions over a two-month period. They were taught how to do pelvic floor muscle contractions, prescribed a home exercise program with progressions, and taught strategies to reduce leakage. Women in the pessary group were fitted and instructed to wear the pessary as they preferred to reduce leakage. Outcome measures included the Patient Global Impression of Improvement (PGI-I), Personal Experiences Questionnaire (SPEQ), and the Pelvic Organ Prolapse- Urinary Incontinence Sexual Function Questionnaire (PISQ). Follow up was done at 3 months.

Results: At 3 months, the authors found that women in any of the three groups who were successfully treated for their SUI symptoms were more likely to experience reduction of incontinence during sexual activity. Of the women successfully treated for their SUI, the mean improvement score for incontinence during sexual activity was 0.42 greater in the behavioral group compared to the pessary group. The combined therapy group showed an improvement score of 0.45 of reducing incontinence during sexual activity compared to the pessary group.

Bottom Line: Women who were successfully treated for SUI experienced improvements in sexual function regardless of treatment group. However, women who were successfully treated with SUI in the behavioral or combination groups were more likely to have improvement of incontinence during sexual activity compared to the pessary group. In a clinical setting, clinicians may consider behavioral therapy when working with patients experiencing problems with incontinence during sexual activity. A limitation to this study is that only 40% of the women had a sexual partner at the time of the study.

Article #5:

Kenton K, Barber M, Wang L, et al. Pelvic floor symptoms improve similarly after pessary and behavioral treatment for stress incontinence. *Female Pelvic Med Reconstr Surg*. 2012;18(2):118-121. doi:10.1097/SPV.0b013e31824a021d.

Level of Evidence: 2b

Purpose: This article is the planned secondary analysis of the study performed in article #3. The authors wanted to determine whether the use of a pessary or behavioral therapy for treatment of SUI reduces in symptoms of bother and improves health-related quality of life for overall urinary, prolapse, and colorectal symptoms.

Methods: This was a secondary analysis trial described in greater detail above in article #4's methods. 446 women with symptoms of SUI were randomized into pessary, behavioral training, or combination groups. Exclusion criteria were continuous urinary leakage, current incontinence drug therapy, stages III or IV POP, incomplete bladder emptying, and neurological disorders. The three groups were followed up for assessments at 3, 6, and 12 months. Outcome measures to assess bother and quality of life were the Pelvic Floor Distress Inventory (PFDI), Pelvic Floor Impact Questionnaire (PFIQ), and Questionnaire for Urinary Incontinence Diagnosis (QUID). The PFDI includes a urinary scale, prolapse, and colorectal scales.

Results: All three groups showed significant improvements on each of the quality of life measures at 3 months. However, scores were not significantly different between groups. At 1 year, all groups still showed improvements since baseline but those improvements were no longer statistically significant. However, the improvements met the minimally important differences for some of the urinary subscales of the PFDI. Statistically insignificant improvements were shown in prolapse symptoms as well among all groups.

Bottom Line: Both behavioral therapy and pessary treatments can significantly improve health related quality of life and can be considered when working with patients with SUI. Clinicians should work with patients to help them decide what treatment they prefer or try the other if one is not successful.

Article #6: de Albuquerque Coelho SC, de Castro EB, Juliato CRT. Female pelvic organ prolapse using pessaries: systematic review. *Int Urogynecol J*. 2016;27(12):1797-1803. doi:10.1007/s00192-016-2991-y.

Level of Evidence: 2a

Purpose: The purpose of this systematic review is to determine the impact pessary therapy has on quality of life (QOL) in women with POP, the success rate of retaining pessary use, and the reasons for discontinuation.

Methods: Studies included were observation studies, cross sectional studies, cohort studies, and RCTs. Languages included were English, Portuguese, and Spanish. There was no limit on year of publication. Exclusion criteria were studies that were not on topic, systematic reviews, and articles that did not use validated questionnaires. The descriptors used included "pelvic organ prolapse AND pessaries AND quality of life" OR "pessary AND quality of life" OR "pessaries." Two reviewers selected which studies to include. When the reviewers could not come to a consensus, a third reviewer would help make the decision.

Results: 89 articles were collected and 7 articles were finally selected. Two articles found improvements in participant reported body perception in stage III and IV POP with pessary use.

Three articles compared pessary use to surgical intervention. The first two found improvements in quality of life, vaginal discomfort, overactive bladder, and constipation but not in urinary

incontinence with pessary therapy. These articles showed that compared to women with surgical intervention, the pessary group showed just as much improvement in symptoms. The third article showed greater improvements in the surgery group.

The final two articles examined sexual function in women treated with pessary therapy. They both found significant improvements of prolapse symptoms, sexual function, and overall wellbeing.

The median discontinuation rate for the pessary treatment of the 7 studies was 49.1%. Reasons for discontinuation were failure to retain the pessary, discomfort, desire for surgery, and inability to remove/insert the pessary. Women who continued with the device reported complications such as infection, ulcers, and discharge.

Bottom Line: All of the articles evaluated in this review showed that pessary use was associated with increased QOL in women with POP symptoms. It is shown to often be just as effective as surgery. High heterogeneity among groups limits the authors' ability to compare the studies included in the review.

Article #7:

Due U, Brostrøm S, Lose G. The 12-month effects of structured lifestyle advice and pelvic floor muscle training for pelvic organ prolapse. *Acta Obstet Gynecol Scand*. 2016;95(7):811-819. doi:10.1111/aogs.12884.

Level of Evidence: 1b

Purpose: This article is a follow up analysis where the authors evaluated the effects of adding PFMT to a lifestyle advice program for women with symptomatic staged I-III POP.

Methods: Women 18 years or older describing pelvic organ prolapse symptoms such as vaginal heaviness, voiding dysfunctions, or defecation problems. Exclusion criteria included previous

PFMT within the last 2 years, childbirth in the last year, more than one surgical intervention related to POP, and women with POP stage I. Women were randomized into a lifestyle advice group or combined lifestyle advice with PFMT. All participants received 6 group sessions in 12 weeks for the lifestyle information. The advice sessions included information about POP promoting factors such as straining, constipation, heavy lifting, and excess body weight. Women in the PFMT group were evaluated by a pelvic floor physical therapist to assess strength and educate proper pelvic floor contraction as needed. Patient Global Index of Improvement Scale (PGI-I), PFDI, and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) were used. Follow ups were performed at 3 and 6 months.

Results: 109 women were included and randomized. At 3 and 6 months, the PFMT group showed significant improvement in the global scale and reduced POP symptoms such as vaginal heaviness. The advice only group showed improvements of SUI from baseline. However, there were no significant differences between groups for health related quality of life, reduction of sexual problems, or improvement in the stage of prolapse. Both groups showed improvements in voiding difficulties.

For the 12-month follow up, there were no significant differences between groups for the global or symptom scores. More women in the advice only group sought further treatment before the 12-month follow up ($p=0.05$).

