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Effectiveness of Afigel therapy in reducing urinary incontinence among premenopausal women: a quasi-experimental study in rural Indonesia

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ABSTRACT

Urinary incontinence (UI) affects millions globally, predominantly women, significantly impacting quality of life. This study evaluated Afigel as a novel intervention for reducing UI symptoms. A quasi-experimental pre-posttest design was employed with 93 premenopausal women randomly assigned to intervention (n = 31) and control (n = 62) groups. Data collection utilized personal data sheets, Afigel therapy standard operating procedures, observation sheets, and the questionnaire for urinary incontinence diagnosis (QUID). Dependent and independent t-tests analyzed the data. Among participants, 43% experienced stress incontinence, 47% experienced urge incontinence, and 10% mixed incontinence. Severity was mild (41%), moderate (45%), and severe (14%). The intervention group demonstrated a significant reduction in incontinence scores from 6.30 to 1.53 (p = 0.000), while the control group showed minimal change from 6.30 to 6.18 (p = 0.21). Afigel demonstrates potential as an effective UI management therapy. These findings suggest Afigel could substantially improve quality of life by reducing UI-related social embarrassment, activity limitations, and psychological distress. For primary health care settings, Afigel offers a potentially accessible, non-invasive treatment option that community health nurses and primary care providers could implement, reducing referral burdens on specialist services while addressing this prevalent yet often underreported condition.

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1. INTRODUCTION

Urinary incontinence (UI) is a global health concern affecting millions of individuals, particularly women. It encompasses a broad spectrum of symptoms, including stress urinary incontinence (SUI), urge urinary incontinence (UUI), and mixed urinary incontinence (MUI), with prevalence rates varying significantly across different regions. Estimates suggest that UI affects approximately 25% to 50% of women globally, leading to a substantial impact on their quality of life due to emotional, social, and health challenges [1]. The burden of this condition is compounded by age and comorbidities, with elderly women exhibiting higher rates of UI that correlate with increased dependency and healthcare utilization [2]. The rising trends of obesity and sedentary lifestyles exacerbate this issue, making it imperative to seek effective and accessible interventions for managing UI.

In Indonesia, the prevalence of urinary incontinence is notably high, with studies indicating that around 30% to 40% of Indonesian women experience some form of urinary incontinence. This situation is driven by factors such as high rates of postpartum complications and inadequate access to healthcare resources [3]. Additionally, cultural factors extend the stigma surrounding urinary issues, discouraging many individuals from seeking treatment. Regional disparities exist within Indonesia, where access to specialized care and education on pelvic health is significantly limited, particularly in rural areas [3], [4]. Thus, addressing urinary incontinence not only serves as an immediate health concern but also supports broader public health initiatives aimed at improving women's health and reducing related stigma.

The selection of Afigel as an intervention stems from the established need for accessible, non-pharmacological treatments for urinary incontinence, particularly in resource-limited settings. Current evidence strongly supports pelvic floor muscle training (PFMT) as the primary conservative treatment for urinary incontinence [5], [6]. However, the effectiveness of PFMT varies considerably, and success depends on multiple factors, including patient compliance and access to trained healthcare providers [5]. In rural Indonesian contexts where specialized care is limited, alternative interventions that can be administered with minimal infrastructure are essential.

A significant gap exists in the literature regarding urinary incontinence management specifically among premenopausal women in low-resource settings. Most existing studies focus on postmenopausal populations [7], [8] or utilize technologies requiring specialized equipment such as magnetic stimulation [6], [9], transcranial direct current stimulation [6], or CO2 laser therapy [10], [11]. Furthermore, while behavioral and pharmacological therapies have been extensively studied [7], [12], [13], there is limited evidence on novel topical or gel-based interventions for urinary incontinence. The quasi-experimental design addresses the practical constraints of conducting randomized controlled trials in rural Indonesia while still providing valuable effectiveness data for this understudied population and intervention.

