



Single-Arm Pilot Study to Determine the Effectiveness of the Support Power of Underwear in Elevating the Bladder Neck and Reducing Symptoms of Stress Urinary Incontinence in...

Ninomiya, Sanae

(Degree)

博士 (保健学)

(Date of Degree)

2013-09-25

(Date of Publication)

2015-09-25

(Resource Type)

doctoral thesis

(Report Number)

甲第5959号

(URL)

<https://hdl.handle.net/20.500.14094/D1005959>

※ 当コンテンツは神戸大学の学術成果です。無断複製・不正使用等を禁じます。著作権法で認められている範囲内で、適切にご利用ください。



**Single-Arm Pilot Study to Determine the Effectiveness of the Support Power of Underwear
in Elevating the Bladder Neck and Reducing Symptoms of Stress Urinary Incontinence
in Women**

Sanae NINOMIYA^{1, 2}, Izumi SAITO³,

Kiyoko MASAKI², Yoshihiro ENDO², Shigehiro MORIKAWA⁴, Hisayo OKAYAMA²

¹Department of Nursing, Kyoto Koka Women's University

²Department of Clinical Nursing, Shiga University of Medical Science

³Department of Nursing, Kobe University Graduate School of Health Science

⁴Department of Fundamental Nursing, Shiga University of Medical Science

ABSTRACT

Objectives: To verify the effectiveness of support power of underwear (the shaper) to elevate bladder neck and to reduce symptoms of stress urinary incontinence (SUI).

Methods: This was a single-arm pilot study conducted in Japan by using the shaper (SLIM-up-Pants with Style Science[®], Wacoal Corporation, Kyoto, Japan). The bladder neck position in a sitting posture was recorded using an open-configuration magnetic resonance system and then compared between parous women with SUI, without and with the shaper. Women wore the shaper during the daytime for 12 weeks, followed by one week during which they did not wear the shaper. The symptoms of urinary incontinence (UI) were assessed based on the 1-h pad test, the Japanese version of the International Consultation Incontinence Questionnaire-Short Form, and the incontinence diary.

Results: Forty-five Japanese women with SUI, aged between 27 and 65 years, were included. When the shaper was worn, the bladder neck was found to be significantly elevated by 11.5 mm (median; $P < 0.05/6 = 0.008$). After 12 weeks, all symptoms of UI decreased significantly ($P < 0.05/3 = 0.016$), and the bladder neck was further elevated by 4.7 mm (median; $P < 0.001$) even when not wearing the shaper. In addition, after one week of not wearing the shaper, the bladder neck position remained elevated and symptoms of UI did not recur immediately.

Conclusion: The shaper was considered to be effective in elevating the bladder neck and reducing symptoms of UI.

Keywords: bladder neck, magnetic resonance imaging, pelvic floor muscles, urinary incontinence

Introduction

Pelvic relaxation results in decreased support for the urinary tract and a descent of the bladder neck, leading to stress urinary incontinence (SUI). Urinary incontinence (UI) is reported to be experienced by 29% of healthy women in age group 30–60, and 78% of such cases are attributed to SUI¹. Stress urinary incontinence is often considered embarrassing in women, and it has a negative impact on their quality of life (QOL)². Many women with SUI try to control themselves by using pads and going to a toilet regularly³. Although SUI can be treated, most women with SUI do not consider treating it. On the other hand, some women have mild SUI and do not feel the necessity of treatment, because of its little influence on their daily life⁴. However, mild SUI may become aggravated later by risk factors such as pregnancy, delivery, aging, menopause, and obesity⁵. Therefore, early treatment and prevention are required.

We are developing a new treatment for women with mild SUI, in which SUI is treated using an open-configuration magnetic resonance system GE SIGNA SP/2, 0.5 tesla (Open MR), which can be performed in a sitting or standing posture. In collaboration with the manufacturer, Wacoal Corporation (Kyoto, Japan), we are investigating the possibility of elevation in the bladder neck caused due to the use of the underwear, and also the validity of the product supportive underwear (SLIM-up-Pant with Style Science[®]; the shaper). The surgical treatment for SUI involves suspending the bladder neck or supporting the lower urinary tract by a sling⁶. This indicates that SUI may improve by elevating the bladder neck and supporting it with a support from the outside by underwear. If SUI could be reduced

simply by wearing underwear, which is easy to continue, it would be a good treatment for SUI. Therefore, in this study, we examined two research questions:

- (1) Is the bladder neck elevated due to the use of the shaper?
- (2) Does SUI reduce during the period of 12 weeks of use of the shaper?

Methods

Study design and setting

This was a single-arm pilot study, interventional clinical trial based on a before-after design, aimed to verify the effectiveness of the shaper to elevate the bladder neck and reduce the symptoms of UI in parous women. This study was done from January 2009 to August 2010.

Ethical considerations

This study was approved by the ethical review board of Shiga University of Medical Science (20–69) and by the ethical review board of Kobe University Graduate School of Health Sciences (63), and it conforms to the provisions of the Declaration of Helsinki. All participants gave a signed informed consent.

