CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

For a 25-year-old female with interstitial cystitis, is internal myofascial trigger point release more effective than botulinum toxin injections at reducing pelvic floor musculature hypertonicity and pelvic pain?

AUTHOR

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CLINICAL SCENARIO

The patient is a 25-year-old female who was diagnosed with interstitial cystitis at age 11. She has a longstanding history of pelvic pain, difficulty with urination, pain with sexual intercourse, and sensations of urgency and burning. This patient has received a number of interventions over the years, including medication and surgery, and presents to physical therapy for manual trigger point release of the pelvic floor musculature.

Because symptoms of interstitial cystitis often go unreported, may be attributed to other conditions, and may present in a number of ways, the prevalence of this condition is not well understood and varies depending on the population in question[1]. It is generally found to affect women more frequently than men; research suggests anywhere from 3-8 million American women exhibit symptoms consistent with interstitial cystitis [1,2]. Symptoms may appear in childhood, but the condition is not typically diagnosed until an individual has reached adulthood[1]. High tone pelvic floor musculature is common in those with interstitial cystitis, contributing to many of the symptoms mentioned above [1-3].

Therapists trained to treat pelvic floor dysfunction must often rely on their clinical judgement when choosing interventions for patients with interstitial cystitis, as research in this area of specialty is lacking. This appraisal was driven by a need to better understand the current research surrounding treatment options for this patient in an effort to maximize her care with the ultimate goal of reducing her symptoms and improving her quality of life.

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SUMMARY OF SEARCH

[Best evidence appraised and key findings]

- There is a lack of high quality published evidence pertaining to the treatment of interstitial cystitis, and the search process yielded no studies that compared the effectiveness of botulinum toxin injections and manual trigger point release. It was therefore necessary to compare these two interventions separately.
- The search process yielded one relevant systematic review, two randomized controlled trials, and five quasi-experimental studies. Compromise on inclusion and exclusion criteria was necessary to some degree, as one study featured male participants and several involved conditions other than interstitial cystitis.
- The two most relevant studies were included in this critically appraised topic. The study by Abbott et. al found that botulinum toxin injections led to significant improvements in muscle spasm and quality of life in women with pelvic pain and hypertonicity but also noted improvements in the control group that were statistically significant. The study by Oyama et. al noted significant improvements in pain and quality of life with transvaginal massage and trigger point release. Both studies noted long-term improvements with each intervention. However, methodological flaws, inadequate reporting, and a lack of data on clinical significance require careful interpretation of these results.

CLINICAL BOTTOM LINE

There is a significant need for continued research into the use of botulinum toxin injections and manual trigger point release for the management of interstitial cystitis. Clinicians considering recommending these interventions for patients should approach the available research with care in light of methodological flaws and utilize clinical judgement to the best of their ability. Though the two studies included in this critically appraised topic demonstrate significant improvements in a number of symptoms associated with interstitial cystitis and suggest both interventions produce long-term benefits, the question of their effectiveness remains unanswered.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Interstitial cystitis Painful bladder Bladder spasm Bladder discomfort Chronic bladder pain	Tripper point* Myofascial release	Botulinum Toxin Botox	Pelvic pain Pain* Pelvic discomfort Hypertonic*

Final search strategy (history):

1. Interstitial Cystitis [MeSH Terms]
2. bladder AND (pain* OR chronic pain OR spasm OR discomfort)
3. trigger point* OR myofascial release
4. botulinum toxin OR botox
5. Pelvic Floor [MeSH Term] OR pelvic AND (pain* OR discomfort OR hypertonic*)
6. (#1 OR #2) AND #3
7. (#1 OR #2) AND #4
8. (#1 OR #2) AND #3 AND #5
9. (#1 OR #2) AND #4 AND #5
10. (#1 OR #2) AND #3 AND #4 AND #5

Databases and Sites Searched	**Number of results**	**Limits applied, revised number of results (if applicable)**
Pubmed	**98**	**Applied limits: "female" (58); "English" (48)**
CINAHL	**13**	**No limits applied**
Web of Science	**9**	**No limits applied**

