Baclofen and Gabapentin suppositories for female pelvic myofascial pain

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Hypothesis / aims of study

Hypothesis

Myofascial pelvic pain (MPP) causes discomfort within the muscles of the pelvic floor and connecting fascial structures. This condition can significantly impede pelvic functionality. Yet, there's a paucity of empirical evidence scrutinizing the efficacy of medical approaches addressing it.

Presently, certain Canadian centers are administering a new off-label formulation comprising Baclofen Gabapentin for myofascial pain, particularly in women with pelvic floor muscle-related myofascial pain, yielding anecdotal reports of positive outcomes.

Baclofen is a skeletal muscle relaxant often used for management of neurological spasticity, and Gabapentin is a neuromodulator that induces soft tissue relaxation and mitigate associated pain. Both medications have showed primitive results supporting their use in chronic pelvic pain.

Our hypothesis is that given the pharmacological properties of both medications and the anecdotal evidence of their benefit, there would be empirical evidence of their efficacy treating MPP.

Aims

The primary aim of this study is to evaluate the effectiveness and safety of Baclofen/Gabapentin suppositories (BGS) in alleviating pain, improving sexual function, and enhancing the quality of life among patients with myofascial pelvic pain who have been prescribed these suppositories as part of their standard care.

Another aim of this study is collecting data that will inform sample size calculations for a future randomized controlled trial (RCT) on this subject.

Study design, materials and methods

A retrospective chart review was conducted for individuals prescribed BGS for myofascial pain as part of their standard care under Dr. Lemos. Eligibility screening encompassed all patients seen by Dr. Lemos from July 2017 until Dec 2022.

Inclusion criteria: females aged 18 and above, proficient in English, diagnosed with myofascial pelvic pain, and prescribed BGS. Exclusion criteria: non-consenting patients and pregnant patients.

The primary outcome was changes in the Visual Analog Scale (VAS). Secondary outcomes included the Pain Catastrophizing Scale (PCS), McGill Pain Questionnaire (MPQ), Pelvic Floor Distress Inventory-20 (PFDI-20), and Female Sexual Function Index (FSFI).

Statistical analyses employed means with standard deviations and medians with interquartile ranges. Paired T-test and Wilcoxon Signed Ranks test were used to analyze the primary and secondary outcomes. A 2-sided p-value of <0.05 was used for statistical significance.

Results and interpretation

A series of 35 patients meeting our predefined inclusion criteria participated in our study. Demographic details of the patients are presented in Table 1.

Our study reported that patients endured MPP for extended durations (mean 7.5 years, SD +/- 8.5 years), with some individuals experiencing symptoms for more than a decade.

All patients diagnosed with MPP in our study received BGS treatment. The average duration of BGS therapy among our cohort was 15 months (SD +/- 8 months), ranging from 2 to 36 months.

Table 1. Patients' demographics and baseline gynecological conditions

Mean age	43.3 (SD +/- 14.7)
Mean BMI	23.7 (SD +/- 5.2)
Ethnicity	
White	28 (80%)
Asian	3 (8.6%)
Hispanic	2 (5.7%)
Black	1 (2.9%)
Other	1 (2.9%)
Level of education	
High school	1 (2.9%)
College	5 (14.3%)
University	4 (11.4%)
Graduate school	6 (17.1%)
N/A	19 (54.3%)
Marital status	
Single	14 (40%)
Married	13 (37.1%)
Common law	2 (5.7%)
Divorced	2 (5.7%)
Widowed	1 (2.9%)
N/A	3 (8.6%)

Our results showed statistically significant improvements in the VAS scores that are not clinically significant.

- In the category "least pain" participants exhibited a reduction in mean VAS scores from 3 to 2 after one year (p-value 0.04), which was reported by 45.7% of the participants (16 out of 35).
- In the category "worst pain" the mean VAS decreased from 5.4 at baseline to 5.0 after one year (p-value 0.02), which was reported by 28.5% of the participants (10 out of 35). I
- In the category "average pain" there was no statistically significant change in VAS scores.

The PCS demonstrated a significant improvement, with mean scores decreasing from 41.97 at baseline to 33.57 at 1-year follow-up (p-value 0.0008).

Conversely, the PFDI-20 and the FSFI scores, did not exhibit significant changes. PFDI-20 median scores remained constant at 150 (p-value 0.83), while FSFI mean values increased from 22.5 at baseline to 24.0 at 1-year (p-value 0.59).

Interpretation

Our case series failed to confirm the positive experience with GBS seen in the Canadian pain clinics. The difference in pain reduction was only one point difference or less on the VAS score. This improvement is not sufficing the clinically significant reduction of pain (Dworkin).

On the other hand, our series showed subjective improvement towards pain, as evident on the PCS. The subjective improvement could be due to placebo effect, stemming from the fact that these participants are now referred to the medical experts in a tertiary care referral clinic. Another factor to consider is the "Hawthorne effect".

In terms of secondary outcomes, our results did not demonstrate significant improvement in female pelvic function and sexual function following GBS administration. Given Baclofen and Gabapentin's predominant pain modulatory actions, the lack of discernible influence on pelvic and sexual functions, as indicated by the PFDI and FSFI results, was not unexpected.

Limitations:

The study's observational design limits the generalizability of the results. However, this is the first trial of such an intervention, therefore we couldn't proceed with a clinical randomized trial before exploring this option in such a cost-effective design.

Additionally, the retrospective nature of the study raises concerns regarding potential recall bias. Given the limited availability of such an intervention, it would be logistically difficult to start with a prospective design to answer the proposed question.

Conclusions

This case series piloted the utility of the BGS as an intervention for females experiencing MPP. Our results showed no clear objective evidence that this intervention helps with pain reduction nor sexual or pelvic function in patients with MPP. Further rigorous clinical trials are imperative to establish comprehensive global recommendations regarding the utilization of this new intervention in patients with MPP.

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