Bottom Line: PFMT does not appear to have a longer-term effect for women with symptomatic POP. At 12 months, it does not show to be superior to lifestyle advice intervention.

Article #8:

McIntosh L, Andersen E, Reekie M. Conservative Treatment of Stress Urinary Incontinence In Women: A 10-Year (2004-2013) Scoping Review of the Literature. *Urol Nurs*. 2015;35(4):179-

203. doi:http://dx.doi.org.libproxy.unm.edu/10.7257/1053-816X.2015.35.4.179.

Level of Evidence: 5

Purpose: To describe two of the most commonly reported conservative treatment options currently available for women with stress urinary incontinence, pessary treatment and pelvic floor strengthening, and to identify the benefits and downfalls of each.

Methods: The authors performed an electronic database search between the years. Key search words were "stress urinary incontinence" along with "conservative management," "complementary therapy," or "alternative therapy." "Pessary" was also used to narrow down results. Articles were limited to English speaking women only and full texts that were available online. 88 articles were retained and reviewed thoroughly.

Results: PFMT has been shown in multiple studies to be an effective treatment for women with SUI in the short term. One study found that it produced objective and subjective cure rates between 35-80%. Another study reported that the improvements that were found at 3 and 6 months were no longer present at 12 months. Other authors found that the reason behind the declining adherence among women practicing a pelvic floor exercise program is lack of motivation if they are not being supervised. Other barriers include illnesses, work/personal conflicts, and boredom with the exercises. One study found that even though most women were not completely continent, they still reported being "satisfied" after PFMT treatment.

Studies show that pessary therapy is most successful when the women can take out and insert the device herself for cleaning and for intercourse. Some women require follow ups after 3-6 months to have the device removed and have the vaginal canal examined for skin breakdown.

Studies show that when PFMT and the pessary therapy are used together, the PFMT group appears to have greater improvements at 3 months but one study found there was no significant difference at 12 months between groups.

Bottom Line: Pelvic floor muscle training has been shown to improve SUI symptoms. It may be the more successful conservative treatment compared to pessary therapy. However, the downfall is lack of adherence to the strengthening program when women are not being overseen. If pessaries are fitted correctly and checked frequently, they can be helpful with managing SUI symptoms as well.

Table 1: Articles selected for analysis

	Study & Origin	Oxford Level of Evidence	Pedro Score	Purpose of Study	Outcome Measures	Results	Accept Results to Answer Clinical Question
1	Panman, C.M.C.R., et al.(2016) Netherlands	2b	6/10	To compare the effect of pelvic floor muscle training (PFMT) to pessary for treating symptoms related to pelvic organ prolapse in women >55 over a 2 year period	-Pelvic Floor Distress Inventory-20 -Pelvic Organ Prolapse Distress Inventory-6 -Pelvic Floor Impact Questionaire-7 -Medical Outcomes Study Short From Health Survey-12 -Degree of prolapse with the POP-Q systems -Digital pelvic floor muscle palpation	-Significant improvements in the pessary group for reduced prolapse specific symptoms compared to PFMT[1] group -Improvement in both groups, but the PFMT group dropped back to baseline while the pessary group did not by 3 months -Pessary treatment less costly than PFMT over the 2 year period -At 24 months, 57% of women successfully retained pessary	Yes
2	Cheung, R., et al. (2016) China	1b	8/10	To compare the use of pessary with PFMT to PFMT alone for women experiencing symptomatic pelvic organ prolapse	- Pelvic Floor Distress Inventory-20 - Visual Analog Scale report of degree of bother -Pelvic Floor Impact Questionaire-7	-Significant improvement in pessary and PFMT group in prolapse symptoms and reported quality of life at 6 and 12 months follow-ups -Pessary found to be effective in prolapse stages I-III -At 12 months, 60% of women successfully retained pessary	Yes

[1] POP: pelvic organ prolapse
PFMT: pelvic floor muscle training
SUI: stress urinary incontinence
PFDI: Pelvic Floor Distress Inventory

3	Richter, H., et al. (2010) US	2b	6/10	To compare effectiveness of continence pessary, behavioral therapy including PFMT, and combined therapy on urinary stress incontinence.	- Patient Global Impression of Improvement -Pelvic Floor Distress Inventory -7 Day bladder diary	-Behavioral therapy is more effective than pessary therapy at three months for SUI. -No significant differences between groups 12 months -Combination therapy was not superior to either single-mode therapies	Yes
4	Handa, V., et al. (2011) US	2b	3/10	To determine which non-surgical intervention improved sexual function for women experiencing stress urinary incontinence. Interventions were pessary, PFMT with and behavioral training, and combined treatments.	-Patient Global Impression of Improvement -Personal Experiences Questionnaire -Pelvic Organ Prolapse-Urinary Incontinence Sexual Function Questionnaire	-Significant improvements in continence aspects of sexual function for women who were successfully treated for SUI. -The participants not successfully treated for SUI[2] showed no improvement of sexual function - No significant improvements for arousal, libido, and dyspareunia - Higher improvement of incontinence during sexual activity for behavioral therapy group compared to the pessary group	Yes
5	Kenton, K., et al. (2012)	2b	5/10	To compare improvements in quality of life measures in women	- Pelvic Floor Distress Inventory - Pelvic Floor Impact Questionnaire	-All groups had a significant improvement of reported symptoms and quality of life measures at 3 months and 1 year -No significant difference between groups at 3	Yes

[2] POP: pelvic organ prolapse
PFMT: pelvic floor muscle training
SUI: stress urinary incontinence
PFDI: Pelvic Floor Distress Inventory

	US			with SUI randomized to pessary treatment, behavioral training, and combination therapy.	-Questionnaire for Urinary Incontinence Diagnosis	months or 1 year.	
6	Coelho, S., et al. (2016) Brazil	2a	N/A	To determine the impact pessary therapy has on quality of life (QOL) in women with POP, the success rate of retaining pessary use, and the reasons for discontinuation	-Quality of Life measures -Reasons for Discontinuation -Success rates	-Improved quality of life in pessary group with decreased POP symptoms - 2 studies found similar improvements between pessary group and surgical groups - Median discontinuation rate for the pessary treatment 49.1% -Reasons for discontinuation: failure to retain the pessary, discomfort, desire for surgery, and inability to remove/insert the pessary -Adverse effects included: infection, ulcers, and discharge	Yes
7	Due. U, et al. (2016) Denmark	1b	4/10	A 12-month follow-up study to evaluate the medium term effects of a structured lifestyle advice program alone compared to PFMT with lifestyle advice program in women with POP	-Patient Global Index of Improvement (PGI-I) -PFDI-20[3] -Pelvic Impact Questionnaire (PFIQ)	-Improvement of global improvement scale for PFMT group -At 12 months, significant improvements in the lifestyle only group for urinary symptoms and improvements in the PFMT group for POP symptoms of vaginal heaviness. -No significant differences between groups. -70% in the lifestyle group and 48% in the PFMT received further treatment for POP symptoms	Yes

[3] POP: pelvic organ prolapse
PFMT: pelvic floor muscle training
SUI: stress urinary incontinence
PFDI: Pelvic Floor Distress Inventory

				staged II-III.			
8	McIntosh, L., et al. (2015) Canada	5	N/A	To describe two of the most commonly reported conservative treatment options currently available for women with stress urinary incontinence, pessary therapy and pelvic floor strengthening, and to identify the benefits and downfalls of each.	None	- Pelvic floor muscle training was shown to improve SUI symptoms -The downfall was lack of adherence to the strengthening program when women are not being overseen which is common after 3 months - If pessaries were fitted correctly and checked frequently, they were helpful with managing SUI[4] symptoms as well	Yes

Table 1: 8 articles shown were selected for analysis. Refer to Appendix A for more in depth analysis.