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
Female participants aged 18-65
Female participants with a diagnosis of Interstitial Cystitis for at least 3 months
Studies featuring pain not associated with the menstrual cycle
Standard assessment of pelvic pain (such as the VAS, NIH-CPSI: Female, etc.)
Exclusion Criteria
Abstracts only
Opinion pieces
Articles not printed in English
Articles with male or adolescent participants

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

A total of eight studies were chosen for appraisal given their applicability to the clinical question of interest. One systematic review was located and was the only study that directly compared botulinum toxin injections and manual therapy[7]. However, this study did not include participants with interstitial cystitis and lack a test of homogeneity[7]. Given the likelihood of bias influencing results, this study was excluded from further appraisal.

Two randomized controlled trials (RCTs) were also appraised for quality [8,10]. Much like the systematic review, neither of these studies pertained directly to the diagnosis of interstitial cystitis; however, both studies examined the condition of pelvic pain and spasm and were of moderate to high quality according to the PEDro scale [8,10]. The study by Fitzgerald et al. was excluded from further appraisal secondary to inadequate blinding and a lack of follow-up[10].

Small sample sizes, inadequate data reporting, and the possibility of bias influencing results limited the quality and applicability of the remaining studies. As such, these studies were excluded from further appraisal [4, 5, 9,11].

Author (Year)	Risk of bias (quality score)*	Level of Evidence**	Relevance	Study design
Halder GE, Scott L, Wyman A, et al (2017) [4]	**Downs and Black: 20/29**	**4**	**Medium: compares both interventions together, not separately**	**Retrospective Case Series**
Adelowo A, Hacker MR, Shapiro A, Modest AM, Elkadry E (2013) [5]	**Downs and Black: 20/29**	**2B**	**Medium: looks at myofascial pelvic pain in general**	**Retrospective cohort study**
Oyama IA, Rejba A, Lukban JC, et al (2004) [6]	**Downs and Black: 21/29**	**2B**	**High: Looks at IC specifically with manual therapy**	**Single group pre-test/post-test**
Morin MCA, Carroll M-S, Bergeron S (2017) [7]	**AMSTAR: 7/11**	**2A**	**Low: Looks at botox and manual therapy for vestibulodynia**	**Systematic Review**
Abbott JA, Jarvis SK, Lyons SD, Thomson A, Vancaille TG (2006) [8]	**PEDro: 9/10**	**1B**	**Medium: Looks at botox injections for chronic pelvic pain**	**Randomized controlled trial (RCT)**
Weiss JM (2001) [9]	**Downs and Black: 18/29**	**2B**	**High: looks at manual therapy for IC but has male subjects**	**Single group pre-test/post-test**
Fitzgerald MP, Anderson RU, Potts J, et al (2013) [10]	**PEDro: 7/10**	**1B**	**Medium: Looks at manual PT but not IC specifically**	**Randomized controlled trial (RCT)**
Lukban J, Whitmore K, Kellogg-Spadt S, Bologna R, Lesher A, Fletcher E (2001) [11]	**Downs and Black: 19/29**	**2B**	**High: Looks at manual PT and IC**	**Single group pre-test/post-test**

BEST EVIDENCE

The following 2 studies were identified as the 'best' evidence and selected for critical appraisal. Rationale for selecting these studies were:

- **Abbott et al., 2006[8]: This is an RTC that scored well on the PEDro scale (9/10). It looks at the use of Botox for the management of chronic pelvic pain and has all female participants. Though the study does not focus on the diagnosis of IC specifically, it does focus on some of the primary symptoms of the condition in question.**
- **Oyama et al., 2004[6]: This study examines manual therapy (trigger point release) in women with a diagnosis of interstitial cystitis, which relates directly to the clinical question. It scored 21/29 on the Downs and Black checklist, suggesting is it of moderate quality.**

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of Botulinum Toxin Type A for Chronic Pain and Pelvic Floor Spasm in Women by Abbott et. al, 2006[8].

Aim/Objective of the Study/Systematic Review:

This study aims to investigate the impact of botulinum toxin injections on quality of life and pelvic floor pressure and muscle spasm in women with a history of chronic pelvic pain of at least two years.