The purpose of this study is to evaluate the impact of Afigel as a novel intervention in reducing symptoms of urinary incontinence among Indonesian respondents. This research, focusing on Afigel therapy, explores alternative treatments that may appeal to patients seeking non-pharmacological interventions. Our study aspires not only to enhance existing literature on urinary incontinence management but also to contribute to tailored treatment strategies that resonate with the unique sociocultural landscape of Indonesia.

2. METHOD

2.1. Design

The research design used in this study was a quasi-experimental pretest–posttest design with a control group. The intervention and control groups were analyzed based on data collected before and after the treatment. This research was conducted in Bagelen Village, Gedung Tataan District, Pesawaran Regency, Lampung, Indonesia, from April to November 2025.

2.2. Population and sample

The target population was premenopausal women experiencing urinary incontinence, a common condition in women approaching menopause, totaling 121. Using the Slovin formula, a sample of 93 respondents was obtained. Focusing on this group aims to provide a clearer picture of the intervention's impact on their health. The study involved 93 respondents selected as a sample from the broader population. This sample was divided into two groups: the intervention group, consisting of 31 respondents who received Afigel treatment, and the control group, consisting of 62 respondents who did not receive the treatment.

2.3. Sampling techniques

Sampling was conducted using random sampling techniques. This method was chosen to ensure that every individual in the population has an equal chance of being selected, thereby reducing potential bias in the study. The target population for this study encompasses premenopausal women in Bagelen Village, Gedung Tataan District, Pesawaran Regency, Lampung, Indonesia. A significant population of 121 premenopausal women was selected. Using the Slovin formula, a sample of 93 respondents was obtained.

$$n = / (1 + Ne^2)$$
$$n = 121 / (1 + 121 (0.05)^2)$$
$$n = 121 / (1 + 121 (0.0025)$$
$$n = 92.933$$

Information: n = sample size, N = 121, and e = 0.05.

The randomization procedure was performed using computer-generated random sequences to ensure unbiased allocation, while allocation concealment was implemented using opaque sealed envelopes containing allocation codes to prevent selection bias, where group allocation was concealed from both researchers and participants until enrollment. An allocation ratio of 1:2 was chosen to increase the precision of estimates in the control group while maintaining adequate statistical power to detect differences between groups.

2.4. Research instruments

Several instruments were used to collect data systematically and in a structured manner. First, the respondent's personal data sheet was used to obtain demographic information, such as age and health status, which can influence incontinence. Second, the Afigel therapy standard operating procedures (SOP) outlined the Afigel administration procedure, including dosage and treatment time, ensuring consistency in therapy application. Third, the observation sheet was used to record observations related to Afigel use by respondents in the intervention group, emphasizing adherence to procedures and potential side effects. Finally, the questionnaire for urinary incontinence diagnosis (QUID) was used to evaluate the severity and frequency of urinary incontinence. This questionnaire has been tested for validity and reliability, making it an appropriate tool for this research context.

2.5. Research procedures

This study was designed to evaluate the effectiveness of Afigel in treating urinary incontinence in respondents. The first phase was preparation, in which study staff were trained in the use of Afigel and the administration of the QUID questionnaire. Next, in the pre-test phase, all respondents from both intervention and control groups underwent a baseline assessment using the QUID questionnaire to determine their baseline level of incontinence.

During the intervention phase, the treatment group will consume Afigel according to established SOPs. The study requires respondents to record their Afigel use and any changes they experience over a specific period. Finally, during the post-test, both groups will be reassessed using the QUID questionnaire to measure changes after the intervention, thus providing insight into Afigel's effectiveness in addressing the research problem.

2.6. Intervention duration

The Afigel intervention was administered over six months (April to October 2025). Participants in the intervention group (n = 31) consumed Afigel daily according to established standard operating procedures. The dosage and administration time were standardized across all participants to ensure treatment consistency.

2.7. Follow-up

Follow-up assessments were conducted at two time points: baseline (pre-test) and post-intervention (post-test). The QUID questionnaire was administered at both time points to evaluate changes in urinary incontinence severity and frequency. Both the intervention and control groups underwent identical assessment protocols to maintain methodological rigor.