[4] POP: pelvic organ prolapse
PFMT: pelvic floor muscle training
SUI: stress urinary incontinence
PFDI: Pelvic Floor Distress Inventory

Discussion:

PFMT and pessary therapy are common conservative treatments for pelvic organ prolapse and the objective of this analysis was to determine which treatment is superior for treatment of POP symptoms. The articles that included women with POP found that pessary use had greater improvements in POP symptoms compared to the PFMT group. Participants found decreases in bothersome symptoms such as "bulging" sensation in the pelvic floor and difficulty voiding. [8,9] Reported increased quality of life along with improved body perception was often reported with pessary therapy among all stages of prolapse. Pessary therapy was also shown to be as successful as surgery at reducing bothersome symptoms of POP.[10]

However, all examined studies showed high attrition rates in their pessary groups. The rate of discontinuation for pessary use among the studies ranged from 50-60%. Reasons for discontinuing the pessary treatment included unsuccessful fitting, infection, ulcers, discharge, and increased urinary incontinence. [9,10] Making sure the patient receives a pessary that fits is crucial to continuation of use. It could take several attempts to get a pessary that does not fall out or cause erosion on the vaginal wall.[11]

Stress urinary incontinence (SUI) often coincides with POP and is not fully understood. It has been shown that increased descent and mobility of the urethra can cause SUI.[12] Though, it appears to involve many factors, it can also involve pelvic floor weakness that counteracts the intraabdominal pressure that greatly increases during a sneeze or running.[13]

One trial by Richter et al that included PMFT, compared pessary to behavioral therapy. The trial found significant improvements in the behavioral group over the pessary group. However, these improvements did not last beyond 3 months.[14] Follow up analyses on Richter's study found that by improving SUI, regardless of treatment mode, sexual function was likely to

improve.[15] Lastly, another follow up analysis on Richter's study found that quality of life was improved in both the behavior and pessary group.[16]

PFMT appears to be an effective treatment as shown in most of the studies included for POP symptoms and SUI but only for the first 3 months. Improvements have been shown to decline from 3 to 12 months.[14,17,18] This is believed to be the result of poor adherence to the pelvic floor strengthening program.[18] PFMT can be used for reducing POP and SUI symptoms, however, caution should be taken about reoccurrence of symptoms after 3 months. The patient should be educated about importance of adhering to their strengthening program. More research is needed to better understand the decline of improvements that occurs with treatment.

The studies comparing pessary treatment with behavioral training for women with SUI included women with SUI but excluded women with POP stages III and IV.[14] This could include women with or without a POP of I and II. The authors did not determine what was causing the SUI in its participants so it is unclear whether either treatment outcome would differ if the inclusion criteria required women with POP or excluded women with all stages of POP. Possibly, the pessary would improve SUI in women with POP and behavioral therapy would improve SUI symptoms in women without SUI symptoms as these women do not need organ support and require pelvic floor strengthening. More research on this is needed.

Pessary therapy has been shown to be superior to PFMT at improving POP specific symptoms such as "heaviness" or "bulging" sensations in the pelvic floor and difficulty voiding. Pessary therapy should be considered among clinicians working with women who are experiencing pelvic floor dysfunction. Pessary therapy would be appropriate for the patient described to reduce POP symptoms. Behavioral therapy, which includes PFMT, should be utilized when treating women with SUI and emphasis should be placed on encouraging patients

to be adherent with pelvic floor training and on working with them to maintain the improvements they gained. This would also be helpful for the patient described to reduce her instances of SUI. Overall, clinical decision-making should be used, as the patient should be treated as a whole. However, both treatments are shown to be effective in women choosing conservative management with POP.

Conclusion:

In this article analysis, pessary therapy was found to be more effective than PFMT at reducing POP specific symptoms. A successful pessary fitting is crucial to allow for improvements to occur. For women experiencing SUI, PFMT with behavioral therapy shows to be more successful at reducing leakage. Adherence to pelvic floor strengthening reduces after 3 months and should be addressed with patients on in individual basis. Both treatments would be appropriate for the patient described in order to treat her POP and SUI symptoms.

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Appendix A:

Article #1- Citation:

Wiegersma M, Panman CMCR, Berger MY, De Vet HCW, Kollen BJ, Dekker JH. Minimal important change in the pelvic floor distress inventory-20 among women opting for conservative prolapse treatment. *Am J Obstet Gynecol*. 2017;216(4):397.e1-397.e7. doi:10.1016/j.ajog.2016.10.010.

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?	-Yes, to compare the cost and effectiveness of pessary therapy compared to pelvic floor muscle training (PFMT) in women with pelvic organ prolapse (POP)
Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	Yes, the authors presented background information of prevalence of POP, how it affects their quality of life, and their risks for surgery. Previous research of pessary treatment and PFMT treatments alone were described along with the need to compare the two interventions.

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry**	The major threat to the internal validity of the study was attrition. 35 of the 82 women in the pessary group did not receive a pessary. 62% of them could not be fitted successfully. Other reasons involved adverse effects such as development of SUI and increased vaginal discharge.