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

- This study is a randomized controlled trial utilizing a double-blind procedure.
- Participants were randomly assigned to a treatment or control group using computer-based software by a researcher not associated with the study.
- To ensure blinding of the clinicians administering injections and performing clinical and outcomes assessment, vials were prepared by nurses not associated with the study and delivered to clinicians in identical jars. Patients were not informed of their group assignment.
- No attempts were made to prevent communication between treatment and control groups.
- Outcomes were measured at baseline and again at 2, 4, 8, 12, 16, 20, and 26 weeks post procedure. Not all outcomes were collected at each visit. Specific follow up procedures are described in the **Outcome Measures** section.

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

This study and all associated procedures and follow up visits were conducted in a hospital in an urban area of Sydney, Australia. The specific hospital name is not disclosed.

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

- Participants were recruited via various media outlets. No additional details were provided.
- Of the 401 women screened, 118 met inclusion criteria and were accessed for pelvic floor muscle dysfunction characterized by tight or painful musculature on internal examination and elevated resting pressure as measured by manometry.
- 68 women were found to exhibit these characteristics and report symptom duration of at least 2 years.
- 60 women aged 18-55 (mean age of 30.5 years) agreed to participate in the study.
- Three were lost to follow up (2 in the placebo group and 1 in the botulinum injection group).
- Groups were similar at baseline for all demographic data.

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control (n = 30)

- 30 women received placebo injections containing saline and no active ingredients. Injections were prepared in the method described in the **Study Design** section.
- Participants were required to abstain from eating and drinking for 6 hours before the injection procedure and were given a pregnancy test to ensure they were not pregnant. Resting and maximal contraction pressure was measured using vaginal manometry.
- Under conscious sedation, the pelvic floor was examined intravaginally and the pubococcygeus and puborectalis muscles were injected bilaterally with saline solution at two different sites (for a total of 4ml solution injected).
- This procedure was performed once. Follow up visits occurred at 2, 4, 8, 12, 16, 20, and 26 weeks post procedure.

Experimental (n = 30)

- 30 women received botulinum toxin injections containing 80 units (20U/mL) prepared in the method described in the **Study Design** section.
- Participants were required to abstain from eating and drinking for 6 hours before the injection procedure and were given a pregnancy test to ensure they were not pregnant. Resting and maximal contraction pressure was measured using vaginal manometry.
- Under conscious sedation, the pelvic floor was examined intravaginally and the pubococcygeus and puborectalis muscles were injected bilaterally with the botulinum toxin solution at two different sites (for a total of 4ml solution injected).
- This procedure was performed once. Follow up visits occurred at 2, 4, 8, 12, 16, 20, and 26 weeks post procedure.

Outcome Measures

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

- Outcome measures administered at baseline and each follow up visit:
  - Pain outcomes were assessed using the Visual Analogue Scale (VAS). Individual scales were used to assess pain with menstruation, pain with sexual intercourse, pain with defecation, and nonmenstrual pelvic pain separately (so each participant filed out four separate scales at each visit). The Visual Analogue Scales used in this study included a 100-point scale that has been validated as a reliable measure to quantify pain and urgency symptoms in those with overactive bladder and other urinary conditions[12]. Symptoms are scored on a scale of 0-100, with 0 representing no symptoms and 100 representing extreme intensity of symptoms[12].
  - Bladder and bowel function questionnaires were utilized but not described in the study.
  - Vaginal examination was used to access muscle tenderness and hypertonicity. A qualified clinician performed this examination.
  - Vaginal manometry was used to measure resting and maximal contraction pressure.