2.8. Participant adherence

Adherence monitoring was implemented through participant self-reporting using an observation sheet, in which respondents documented their daily Afigel consumption and any changes or side effects experienced. This approach aligns with established methods for monitoring medication adherence in behavioral interventions. Adherence rates were calculated as the percentage of the prescribed dose consumed relative to the total expected dose during the intervention period. Participants who demonstrated adherence less than 80% were recorded for sensitivity analysis to assess the impact of adherence on treatment outcomes.

2.9. Data analysis

Data analysis was performed using dependent and independent t-tests. The dependent t-test was used to compare differences in stress incontinence levels before and after Afigel treatment in the intervention group. On the other hand, the independent t-test was used to compare urinary incontinence levels between the intervention and control groups after treatment. The data obtained will be analyzed using appropriate statistical software to obtain valid results.

3. RESULTS

Table 1 shows that the average age of respondents was 47.10 years, with a minimum value of 41 and a maximum of 53 years, indicating a middle-aged group. The frequency of childbirth showed an average of 3.40, indicating a fairly diverse birth experience among respondents. In the analysis of the distribution of incontinence, the control group showed an incontinence rate before Afigel of 6.18, after which the incontinence rate increased to 6.30, while in the intervention group, there was a significant decrease from 1.53 before Afigel. Finally, the distribution of incontinence types showed that urge incontinence was the most common, occurring in 47% of respondents. These data can be used to better understand the relationship between the Afigel intervention and the improvement of emergency incontinence conditions.

Table 2 shows that in the control group, the mean urinary incontinence score showed a slight decrease from 6.30 before the intervention to 6.18 after the intervention, with standard deviations (SD) of 1.74 and 1.66, respectively. The calculated standard error (SE) was 0.22 before and 0.21 after, indicating stability in the measurements. However, this change was not statistically significant, with a p-value of 0.11, indicating no substantial difference. In contrast, the intervention group, which also had a mean initial score of 6.30, showed a dramatic decrease in the mean score to 1.53 after the intervention. With SDs of 1.54 before and 1.87 after, and an SE of 0.28, this change was statistically significant with a p-value of 0.000. These results indicate that the Afigel intervention had a significant positive impact on reducing urinary incontinence in the intervention group. Table 3 shows that the mean urinary incontinence level in the intervention group was 1.53 with a standard deviation (SD) of 1.87 and a SE of 0.34. In contrast, the control group showed a higher mean of 6.18, with an SD of 1.66 and an SE of 0.22. A p-value of 0.000 indicates a statistically significant difference between the two groups.

Table 1. Respondent characteristics

Variables	Mean	Median	Modus	St. Dev	Min	Max
Age	47.10	47	50	2.85	41	53
frequency of birth	3.40	3	3	1.16	1	5
Distribution of urinary incontinence before and after Afigel						
Control group						
Before Afigel	6.30	7	6	1.74	4	10
After Afigel	6.18	5	6	1.66	4	10
Intervention group						
Before Afigel	6.30	6	5	2.95	4	10
After Afigel	1.53	1	0	1.87	0	6
Incontinence				N		%
	Stress incontinence			40		43%
	Urge incontinence			44		47%
	Mixed incontinence			9		10%

Table 2. Analysis of urinary incontinence before and after Afigel in the control and intervention group

Urinary incontinence	Mean	Elementary school	SE	p-value
Control group				
Before	6.30	1.74	0.22	0.11
After	6.18	1.66	0.21	
Intervention group				
Before	6.30	1.54	0.28	0.000
After	1.53	1.87	0.34	

Table 3. Statistical test of urinary incontinence after Afigel in the intervention and control groups

Variables	Mean	Elementary school	SE	p-value
Urinary incontinence				
Intervention	1.53	1.87	0.34	0.000
Control	6.18	1.66	0.22	

4. DISCUSSION

The present study aimed to assess the effect of Afigel on urinary incontinence among respondents, showcasing promising outcomes in reducing the severity and frequency of this condition. The demographic data illustrate that the average age of respondents was 47.10 years, with a median age of 47 years, reflecting middle-aged women who are significantly affected by UI [14]. The distribution of urinary incontinence types revealed that 43% of respondents experienced SUI, 47% with UUI, and 10% with mixed incontinence. This pattern is consistent with findings from epidemiological studies indicating that the

prevalence of SUI and UUI varies markedly among women across different age groups, primarily impacting their quality of life [14].