➢ **Statistical Regression**	

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
1. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	Yes, the participants were randomly assigned to pessary or PFMT treatment groups.
2. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	It was not stated or shown that the groups were similar at the start. The authors did mention that there were no differences between the women successfully and unsuccessfully fitted for the pessary.
3. Did the subjects know to which treatment group they were assign? **a. If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, the participants were aware of which treatment they were getting. Possible consequences included participants not believing they are in what they considered the most appropriate treatment group.
4. Did the investigators know who was being assigned to which group prior to the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	The research physician enrolling participants was not aware of allocation sequence or size of the blocks used for the block randomization.
5. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	They were not managed equally. The pessary group underwent a fitting. The time it took was variable per individual and each individual was evaluated after 2 weeks. The PFMT group had face-to-face time with the physiotherapists to teach lifestyle education and pelvic floor strengthening. This could affect the participant's belief that they were or were not receiving optimal treatment.
6. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, the 3, 12, and 24 months were enough time to determine the effectiveness of the two interventions.
7. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?**	-No, there were 97 participants that completed the 12-month follow up (60%). -The authors found that they needed to enroll 148 women to account for a 70% success rate for

b. **What, if anything, did the authors do about this attrition?** c. **What are the implications of the attrition and the way it was handled with respect to the study's findings?**	pessary fitting. -Their expectation was a 15% attrition rate for the pessary group. However, they ended up with a higher rate of 25%
8. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)? a. **If not, what did the authors do with the data from these subjects?** b. **If the data were excluded, what are the potential consequences for this study's results?**	-Not all the subjects completed the study. -They lost 67 participants -The authors performed an intention to treat analysis (ITTA) that they included in their data along with a per-protocol analysis (PPA). The subjects unsuccessful with pessary fittings were excluded from the PPA but included in the ITTA.
Are the valid results of this RCT important?	
Appraisal Criterion	***Reader's Comments***
9. What were the statistical findings of this study? a. **When appropriate use the calculation forms below to determine these values** b. **Include: tests of differences? With p-values and CI** c. **Include effect size with p-values and CI** d. **Include ARR/ABI and RRR/RBI with p-values and CI** e. **Include NNT and CI** **10. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?**	-A multilevel analysis was performed. The restricted iterative generalized least squares algorithm was used to estimate the regression coefficients and the Wald test was use to obtain a P value for each regression coefficient. A linear multilevel analysis that had a fixed and random intercept was performed to test the longitudinal difference between treatment groups with the PFDI and other outcome measures used. Self-reported changes of symptoms were compared between groups with a chi squared test. All statistical tests were performed two –sided at a 5% significant level. Intention to treat and per-protocol analysis were conducted with and without adjusting for the questionnaire and the POP stage baseline scores. -They found that there was no significant difference in the PFDI between groups. Both groups showed improvement in symptoms at 3 months. But the PFMT groups slowly went back to baseline while the pessary group maintained their improvements. The ITTA found a significant difference in favor of the pessary group for prolapse symptoms in a secondary outcome measure. The PPA showed a difference between groups for sexual function in favor of the pessary group. -Though the study found improvements in some of the outcome measures,
11. Do these findings exceed a minimally important difference? a. **If not, will you still use this evidence?**	-The MID for the PFDI was found to be 13.5 points [19] and their findings did not meet it. -I will still use this evidence in my clinical practice.
Can you apply this valid, important evidence about an intervention in caring for your	

patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
12. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	-Yes, pessary intervention is appropriate for some women.
13. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you use this intervention in spite of the differences?**	The age of women for this study was 55 years or older. My patient is 42 years old. I would suggest pessary therapy over PFMT for my patient regardless of this difference.
14. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	For pessary therapy, the potential benefits outweigh the risks. If my patient experiences adverse effects, she can be re-fitted for a new pessary or discontinue using one. PFMT is not associated with risks.
15. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	My patient was willing to try pessary therapy but had her reservations about usage and expectations. If she decided to discontinue or experienced adverse effects with the pessary, PFMT would be next.
16. Are there any threats to external validity in this study?	There are no threats to the external validity.

What is the bottom line? What pedro score would you give this trial?:

Pessary use shows greater improvements in POP symptoms compared to PFMT. Regardless, the differences were small and the clinical relevance is questionable. However, I accept this study into my clinical practice. The high attrition rate may affect the outcome of study but it is generalizable to a clinical setting since only about half of women adhere to pessary therapy**.

Pedro score: 6/10

Article #2- Citation:

Cheung RYK, Lee JHS, Lee LL, Chung TKH, Chan SSC. Vaginal Pessary in Women With Symptomatic Pelvic Organ Prolapse. *Obstet Gynecol*. 2016;128(1):73-80. doi:10.1097/AOG.0000000000001489.

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study? **Literature** Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	Yes, the purpose of this study was to compare PFMT to pessary/PFMT therapy in women with symptomatic POP for 12 months. The background literature presented previous studies findings of PFMT and pessary use, but noted the absence of studies comparing the two together.

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	Threats to internal validity in this study included attrition. 40% of the women in the pessary group were unable to be fitted. They received other conservative treatment or surgery.

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
17. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	Yes, stratified randomization was performed for POP stages I, II, and III by a random number series in sealed envelopes.
18. Were the groups similar at the start of	Yes, there were no differences between groups at

the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	the start of the study.
19. Did the subjects know to which treatment group they were assign? **a. If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, the participants knew which treatment they were receiving. This could affect the outcome of the study if the women had a preference or bias of either intervention.
20. Did the investigators know who was being assigned to which group prior to the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	No, the investigators were blinded to assignment of participants.
21. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	No, the pessary group underwent a pessary fitting where up to 3 pessaries were attempted before deemed unsuccessful. The rest included the same management. All the women received PFMT by a nurse. It included a individual teaching session at 2, 4, 8, and 16 weeks along with a HEP. Both groups received a phone call at 2 weeks.
22. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, 12 months was sufficient time to compare the two groups.
23. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	No, 7 women out of the pessary group and 9 out of the PFMT group did not complete the questionnaires at 12 months. In the pessary group, 92 out of 139 women were successfully fitted. At 12 months, 83 retained the pessary (60%).
24. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?** **b. If the data were excluded, what are the potential consequences for this study's results?**	There was an ITT analysis on all the participants randomized in the study.
Are the valid results of this RCT important?	

Appraisal Criterion	***Reader's Comments***
25. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI** **26. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?**	Demographic data was analyzed using descriptive statistics. The PFDI and Pelvic Floor Impact Questionnaire (PFIQ) were compared between baseline and 12 months by a multiple linear regression model. The groups were compared to by a paired t test and Mann-Whitney U test. Within group improvement by Wilcox signed rank test. Linear logistic regression analysis was used to find the effect different factors had on improvements of the subjects. The authors assigned the p-value to be greater than 0.05. POP symptoms were significantly improved in the pessary group compared to the PFMT only group in the in Pelvic Organ Prolapse Distress Inventory score (p=0.01). VAS scores decreased in the pessary group shown by the Friedman test (p=0.001), no difference in the PFMT group.
27. Do these findings exceed a minimally important difference? **a. If not, will you still use this evidence?**	More women in the pessary group met the MID in the Pelvic Organ Prolapse Impact Questionnaire than the PFMT group.
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
28. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	Pessary therapy was shown to be an appropriate intervention to refer women with symptomatic POP.
29. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you use this intervention in spite of the differences?**	Yes, except the mean age of this study was around 62 years old. Though, I feel the intervention is useful.
30. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, the benefits outweigh the risks. As the adverse effects of the pessary can be easily treated.
31. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	My patient was willing to try pessary therapy but had her reservations about usage and expectations. If she decided to discontinue or experienced adverse effects with the pessary, PFMT would be next.
32. Are there any threats to external validity in this study?	This study did not include general maintenance for women who could not remove the pessary on their own. This is a common practice in the clinical setting where patients go in every few months to check for skin breakdown and clean the pessary.