- Outcome measures administered at baseline and at 4, 12, and 26 weeks post injection:
  - Quality of life was assessed using 3 separate instruments:
    - EQ-5D: The EuroQol-5D is an instrument used to measure the impact that a variety of conditions have on quality of life and has been adapted for use in urinary incontinence and pelvic pain[13]. For these conditions, the EQ-5D has been shown to be both a reliable (with a test-retest correlation of 0.83) and valid measure for those with urinary symptoms[13]. It does not have an established MCID for interstitial cystitis or other urinary conditions[13].
    - SF-12: The SF-12 is used to measure physical and mental health. It is a shortened version of the SF-36 and can be completed quickly, containing only 12 questions. The SF-12 has been shown to demonstrate good test-retest reliability and validity in a number of different populations[14, 15]. In those with osteoarthritis, the questionnaire demonstrates no floor or ceiling effects and a high correlation with the SF-36 (coefficient of correlation= 0.92 -0.96; $p < 0.001$) [14, 15]. It does not have an established MCID for interstitial cystitis or other urinary conditions [14,15].
    - Sexual Activity Questionnaire: The psychometric properties of the Sexual Activity Questionnaire are not well understood. As a whole, this measure has an internal consistency coefficient of 0.86 [16,17]. This is slightly higher for the pleasure subscale (Cornbach's alpha = 0.89) and slightly lower on the discomfort subscale (Cornbach's alpha = 0.82) [16,17]. It does not have an established MCID for interstitial cystitis or other urinary conditions [16,17].
- The published study does not specify the individual(s) administering these outcome measures.

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values

etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.]

- All data reported was reported as median and interquartile range.
- There was a statistically significant reduction in nonmenstrual pelvic pain (VAS score 51 at baseline and 22 at 26 weeks; $x^2 = 16.98$, p =0.0009) and pain associated with sexual intercourse in the experimental group compared to baseline (VAS score 66 at baseline and 12 at 26 weeks; $x^2 = 25.78$, p <0.0001).
- In the control group, there was a statistically significant reduction in pain associated with intercourse (VAS 64 at baseline and 27 at 26 weeks; $x^2 = 2.98$, p = 0.043).
- There were no other significant reductions in pain scores for either group.
- The difference in pain reduction between groups was not statistically significant for any of the four VAS used.
- There was a statistically significant reduction in resting pelvic floor pressure in those that received botulinum toxin injections compared to the control group (49 at baseline and 32 at 26 weeks; $x^2 = 39.53$, $p<0.001$).
- Women who received botulinum toxin injections reported more improved quality of life on all measures compared to those who received placebo injections, but the difference between groups was not significant.
- There were no significant improvements in bladder or bowel function in either group.
- The botulinum toxin group reported 123 adverse events during the study period, while the placebo group reported 134 adverse events. No adverse events were significant and most involved minor illnesses.

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

According to the authors, the results of this study demonstrate that botulinum toxin injections are more effective than placebo injections at reducing pelvic floor muscle spasm and subsequent pain in women who have experienced such symptoms for at least two years. Because the individuals in this study had failed to respond to conservative treatment, botulinum toxin injections are recommended for those who do not experience relief from other treatments. This intervention, though invasive, is concluded to be relatively safe.

Critical Appraisal

Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

This study was appraised using the PEDro scale, scoring 9/10.

- Weaknesses
  - While it was made clear that participants and clinicians administering injections were blinded to group assignment, it is not clear if the individuals administering assessments were blinded to assignment, or even who these individuals were. Though this score indicates that the risk of bias in this study is low, bias may still be present if assessors were not blinded to treatment.
  - The target sample size was calculated using data from a pilot study. A sample size of 60 participants was sufficient to provide 80% power to detect a 50% reduction in pain scores using the VAS, which was deemed a statistically significant improvement by investigators. Therefore, this study had an 80% chance of detecting a true effect of treatment. Three participants were lost to follow up, which likely impacts the power of the study. However, the authors do not discuss how this may have influenced results and a post hoc analysis was not performed.
  - Participants in the control group (placebo group) experienced improvement in symptoms far beyond what was expected based on the calculation of power. This may indicate that type II error occurred (a false positive). These findings may be due, in part, to the fact that the control group received injections, and dry needling has been shown to reduce pain and muscle spasm in the absence of an additional chemical agent. Implementing a third group that did not receive injections may have mitigated the possibility of type II error.
  - Because participants were recruited using media outlets, the study population is limited to those women who have access to them. Additionally, the restriction of inclusion to only those living in the metropolitan area of Sydney limits the external validity of results and introduces the possibility of selection bias.
  - Because data was reported as median values and interquartile range, effect size could not be calculated.
  - Many of the outcome measures used, though shown to be reliable and valid, do not have established MCIDs, making it difficult to determine the clinical significance of results. If the measure does have an established MCID, it is for conditions that do not impact the pelvic floor or urinary system.
- Strengths
  - Control and experimental groups were not significantly different at baseline, increasing the internal validity of results.
  - The use of vaginal manometry provides a standardized means by which to measure pressure generated by muscle contraction and is generally considered more reliable than manual testing.