The assessment of urinary incontinence severity within the sample indicated that 41% experienced mild, 45% moderate, and 14% severe symptoms. This aligns with other research that found a direct correlation between the severity of urinary incontinence and reduced quality of life, particularly indicating that higher severity levels may lead to increased social isolation and psychological distress [15], [16]. The substantial severity levels observed in this population underline the necessity for effective intervention strategies such as Afigel, which may provide relief from symptoms.

A significant finding from the study was the marked improvement in urinary incontinence symptoms after the administration of Afigel. Specifically, the intervention group exhibited a notable decline in mean UI scores from an average of 6.30 to 1.53 post-intervention, while the control group showed no change (remained at 6.30). This reduction reflects findings from similar studies demonstrating that PFMT and interventions involving muscle strengthening can produce significant improvements in urinary control [15], [17]. For example, research highlights that consistent pelvic floor exercises lead to significant reductions in urinary leakage and can effectively enhance pelvic muscle strength, which is crucial for managing incontinence [15], [18].

The effectiveness of Afigel can also be compared to established therapeutic approaches such as electromyographic biofeedback, which has shown significant improvement in pelvic floor muscle strength and patient-reported outcomes related to the severity of urinary incontinence [17], [19]. These therapies focus on enhancing the physiological mechanisms involved in urinary control. The findings presented in this study suggest that Afigel may share mechanisms similar to those seen with PFMT and biofeedback, as both aim to strengthen the pelvic floor and rehabilitate muscle function, leading to improved bladder |control [17], [20].

Moreover, considering the implications of lifestyle factors such as obesity and physical activity, which are recognized as contributing elements to urinary incontinence, Afigel administration should ideally be paired with lifestyle modifications for optimal outcomes [14]. Engaging in weight management and physical exercises has been shown to provide additional benefits, supporting bladder health and improving overall wellness [21], [22]. This multifaceted approach could significantly enhance the efficacy of treatments like Afigel.

According to the data presented, the control group exhibited minimal change in urinary incontinence scores, with a mean score decrease from 6.30 (SD = 1.74) to 6.18 (SD = 1.66) post-intervention, leading to a p-value of 0.21, indicating that the results were not statistically significant. Conversely, the intervention group demonstrated a substantial reduction in urinary incontinence, with scores decreasing from 6.30 (SD = 1.53) to 1.53 (SD = 1.87), demonstrating a significant p-value of 0.000. This stark contrast suggests that Afigel has a profound effect on alleviating urinary incontinence symptoms.

The findings align with existing literature that supports various interventions, including pharmacological treatments and pelvic floor muscle training, in addressing urinary incontinence. For example, studies have shown that pelvic floor muscle exercise can lead to significant improvements in incontinence conditions among women [1], [17], [23]. The results from this study indicate that Afigel may serve a similar role, potentially functioning as a necessary adjunct or alternative to current therapeutic strategies.

The results from Table 3 further corroborate the significant impact Afigel had on reducing urinary incontinence when compared to the control group. With a mean score of 1.53 (SD = 1.87) post-treatment in the intervention group versus a mean score of 6.18 (SD = 1.66) in the control group, the statistical significance (p-value = 0.000) demonstrates a level of effectiveness that warrants clinical consideration. Such data reflect an essential criterion for evaluating treatment efficacy in clinical settings, emphasizing the need for more integrative approaches in managing urinary incontinence [24], [25].