What is the bottom line? What pedro score would you give this trial?:

Pessary therapy with pelvic floor strengthening is more effective at treating POP symptoms than pelvic floor strengthening alone.

Pedro score: 8/10

Article #3- Citation:

Richter HE, Burgio KL, Brubaker L, et al. Continence pessary compared with behavioral therapy or combined therapy for stress incontinence: a randomized controlled trial. *Obstet Gynecol*. 2010;115(3):609-617. doi:10.1097/AOG.0b013e3181d055d4.

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?	Yes. The purpose of this study is to evaluate the effectiveness of pessary therapy compared to PFMT and combined therapy in women with SUI.
Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	Yes, the authors described prevalence and alternative surgical treatments for SUI. They described the reasoning behind pessary therapy for continence and the gap in knowledge over comparing the 2 interventions.

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History**	Maturation may have been a risk to internal validity as the women may become less adherent to their PFMT program after 3 months. Attrition is another risk as there were a high number of participants who did not complete the study. That leads to group inequality and reduced

➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	sample size.

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
33. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	Yes, the subjects were stratified by 7-day bladder results then randomized into pessary therapy, PFMT, or combined treatment groups.
34. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	Yes, all the participants were similar at the beginning of the trial
35. Did the subjects know to which treatment group they were assign? **a. If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, this could have allowed the participants to have a bias over what intervention they have been placed in.
36. Did the investigators know who was being assigned to which group prior to the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	The investigators were blinded to assignment.
37. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	No, the behavioral and combined group attended 4 visits at 2 week intervals and then were given an individualized home maintenance program. The pessary and combined group were fitted for a pessary and given up to 3 chances for a re-fitting.
38. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, 12 months was an appropriate amount of time to assess outcomes.
39. Did all the subjects originally enrolled	No, 39 out of 149 were lost in the pessary group,

complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	22 out of 146 in the behavioral group, and 18 out of 150 in the combination group. The authors used the "next value carried backward" method for missing data. If this could not be used, the observation was set to "failure."
40. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?** **b. If the data were excluded, what are the potential consequences for this study's results?**	Yes, an intention to treat analysis was performed.
Are the valid results of this RCT important?	
Appraisal Criterion	***Reader's Comments***
41. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI** **42. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?**	ANOVA was used to compare baseline characteristics. Logistical regression was used to compare differences between groups. Each of the two treatment groups were compared to a combination group in separate analyses. Statistical significance was defined at 5%. ITT analysis showed that 46% of participants reported being "much better" at 3 months with no statistical difference between them on the PGI-I (patient Global Improvement Index). At 3 months on the PFDI, significantly more women in the behavioral group reported less bothersome incontinence symptoms compared to the pessary group (p=0.006). More women in the behavioral group reported being more satisfied (p=0.03). Between 3 and 12 months, treatment success declined in all groups with no significant differences between groups.
43. Do these findings exceed a minimally important difference? **a. If not, will you still use this evidence?**	The authors did not include data from the PFDI or PGI-I so it cannot be determined whether they made the MID. I will accept this evidence with caution.
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
44. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	Behavioral training, which was shown to be more effective than pessary treatment for SUI, is an appropriate intervention for my clinical setting.

45. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you use this intervention in spite of the differences?**	Yes, the demographics of my patient fit within the demographics of this study.
46. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, there are no risks associated with behavioral therapy and pessary risks can be treated easily.
47. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	Yes, I can see her benefiting from behavioral therapy for her occasional SUI.
48. Are there any threats to external validity in this study?	There are no threats to external validity.

What is the bottom line? What pedro score would you give this trial?:

Behavioral therapy is a superior intervention for women with SUI for up to 3 months. After 3 months, there is no difference between pessary, behavioral, or combined therapy. However, after three months, improvements decline and there are no differences between groups.

Pedro Score: 7/10

Article #4- Citation:

Handa VL, Whitcomb E, Weidner AC, et al. Sexual function before and after non-surgical treatment for stress urinary incontinence. *Female Pelvic Med Reconstr Surg*. 2011;17(1):30-35. doi:10.1097/SPV.0b013e318205e263.

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study? **Literature**	To compare pessary therapy, PFMT, and combined therapy in women with SUI and to find whether successful treatment of incontinence improves reported sexual function. This was a secondary analysis of article # 3.

Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	Yes, the authors provided background information of prevalence of women experiencing sexual dysfunction related to pelvic floor dysfunction. They referenced a couple studies that suggest symptoms of pelvic floor dysfunction are risk factors for sexual impairments.

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	Attrition is a threat to the internal validity, as 100 women did not complete the 3-month assessment. Selection is another threat, 40% of the participants did not have a sexual partner which does not fully represent the population of interest.

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
49. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	Yes, the subjects were stratified by 7-day bladder results then randomized into pessary therapy, PFMT, or combined treatment groups.
50. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	Yes, all the participants were similar at the beginning of the trial. 281 participants reported sexual activity 3 months prior to enrollment. There was no difference of proportion of women who reported sexual activity or having a current partner between groups.
51. Did the subjects know to which treatment group they were assign? **a. If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, this could have allowed the participants to have a bias over what intervention they were placed in.
52. Did the investigators know who was being assigned to which group prior to	The investigators were blinded to group allocation.

the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	
53. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	No, the behavioral and combined group attended 4 visits at 2-week intervals and then were given an individualized home maintenance program. The pessary and combined group were fitted for a pessary and given up to 3 chances for a re-fitting.
54. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, 12 weeks was enough time to sufficiently answer the questions posed.
55. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	No, 39 out of 149 were lost in the pessary group, 22 out of 146 in the behavioral group, and 18 out of 150 in the combination group. The authors used the "next value carried backward" method for missing data. If this could not be used, the observation was set to "failure." 100 women did not complete the 3 month assessment for the Pelvic Organ Prolapse-Urinary Incontinence Sexual Function Questionnaire (PISQ).
56. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?** **b. If the data were excluded, what are the potential consequences for this study's results?**	Yes, an intention to treat analysis was performed.
Are the valid results of this RCT important?	
Appraisal Criterion	***Reader's Comments***
57. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI**	ANOVA was used to compare participant characteristics. ANOVA was also used to compare Likert scales describing sexual function at baseline by incontinence type and frequency. ANOVA was also used to compare changes in sexual function at follow up per group and to investigate the impact of changes in pelvic muscle function in sexual function. For all analyses, a P value of less than 0.05 was considered statistically significant. 3 months after randomization, there was no significant difference of sexual function between groups in either the PISQ or Personal Experiences

58. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?	Questionnaire (SPEQ). 203 women met the definition for successful treatment of SUI. Those women experienced greater improvement in PISQ score (p=0.0007) and greater improvement with incontinence with sexual activity (p=0.0002) and more significant reduction in restriction of sexual activity related to fear of incontinence (p=0.008). Among those successfully treated for SUI, the mean improvement score for incontinence during sexual activity was 0.42 greater in the behavioral group compared to pessary (p=0.02). There was no significant difference among the groups that were not successfully treated for SUI in regards to sexual function. .
59. Do these findings exceed a minimally important difference? **a. If not, will you still use this evidence?**	The MID for the PISQ has been found to be about 5.8 points [20] which is often found after surgical intervention. This study had improvements of 2.26 ± 3.24 points, so the MID was not met. I will still keep this evidence in mind since I'm focusing on conservative treatments.
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
60. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	While there didn't seem to be one treatment protocol that made a significant effect on sexual function, the behavioral group showed the greatest improvement on reducing incontinence during intercourse. This will be useful in a clinical setting.
61. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you use this intervention in spite of the differences?**	Yes, the subject's demographics are similar to my patient. However, my patient was not experiencing sexual dysfunction with intercourse at this point.
62. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, there are no risks associated with behavioral therapy and pessary use has risks that can be treated easily.
63. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	Yes, behavioral therapy fits within her values and expectations.
64. Are there any threats to external validity in this study?	There are no threats to external validity.

What is the bottom line? What pedro score would you give this trial?:

Overall, improvements of sexual function are limited to women who experienced successful treatment of SUI. The outcome measures did not show significant differences between groups in regards to improvement of sexual function; however, the previous study found that there were more women treated successfully with behavioral therapy.

Pedro Score: 7/10

Article #5- Citation:

Kenton K, Barber M, Wang L, et al. Pelvic floor symptoms improve similarly after pessary and behavioral treatment for stress incontinence. *Female Pelvic Med Reconstr Surg*. 2012;18(2):118-121. doi:10.1097/SPV.0b013e31824a021d.

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?	To determine whether the use of pessary, behavioral therapy, or combined therapy results in greater improvements in bother and health related quality of life from global urinary, prolapse, and colorectal symptoms. This is a planned secondary analysis from article #3.
~~Literature~~ Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	Background literature is presented, describing prevalence of SUI and the social and personal implications. They identified the gap in knowledge about examining women's change in quality of life with conservative treatment.

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
➢ **Discuss possible threats to internal validty in the research design. Include:** ➢ **Assignment**	Attrition was a threat to the internal validity, especially in the pessary group which leads to reduced sample size and unequal group sizes.

➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
65. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	Yes, the subjects were stratified by 7-day bladder results then randomized into pessary therapy, PFMT, or combined treatment groups.
66. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	Yes, they were similar at the beginning of the trial.
67. Did the subjects know to which treatment group they were assign? **a. If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, this could have allowed the participants to have a bias over what intervention they were placed in.
68. Did the investigators know who was being assigned to which group prior to the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	No, they were blinded to allocation.
69. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	No, the behavioral and combined group attended 4 visits at 2 week intervals and then were given an individualized home maintenance program. The pessary and combined group were fitted for a pessary and given up to 3 chances for a re-fitting.
70. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge**	Yes, 12 months was long enough to answer the question.

for the study's results?	
71. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	No, 39 out of 149 were lost in the pessary group, 22 out of 146 in the behavioral group, and 18 out of 150 in the combination group. The authors used the "next value carried backward" method for missing data. If this could not be used, the observation was set to "failure." 95% of subjects completed the symptom and quality of life measures at baseline and 71% at 3 months.
72. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?** **b. If the data were excluded, what are the potential consequences for this study's results?**	There was an intention to treat analysis that did not significantly differ from the per-protocol analysis.
Are the valid results of this RCT important?	
Appraisal Criterion	***Reader's Comments***
73. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI** **74. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?**	Baseline characteristics were compared by chi square or 2 sample t tests. Changes made in the PFDI, PFI, and QUID scores were calculated and compared with paired t tests for within group changes. Between group changes were analyzed with ANOVA. All groups had a significant with-in group improvement of symptoms and quality of life at 3 moths. However, there was no significant difference between groups. Again, at 1 year, there was no differences between groups. The findings showed that the interventions similarly improved health related quality of life significantly.
75. Do these findings exceed a minimally important difference? **a. If not, will you still use this evidence?**	The minimally important difference for the UDI and UIQ are 11 and 16[21]. These were seen at 3 months and 1 year.
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
76. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	Both pessary and behavioral therapy are appropriate in a clinical setting
77. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you**	My patient is similar to the women in this study. The mean age in the study is slightly older but not enough to make much of a difference.

use this intervention in spite of the differences?	
78. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, the benefits outweigh the risks.
79. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	Yes
80. Are there any threats to external validity in this study?	There are no threats to external validity.

What is the bottom line? What pedro score would you give this trial?:

For women with SUI, pessary, behavioral, and combined therapy are just as effective at improving health related quality of life and reducing symptoms and bother. This shows that symptom improvement occurs with either treatment and the therapist can work with the patient to help them decide which intervention they prefer.

Pedro score: 7/10

Article #6- Citation:

de Albuquerque Coelho SC, de Castro EB, Juliato CRT. Female pelvic organ prolapse using pessaries: systematic review. *Int Urogynecol J*. 2016;27(12):1797-1803. doi:10.1007/s00192-016-2991-y.

Does the design follow the Cochrane method?	
Appraisal Criterion	***Reader's Comments***
Step 1 – formulating the question • Do the authors identify the focus of the review • A clearly defined question should specify the types of: • people (participants), • interventions or exposures, • outcomes that are of interest • studies that are relevant to answering the question	This review was performed to determine the effectiveness of pessary therapy on the quality of life of women with POP, the acceptance rate, and reasons for discontinuation.
Step 2 – locating studies • Should identify ALL relevant literature • Did they include multiple databases? • Was the search strategy defined and include: - Bibliographic databases used as well as hand searching - Terms (key words and index terms) - Citation searching: reference lists - Contact with 'experts' to identify 'grey' literature (body of materials that cannot be found easily through conventional channels such as publishers) - Sources for 'grey literature'	The following databases were used: PubMed, Latin-American and Caribbean Literature in Health Sciences, and Scientific Electronic Library On-line. Search terms included: "pelvic organ prolapse AND pessaries AND quality of life" OR "pessary AND quality of life" OR "pessaries."
Step 3 – Critical Appraisal/Criteria for Inclusion • Were criteria for selection specified? • Did more than one author assess the relevance of each report • Were decisions concerning relevance described; completed by non-experts, or both? • Did the people assessing the relevance of studies know the names of the authors, institutions, journal of publication and results when they apply the inclusion • criteria? Or is it blind?	-The inclusion criteria consisted of: observational studies, cross section, cohort study, RCTs, studies published in English, Portuguese, and Spanish, and studies whose participants are women with pelvic organ prolapse treated using a pessary. There were no limits on year of publication. Exclusion criteria included: studies not on topic, systematic reviews, and articles that did not use validated questionnaires. -Two reviewers independently determined which studies to include, one an assistant professor and an expert in POP and the other a master's degree student. If they did not agree, a third reviewer made the decision. -It was not mentioned whether the reviewers were blinded or not to the names of authors or institutions.
Step 3 – Critically appraise for bias: Selection – • Were the groups in the study selected differently?	Selection: -The review does not describe the selection process for the articles.