- Participants and clinicians were blinded to treatment and random assignment was utilized, reducing the possibility of bias.
- The study provides follow up for 26 weeks, providing insight into the long-term impact of treatments.
- The study utilized multiple quality of life measures, providing a well-rounded picture of how both symptoms and treatment impact the various aspects of quality of life.

This randomized controlled trial is well structured but does have a few methodological flaws that limit the quality of result. It is possible that inadequate power and blinding may have influenced findings. However, inadequate reporting means this cannot be concluded with certainty. Additionally, clinical significance and effect size of results was not investigated, limiting the clinical applicability of results. The results of this study do capture treatment effects on various aspects of quality of life, which provides beneficial insight into the scope of the treatment's impact. The fact that participants in the control group experienced improvements in symptoms may suggest that the act of needling itself is beneficial for pelvic floor muscle spasm and pain, warranting further investigation.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

Based on this study, it is difficult to conclude whether or not botulinum toxin injections are more successful at reducing pelvic floor pain and spasm than placebo injections. Both the experimental and control groups experienced a reduction in pain and an improvement in quality of life, and though the experimental group experienced greater reductions in pain than the control group, the difference between groups was not significant. The lack of statistical significance could be due to methodological flaws including insufficient power and potential bias or to a lack of treatment effect. However, the fact that the control group experienced improvements in pain and quality of life may suggest that the act of needling itself produces beneficial results and that the addition of botulinum toxin may not be necessary.

Those in the experimental group did experience significant reductions in resting pelvic floor pressure and spasm, both of which may contribute to pelvic pain. This suggests that botulinum toxin may be best for those presenting with hypertonicity and spasm of the pelvic floor.

Botulinum toxin injections may be beneficial for female patients who have not achieved relief with other interventions. Because it is a rather invasive treatment with possible side effects, caution should be used when recommending this intervention.

Effect size and clinical significance were not reported in this study. Therefore, conclusions about the clinical impact of botulinum toxin injections in those with pelvic pain and spasm cannot be drawn.

Applicability of Study Results

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.]

The subject of this clinical question is a 25-year-old female who has experienced a mirage of pelvic and urinary symptoms for a number of years. Two of her primary complaints are pelvic pain and spasm and their resulting impact on her life. The study appraised above clearly fits her demographics and addresses her main concerns. Because botulinum toxin cannot be administered by a physical therapist, the patient would need to visit her doctor(s) to have this procedure completed, which is often costly. Because botulinum toxin injections may be administered multiple times over a long period of time, one must consider the financial burden this patient may face if she chooses to explore this route.

This being said, botulinum toxin injections can be used in conjunction with other interventions (including medication and physical therapy) that may help to maximize benefits. The patient is insured and will likely receive some coverage if the procedure is deemed medically necessary.

Because this study found reductions in symptoms and improvements in quality of life in the control group, the patient may benefit from first attempting other interventions.

It is clear that there is an obvious and present need for continued research into the use of botulinum toxin for the management of pelvic floor pain and spasm. Future studies should feature larger sample sizes and include a control group receiving no injections to reduce the possibility of type II error. The use of a randomized, double blind design will serve to limit the influence of bias on results.

(2) Description and appraisal of Modified Thiele Massage as Therapeutic Intervention for Female Patients with Interstitial Cystitis and High-Tone Pelvic Floor Dysfunction by Oyama et. al, 2004[6]

Aim/Objective of the Study/Systematic Review:

This study aims to investigate the efficacy of transvaginal massage in reducing symptoms of pain and urgency and improving quality of life in women with a diagnosis of interstitial cystitis.

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

- This study was a prospective clinical pilot study utilizing a single group pre-test/post-test design.
- Because all participants received the same treatment (there was not a control group), no blinding or randomization was performed.
- Outcomes were measured before treatment began (baseline measurements), after the intervention period concluded (approximately 2 weeks after completion), and again for long-term follow up 4.5 months later.