Furthermore, multiple studies explore the efficacy of conservative treatments, such as PFMT and biofeedback systems. For instance, Li *et al*. [26] performed a systematic review and meta-analysis, indicating varying results for different conservative interventions and found electrical stimulation to be one of the more effective treatments for improving urinary incontinence scores. Wang *et al*. [27] also underscore that while PFMT is recommended as a first-line treatment, further evidence is needed concerning adjunctive methods, indicating that the integration of technologies like biofeedback may not universally enhance outcomes. Lastly, while advancements in digital health technologies combining PFMT with motion-based therapies may suggest improved symptom relief and quality of life, the specific claims about the outcomes of novel multifaceted strategies need substantiation that aligns with rigorous clinical research [28].

Moreover, the implications of this study are pertinent considering the rising prevalence of urinary incontinence, which is influenced by numerous factors including age, obesity, and childbirth [14], [29], [30]. The pronounced improvement noted in the intervention group indicates a potential to improve quality of life for individuals suffering from this condition, supporting further research in this domain.

The significant findings from this study suggest that Afigel may be an effective treatment option for urinary incontinence, particularly for individuals who have not found relief through traditional therapies. Future studies should consider longer follow-up periods to assess the sustainability of Afigel's effects while also exploring its effectiveness across different demographic groups and types of incontinence [31], [32]. The inclusion of larger sample sizes and varied methodologies may also enhance the robustness and generalizability of the findings.

A systematic review indicates that various treatment modalities, including conservative methods such as pelvic floor muscle training and acupuncture, have shown efficacy across demographic groups [33]. Notably, extended follow-up periods are crucial for evaluating the sustainability of urinary incontinence treatments, as existing literature highlights the necessity of long-term assessment regarding their effects [34], [35]. Furthermore, expanding sample sizes and employing diverse methodologies would significantly enhance the reliability and applicability of findings in urinary incontinence research [36].

The single-site design conducted exclusively in Bagelen Village, Pesawaran Regency, limits the generalizability of findings to broader Indonesian populations or other low-resource settings. Despite these limitations, the findings carry significant practical implications for urinary incontinence management in resource-limited settings. The substantial reduction in QUID scores (from 6.30 to 1.53) in the intervention group suggests Afigel may serve as an accessible alternative where specialized pelvic floor muscle training programs are unavailable. This is particularly relevant given that conservative treatments like PFMT require trained healthcare providers, who are scarce in rural Indonesian contexts. The intervention's applicability to premenopausal women addresses an understudied population, as most existing research focuses on postmenopausal women.

5. CONCLUSION

This study demonstrated that Afigel effectively reduced urinary incontinence symptoms in the intervention group compared to the control group, which showed minimal changes. The highly statistically significant difference between the two groups confirmed Afigel's effectiveness as a therapeutic intervention. The demographic profile of the respondents, predominantly middle-aged women with various types of incontinence (SUI, UUI, and mixed), confirms the clinical relevance of this intervention in improving the quality of life of people with urinary incontinence. These findings align with the literature showing that pelvic floor muscle strengthening techniques and similar interventions can produce significant improvements. Future research recommends longer-term follow-up and comparisons across populations and types of incontinence to ensure the sustainability and generalizability of Afigel's effects to a broader population.

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AUTHOR CONTRIBUTIONS STATEMENT

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C : **C**onceptualization
M : **M**ethodology
So : **So**ftware
Va : **Va**lidation
Fo : **Fo**rmal analysis
I : **I**nvestigation
R : **R**esources
D : **D**ata Curation
O : Writing - **O**riginal Draft
E : Writing - Review & **E**diting
Vi : **Vi**sualization
Su : **Su**pervision
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CONFLICT OF INTEREST STATEMENT

Authors state no conflict of interest.

ETHICAL APPROVAL

This research has received ethical approval from the Mataram Ministry of Health Polytechnic with the number: 442/KEPK-TJK/V/2025.

DATA AVAILABILITY

The data that support the findings of this study are available from the corresponding author, [S], upon reasonable request.

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