• Random? Concealed? Performance- • Did the groups in the study receive different treatment? • Was there blinding? Attrition – • Were the groups similar at the end of the study? • Account for drop-outs? Detection – • Did the study selectively report the results? • Is there missing data?	Performance: -The treatment the groups received varied per article. Some compared pessary to no treatment, others compared pessary treatment to surgery. -Blinding was difficult in these studies where the participants know what treatment they are receiving. Attrition: -Attrition rates were not reported. The pessary discontinuation mean out of the 7 studies was 50% (37-80). Detection -There is no missing data known
Step 4 – Collection of the data • Was a collection data form used and is it included? • Are the studies coded and is the data coding easy to follow? • Were studies identified that were excluded & did they give reasons why (i.e., which criteria they failed).	-A collection data form was used but not included in this review. -Studies that were not included were given reasons why they were not included.

Are the results of this SR valid?	
Appraisal Criterion	***Reader's Comments***
1. Is this a SR of randomized trials? Did they limit this to high quality studies at the top of the hierarchies a) If not, what types of studies were included? b) What are the potential consequences of including these studies for this review's results?	This study not was limited to RCTs. a) Observational studies, cross-section, and cohort studies were included as well. b) The potential consequence is that it lowers the level of evidence and is not as generalizable to the public
2. Did this study follow the Cochrane methods selection process and did it identify all relevant trials? If not, what are the consequences for this review's results?	It did follow the Cochrane methods selection process and identified all 7 trials.
3. Do the methods describe the processes and tools used to assess the quality of individual studies? If not, what are the consequences for this review's results?	No, this might have allowed lower quality of evidence to be included in the review.
4. What was the quality of the individual studies included? Were the results consistent from study to study? Did the investigators provide details about the research validity or quality of the studies included in review?	-Yes, the results were consistent from study to study. -Yes, the authors mentioned that quality articles were selected with good methodologies and tested with validated questionnaires.
5. Did the investigators address publication bias?	No.
Are the valid results of this SR important?	
Appraisal Criterion	***Reader's Comments***
6. Were the results homogenous from study to	The authors did not measure the homogeneity

study? If not, what are the consequences for this review's results?	of the studies. This makes it harder to compare the studies when are different from each other.
7. If the paper is a meta-analysis did they report the statistical results? Did they include a forest plat? What other statistics do they include? Are there CIs?	This paper was not a meta-analysis
8. From the findings, is it apparent what the cumulative weight of the evidence is?	No.
Can you apply this valid, important evidence from this SR in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
9. Is your patient different from those in this SR?	My patient is similar
10. Is the treatment feasible in your setting? Do you have the facilities, skill set, time, 3rd party coverage to provide this treatment?	Yes, pessary therapy is feasible in my setting. It is not within my scope of practice to fit them. But I can refer and help with supportive therapy.
11. Does the intervention fit within your patient/client's stated values or expectations? If not, what will you do now?	Yes, this intervention fits with my patient's values and expectations.

What is the bottom line?	
Appraisal Criterion	***Reader's Comments***
Summarize your findings and relate this back to clinical significance.	Pessary therapy was shown to be a conservative option for women with symptomatic POP. All the articles evaluated in this review were associated with an improved quality of life. All of the articles (4) that compared pessaries to surgery found improved quality of life with both. More than half the women using a pessary continued to use the device

What is the bottom line?

Overall, pessary therapy was shown to have similar improvements in quality of life as surgery.

The authors found that prolapse symptoms allow women to return to their daily activities. Not all women are candidates for surgery so a pessary can be a tool manage the bothersome symptoms.

Article #7- Citation:

Due U, Brostrøm S, Lose G. The 12-month effects of structured lifestyle advice and pelvic floor muscle training for pelvic organ prolapse. *Acta Obstet Gynecol Scand*. 2016;95(7):811-819. doi:10.1111/aogs.12884.

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study? **Literature** Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	The purpose of this study is to evaluate the medium term effects of adding PFMT to a lifestyle advice program in women with symptomatic POP staged II-III. This is a 12 month follow up study of a trial the authors performed earlier. Background information was included about improvements PFMT and lifestyle advice leaflets have on reducing POP symptoms. They discuss the gap of knowledge of comparing an active intervention with and without PFMT.

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	Maturation could be a threat to the internal validity where the patients are not being adherent to the pelvic floor strengthening program. Compensatory equalization of treatments could occur where the lifestyle group reads about PFMT as being an effective treatment for POP and they start it on their own which could equalize treatments.

Are the results of this therapeutic trial valid?

Appraisal Criterion	*Reader's Comments*
81. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	The women were randomized and stratified for age groups greater than 60 years old
82. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	The two groups were similar with no significant differences.
83. Did the subjects know to which treatment group they were assign? **a. If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, the subjects knew their treatment.
84. Did the investigators know who was being assigned to which group prior to the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	The primary investigator remained blinded throughout the study.
85. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	All participants received 6 group sessions in 12 weeks. Only the participants in the combined PFMT group and lifestyle advice group attended a visit with a pelvic floor physical therapist for pelvic floor muscle assessment and instruction of PFMT before starting the group session. The lifestyle group did not receive information about PFMT.
86. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, 12 months was sufficient time to see the treatment results.
87. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	The authors planned to enroll 45 women in each group. To compensate for possible dropouts, they recruited 54 women in each group.
88. Were all patients analyzed in the groups to which they were randomized (i.e. was	Yes, there was an intention to treat analysis.

there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?** **b. If the data were excluded, what are the potential consequences for this study's results?**	
Are the valid results of this RCT important?	
Appraisal Criterion	***Reader's Comments***
89. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI** **90. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?**	Descriptive statistics were used to describe baseline and follow-up data. Categorical data were analyzed using the chi squared test. Logistic regression analysis was performed to find possible factors related to participants seeking further treatment. Between group differences for the PFDI and the PFIQ (Pelvic Floor Impact Questionnaire Short Form) scores were performed using paired t-tests. A p value of 0.05 or less was defined as significant. At 12 months, 34 total women had not received further treatment of the POP, 13 in the lifestyle and 21 in the PFMT group (p=0.05). The lifestyle group had a significant improvement from baseline in bladder symptoms. The PFMT group had significantly reduced POP symptoms and bowel related problems compared to baseline. There were no significant differences between the groups or in the outcome measures.
91. Do these findings exceed a minimally important difference? **a. If not, will you still use this evidence?**	The PFDI met the MID for both treatment groups.
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
92. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	Yes, both treatments reduced POP symptoms and were shown to be a good place to start with patients who are wanting to avoid surgery or who are not wanting/cannot be fitted for a pessary.
93. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you use this intervention in spite of the differences?**	The mean age in this study was 60 years old, so the age is not similar to my patient. The interventions are still relevant.
94. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, the benefits outweigh the risks as there are no risks associated with these treatments.
95. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	Yes.