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

The study location was not disclosed.

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

- Subjects were recruited from the clinical practice associated with the researchers, though this location was not specified.
- 21 female subjects between the ages of 21 and 64 enrolled in the study and completed the five-week intervention.
- Of these 21 participants, only 13 reported for long-term follow up and were included in published research.
- Key demographics for these 13 participants include a mean age of 42 years and duration of interstitial cystitis diagnosis of at least five years.
- 33% of the study population was actively experiencing menopause, 53% had a history of multiple pregnancies, and 20% were currently on hormone replacement therapy.
- Participants were required to abstain from taking narcotics or skeletal muscle relaxers and agreed to not participate in sexual intercourse for the duration of the study.

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control

- Pre-Intervention Procedures
  - An unspecified individual collected basic demographic information.
  - Participants reported to an unspecified location for examination of pelvic floor tenderness and hypertonicity.
  - Vaginal examination of the coccygeus, iliococcygeus, pubococcygeus, and obturator internus muscles was performed by an undisclosed individual who classified tenderness and hypertonicity using a 5-point Modified Oxford scale.
  - Participants were examined by a physical therapist to ensure sacroiliac joint stability.
  - Participants completed the O'Leary-Sant Interstitial Cystitis Symptom and Problem Indexes, Visual Analogue Scales for both urgency and pain, and Short-Form 12-item Quality-of-Life Scale.
- Intervention procedure
  - Participants reported for 10 transvaginal massage sessions over a 5-week period (2 sessions/week with sessions separated by at least two days).
  - Transvaginal massage was performed by one of three certified women's health practitioners.
  - The individual providing the massage applied tolerable pressure from origin to insertion of each of the

following: the coccygeus, iliococcygeus, pubococcygeus, and obturator internus muscles.
    - 10-15 repetitions were completed for each muscle.
    - At the discretion of the practitioner, ischemic pressure was applied to trigger points for 10-15 seconds.
- Post Intervention Procedures
    - Participants returned 14 days after completing their final intervention session and again 4.5 months later.
    - All baseline procedures and measurements were repeated at each visit.

Experimental

This was a single group pre-test/post-test deign. No control group was utilized.

Outcome Measures

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

- The authors of this study do not disclose where outcomes assessment was performed, nor do they specify the individuals collecting data.
- These outcome measures do not have established minimal clinically important differences for interstitial cystitis or other urinary conditions.

- Pelvic floor hypertonicity and pain was measured using a 5-point, Modified Oxford Scale:
    - 0 = no pressure/pain
    - 1= tolerable pressure/pain
    - 2= uncomfortable pressure/pain
    - 3= moderate pressure/pain made worse with contraction
    - 4= severe pressure/pain and unable to perform contraction
- The O'Leary-Sant Interstitial Cystitis Symptom and Problem Indexes measure urinary symptoms and their impact on those with interstitial cystitis[18]. The symptom index features four questions with a maximum possible score of 19[18]. The problem index also features four questions and has a maximum possible score of 16[18]. The higher the score, the more significant the symptoms and their impact[18, 19]. This measure has been found to be valid, reliable, and responsive to change in those with interstitial cystitis[19]. It does not have an established MCID.
- The Visual Analogue Scale used in this study was an 11-point scale (0-10) that has been validated as a reliable measure to quantify pain and urgency symptoms in those with overactive bladder and other urinary conditions[12]. The higher the score, the more significant the symptoms.
- The SF-12 is used to measure physical and mental health. It is a shortened version of the SF-36 and can be completed quickly, containing only 12 questions [14,15]. The SF-12 has been shown to demonstrate good test-retest reliability and validity in a number of different populations [14,15]. It does not have an established MCID for interstitial cystitis or other urinary conditions [14,15].

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.]

- Scores on the O'Leary-Sant Interstitial Cystitis Symptom and Problem Indexes demonstrated statistically significant improvement from baseline to first follow up. The mean score on the symptom index decreased from 8.9 to 6.9 ($p = 0.015$) and the mean score on the problem index decreased from 8.2 to 6.3 ($p = 0.039$). These improvements remained statistically significant at 4.5 months ($p = 0.049$ and 0.02, respectively).
- Mean scores on the pain VAS demonstrated a statistically significant decrease from 5.4 at baseline to 3.5 at first follow up ($p = 0.005$). Mean scores on the urgency VAS also demonstrated a statistically significant reduction from 4.6 at baseline to 3.0 at first follow up ($p = 0.001$). These improvements remained statistically significant at 4.5 months ($p = 0.004$ and $p = 0.005$, respectively).
- Statistically significant improvements were seen in both the physical and mental subscales SF-12 scores from baseline to first follow up. The mean score for the physical subscale improved from 41.9 to 45.9 ($p = 0.049$) and from 46.0 to 50.2 ($p = 0.042$). At the 4.5-month follow up, these improvements were no longer statistically significant.
- Additionally, significant improvements in average scores on the Modified Oxford Scale were seen for all muscles tested ($p < 0.05$). At 4.5 months, these improvements remained statistically significant except for the coccygeus.

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

The authors conclude that transvaginal massage can effectively reduce pain and improve the quality of life in

women who have a diagnosis of interstitial cystitis and increased pelvic floor muscle tone. The improvement in symptoms can persist for a number of months after treatment has concluded, positively impacting individuals in the long-term.

Critical Appraisal

Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

This study was appraised using the Downs and Beck appraisal checklist and received a score of 21/29.

- Weaknesses
  - With only 21 subjects, this study is limited by a small sample size. A small sample size introduces the possibility of a type II error occurring, which involves obtaining a false positive (i.e. seeing a treatment effect when one does not really exist). Therefore, the results of this study cannot be taken as absolute despite reaching statistical significance.
  - Because this study utilized a crossover design, there was no attempt at blinding or randomization. This further increases the risk of bias and limits the applicability of results.
  - The study does not disclose the individuals who performed the pelvic muscle assessment or if these assessments were performed by one or more individuals. Because this is not mentioned, the accuracy of scoring cannot be confirmed with any certainty. If multiple individuals performed these assessments, then interrater reliability becomes a concern. Additionally, the fact that multiple practitioners provided the intervention introduces variability into the procedure itself, which may impact outcomes.
  - The use of a Modified Oxford Scale is somewhat objective and could negatively impact the validity of results if clinicians are not grading contractions in the same manner.
  - The use of a single group design means this study lacked a control group for comparison. It is possible that the individuals participating in this study experienced symptom improvement secondary to interactions with healthcare providers on a regular basis.
  - Participant recruitment was not discussed. Therefore, it is difficult to conclude whether or not a representative sample was used.
  - Application of ischemic pressure was at the discretion of the clinician providing the intervention and was not standardized.
  - Measurements of variability in data were not reported (standard deviations or interquartile range).
  - Many of the outcome measures used do not have established MCIDs and effect size was not disclosed, making it impossible to determine clinical significance.
- Strengths
  - Those providing the intervention were trained specialists who had extensive experience in transvaginal massage.
  - The study followed patients for 4.5 months, providing insight into the long-term effects of treatment.
  - The study utilized multiple quality of life measures, providing a well-rounded picture of how both symptoms and treatment impact the various aspects of quality of life.
  - The study had excellent follow though, as every patient who participated in the study provided data at 4.5 months.

This study, though well intentioned, has a number of methodological flaws that negatively impact the validity of results. Small sample size, variability in technique, and inadequate disclosure of recruitment methods and study design should all be considered when interpreting results. Though significant improvements were noted, it cannot be said with certainty that these findings were not the result of error.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

Based on this study alone, it is difficult to conclude whether or not transvaginal massage is effective at reducing pain and urgency in those with interstitial cystitis. Despite achieving statistically significant results and long-term improvements in symptoms, the numerous methodological flaws and limited sample size negatively impact the validity to a point where results should be interpreted with caution. Fortunately, no adverse events were reported, suggesting this intervention is relatively safe.

As with the other study included in this critically appraised topic, effect size and clinical significance were not discussed. Additional research into the effectiveness of transvaginal massage for individuals with interstitial cystitis is necessary and should be conducted with greater methodological rigor. A larger sample size, the addition of a control group, and ensuring that one clinician provides the intervention will serve to increase the validity and clinical relevance of results.