96. Are there any threats to external validity in this study?	There are no threats to external validity.

What is the bottom line? What pedro score would you give this trial?:

At 12 months, a structured lifestyle advice program improved urinary symptoms. PFMT with the lifestyle advice improved the "heaviness" symptoms in the pelvic floor and bowel related symptoms. However, neither group showed significant improvements in the majority of the symptom and quality of life scores. There were no between group differences. These two interventions may give some improvement for POP, but do not appear to make drastic changes.

Pedro Score: 8/10

Article #8- Citation:

McIntosh L, Andersen E, Reekie M. Conservative Treatment of Stress Urinary Incontinence In Women: A 10-Year (2004-2013) Scoping Review of the Literature. *Urol Nurs*. 2015;35(4):179-203. doi:http://dx.doi.org.libproxy.unm.edu/10.7257/1053-816X.2015.35.4.179.

Does the design follow the Cochrane method?	
Appraisal Criterion	***Reader's Comments***
Step 1 – formulating the question • Do the authors identify the focus of the review • A clearly defined question should specify the types of: • people (participants), • interventions or exposures, • outcomes that are of interest • studies that are relevant to answering the question	This literature review focused on describing PFMT and pessary therapy for the treatment of women with SUI and identified the benefits and drawbacks of each treatment.
Step 2 – locating studies • Should identify ALL relevant literature • Did they include multiple databases? • Was the search strategy defined and include: - Bibliographic databases used as well as hand searching	-The following databases were searched between the years January 2004- December 2013: Pubmed, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Embase, cIRcle, and ProQuest. Key search phrases included "urinary incontinence, stress" and "stress urinary incontinence" used with "conservative

- Terms (key words and index terms) - Citation searching: reference lists - Contact with 'experts' to identify 'grey' literature (body of materials that cannot be found easily through conventional channels such as publishers) - Sources for 'grey literature'	management," "alternative therapy," or "complementary therapy." - No references were made to grey literature
Step 3 – Critical Appraisal/Criteria for Inclusion • Were criteria for selection specified? • Did more than one author assess the relevance of each report • Were decisions concerning relevance described; completed by non-experts, or both? • Did the people assessing the relevance of studies know the names of the authors, institutions, journal of publication and results when they apply the inclusion • criteria? Or is it blind?	-Inclusion criteria were articles published in English, restricted to females, and with full texts online. Key words were first entered individually then together to maximize search results. -It was not mentioned whether the authors knew names of authors or if they were blinded, or if more than one author was involved in the selection process.
Step 3 – Critically appraise for bias: Selection – • Were the groups in the study selected differently? • Random? Concealed? Performance- • Did the groups in the study receive different treatment? • Was there blinding? Attrition – • Were the groups similar at the end of the study? • Account for drop-outs? Detection – • Did the study selectively report the results? • Is there missing data?	Selection: -The review did not describe the selection process for the articles. Performance: -The treatment the groups received varied per article. Some studies compared pessary to PFMT and others just examined one treatment compared to no treatment. -Blinding is difficult in these studies where the participants know what treatment they are receiving. Attrition: -Attrition rates were not reported. Detection -There was no missing data known
Step 4 – Collection of the data • Was a collection data form used and is it included? • Are the studies coded and is the data coding easy to follow? • Were studies identified that were excluded & did they give reasons why (i.e., which criteria they failed).	-A collection data form was used but not included. -Studies that were not included were given reasons why they were excluded from this review.

Are the results of this SR valid?

Appraisal Criterion	*Reader's Comments*
1. Is this a SR of randomized trials? Did they limit this to high quality studies at the top of the hierarchies c) If not, what types of studies were included? d) What are the potential consequences of including these studies for this review's results?	This study was not limited to RCTs. a) Chart reviews, literature reviews, narrative reviews, prospective studies, quantitative, and qualitative studies were included as well. b) The potential consequence was that it lowered the level of evidence and reduced the validity of the review.
2. Did this study follow the Cochrane methods selection process and did it identify all relevant trials? If not, what are the consequences for this review's results?	No. Consequences are that there may be increased bias and reduced appropriate synthesis of data.
3. Do the methods describe the processes and tools used to assess the quality of individual studies? If not, what are the consequences for this review's results?	No, this could have lead to lower quality of evidence being included in the review.
4. What was the quality of the individual studies included? Were the results consistent from study to study? Did the investigators provide details about the research validity or quality of the studies included in review?	-The results were mostly consistent throughout the studies but not all. -No, the authors did not include details about research validity.
5. Did the investigators address publication bias?	No.
Are the valid results of this SR important?	
Appraisal Criterion	***Reader's Comments***
6. Were the results homogenous from study to study? If not, what are the consequences for this review's results?	The authors did not measure the homogeneity of the studies. This makes it harder to make comparisons between studies when they are different from each other.
7. If the paper is a meta-analysis did they report the statistical results? Did they include a forest plat? What other statistics do they include? Are there CIs?	This paper was not a meta-analysis
8. From the findings, is it apparent what the cumulative weight of the evidence is?	No.
Can you apply this valid, important evidence from this SR in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
9. Is your patient different from those in this SR?	My patient is similar
10. Is the treatment feasible in your setting? Do you have the facilities, skill set, time, 3rd party coverage to provide this treatment?	Yes, both PFMT and pessary therapy are feasible conservative therapies in my setting.
11. Does the intervention fit within your patient/client's stated values or expectations? If not, what will you do now?	Yes, this intervention fits with my patient's values and expectations.

What is the bottom line?

Appraisal Criterion	*Reader's Comments*
Summarize your findings and relate this back to clinical significance.	This literature review found that SUI decreases with PFMT. However, after 3 months, the improvements made were not sustained with PFMT. They identified the key problem as lack of adherence. PFMT compared to pessary therapy has been shown in some studies to improve incontinence without significant differences.

Bottom line: This literature review found that PFMT was only effective short-term for SUI, with most studies showing that improvements made decline after three months. This was suggested by one study to be due to lack of adherence wherein the women lose motivation to continue with their strengthening program. If the pessary could be removed and inserted by the patient, it could be successful in reducing SUI symptoms. Pessary use compared to PFMT has been shown in a couple studies to have no significant difference when compared to PFMT at 12 months.