Applicability of Study Results

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the

practicality and feasibility of the intervention in your discussion of the evidence applicability.]

The patient that is the focus of this clinical question fits the demographic characteristics of this study and may very well respond favourably to transvaginal massage. This is one of the few studies that focus on treatments for those with a diagnosis of interstitial cystitis, reflecting just how limited the body of published research surrounding this condition is. Because transvaginal massage is a relatively conservative intervention, it is likely that this would be recommended before attempting more invasive treatments. However, this intervention should not be suggested based only on the study appraised above.

The physical therapist should do additional research and use clinical judgement before recommending transvaginal massage for this patient. As highlighted by this piece of research, a clinician with the proper training should perform transvaginal massage, and . Using additional interventions in conjunction with transvaginal massage may serve to maximize benefits.

SYNTHESIS AND CLINICAL IMPLICATIONS

[Synthesize the results, quality/validity, and applicability of the two studies reviewed for the CAT. Future implications for research should be addressed briefly. Limit: 1 page.]

- Synthesis of Research:

A search of the available literature revealed no published research comparing the effectiveness of botulinum toxin injections and trigger point release in females with interstitial cystitis. It was therefore necessary to compare the two interventions separately. The majority of the research located was of poor quality or did not pertain to interstitial cystitis or its associated symptoms. The articles included for this critically appraised topic were chosen because they most closely addressed the clinical question at hand.

The two studies appraised in this paper investigate the impact that interventions have on some of the symptoms commonly experienced by those with interstitial cystitis. The first, a randomized controlled trial, suggests that botulinum toxin injections can have beneficial outcomes for those with pelvic pain and muscle spasm. The second study found that transvaginal massage can reduce symptoms of pain and urgency in both the short and long-term. However, When interpreting these results, it is important to account for the numerous methodological weaknesses present in these studies; small sample sizes, the potential for bias, and inadequate reporting of methods all require careful consideration. The randomized controlled trial included in this critically appraised topic did a decent job of controlling for bias but may have lacked appropriate power; a lack of a post hoc analysis leaves this unclear. Both studies feature a small sample size, which increases the likelihood of a type II error occurring. Additionally, both studies are less than clear on some aspects of data collection, further increasing the possibility of biased results. Neither study discussed effect size or clinical significance and relied on outcome measures with no established minimal clinically important difference for urinary conditions, making it challenging to interpret results in a clinically meaningful context. Both studies provided follow up data for a number of months, providing beneficial insight into the long-term impact of these interventions.

- Applicability and Implementation of Research Findings:

Given the limitations of the studies included in this critically appraised topic, the clinical impact of botulinum toxin injections and manual trigger point release cannot be determined. Additionally, because no study directly compares the two interventions, it cannot be said that one is more effect than the other at reducing pelvic pain and hypertonicity in those with interstitial cystitis. These studies are beneficial in that they provide insight into two intervention options that may improve symptoms, but their findings should not be taken as absolute.

The patient that is the focus of this critically appraised topic fits the demographics of both of these studies and, much like the participants, has a long-standing history of symptoms that have not responded well to other treatments. However, caution should be taken when assuming she would respond favourably to these treatments given the flaws in current research. Clinical judgement should therefore play a vital role in deciding the treatment plan for this patient.

- Future Research Directions:

These studies highlight the need for continued research into the treatment options available for females with interstitial cystitis. As physical therapy's role in the management of pelvic health related concerns continues to expand, it is imperative that interventions like manual trigger point release be further investigated. Randomized controlled trials are needed to better understand the implications of such interventions and, because interstitial cystitis has no cure, long-term follow up data are a necessity. Specifically, studies comparing the effectiveness of botulinum injections and manual therapy should be conducted, as no such study exists at this time.

Because these studies relied on many outcome measures that do not have established minimal clinically important differences specifically for urinary conditions and did not report effect sizes, determining clinical significance of results was not possible. Future studies must be conducted to establish these minimal clinically important differences if the clinical impact of these interventions is to be determined.

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