Participants

The participants were parous women with SUI, as defined by the International Continence Society (ICS)⁷. The inclusion criteria for the participants were as follows: age 20–65 years, SUI or mixed urinary incontinence (MUI) with urinary leakage episodes at least once a week, and possibility of wearing the shaper for 12 weeks. The prevalence of

SUI in the women with a history of cesarean section is higher than in nulliparous women⁸, therefore, this study included women who had undergone cesarean section. The following were excluded: women within 3 months post-partum, women showing symptoms of only urge incontinence, pregnancy, use of medication affecting micturition, history of urological diseases expect UI or gynecological diseases or digestive diseases, and presence of metallic inserts such as pacemakers or artificial joints inside their bodies that cannot be removed during magnetic resonance imaging (MRI) scanning. The participants were recruited by advertising in local newspaper for women.

The shaper

The shaper used in this study was SLIM-up-Pant with Style Science[®] (stock number; EQ0832, Wacoal Corporation, Kyoto, Japan). Style Science[®] is a functional underwear with a cross structure (Japanese patent No. 3924586; United States patent No. 1752054), which stimulates the quadriceps femoris muscle, and promotes a large-stride during walking. The muscles of buttocks can be strengthened by walking more than 6000 steps per day, while wearing this underwear during the daytime for 12 weeks. In other words, this underwear was developed for muscle strengthening and for the correction of body shape, but not for elevating the bladder neck and reducing the symptoms of UI. It has the same shape as common long leg shapers, and most of the women are comfortable in shapers of suitable size.

Measurements

MRI for measuring the bladder neck position

The bladder neck position was assessed based on sagittal T₁-weighted spoiled gradient-echo images of the pelvis, using a surface coil in a toilet seat and an Open MR taken in a sitting posture, because evaluation of the pelvic organ in SUI is better if done in a posture subject to vertical gravity⁹.

Because MRI was performed without using any contrast agent, the participants were requested not to urinate for an hour before MRI to ensure full bladder. Image parameters used were repetition time of 68 ms, echo time of 4.3 ms (in phase), flip angle of 90°, field of view of 350 × 350 mm, matrix of 256 × 256, and slice thickness of 8 mm for three slices. MRI of the pelvis was performed in three motions: "at rest", "at pelvic floor muscle (PFM) contraction", and "at pelvic strain". The order was "at rest", "at PFM contraction", "at rest", "at pelvic strain". This was repeated twice, and the imaging time was 9 sec/motion. Before MRI, the participants were instructed by the researcher using the explanatory leaflet about "at PFM contraction" and "at pelvic strain". MRI was completed in 10 min.

The bladder neck position was analyzed on the mid-sagittal images. The pubococcygeal line (PC line) was used to represent the normal location of the pelvic floor¹⁰. The PC line was used as the reference point (0 mm), the perpendicular distance up to the bladder neck was measured (in mm). Accordingly, the bladder neck position was shown as higher (+) or lower (−) with respect to the PC line. For each image, measurements were performed twice, and the mean values were calculated.

Symptoms of UI

Four outcome measures were used evaluate the symptoms of UI: the 1-h pad test, the

Japanese version of the International Consultation Incontinence Questionnaire-Short Form (ICIQ-SF)¹¹, the number of incontinence episodes per week, and the frequency of voiding per day. The 1-h pad test was performed according to the recommendations by the ICS¹², to evaluate severity and objective symptoms of UI. Higher ICIQ-SF scores indicate a greater severity of UI symptoms and a larger impact on the QOL. Since the Japanese version of the ICIQ-SF includes a question about the causes of urinary leakage, which was not included in the score, this question was used to differentiate between SUI and MUI in this study. The incontinence episodes and frequency of voiding were recorded daily by the participants in an incontinence diary. In this diary, free space was included for participants to enter changes, comments, etc. every day.

Procedures

Figure 1 shows the flow diagram of the study. First, for research question (1), the bladder neck position in a sitting posture was recorded using an Open MR, and it was compared between participants without and with the shaper. The interval between each MRI was about 5 min. Second, for research question (2), the participants wore the shaper during daytime and continued usual activities for 12 weeks, followed by one week during which they did not wear the shaper. This helped to verify whether UI symptoms recur immediately if the use of the shaper was stopped for one week, even if the UI were improved earlier. During the study period, the participants counted the number of steps using a pedometer.

At the end of this study, the participants were asked whether they wanted to continue

wearing the shaper after this study, and were requested to grade how comfortable they were by wearing the shaper into five grades from "very good" to "very poor".

Statistical analysis

Statistical analyses were carried out using the software SPSS Version 19.0 for Windows (IBM Japan). Continuous data were checked for normality by Shapiro–Wilk tests. Subgroup analyses were performed using various tests as indicated in the Tables: Wilcoxon signed-ranks test, with or without Bonferroni correction ($\alpha = 0.05/3 = 0.016$, $\alpha = 0.01/3 = 0.003$; $\alpha = 0.05/6 = 0.008$), and 95% confidence intervals (CI) for the median difference using the Hodges-Lehmann estimator. P-values less than 0.05 were considered statistically significant.

Results

Study overview

This was a single-arm pilot study conducted on Japanese women with SUI, implemented as depicted in Figure 1. Fifty women who wished to participate were telephonically screened, 45 of them participated and 41 completed this study (dropout rate: 8.9%). The characteristics of participants at baseline are shown in Table 1. Severity of UI was graded based on the standard of ICS in the 1-h pad test of baseline. Although there were 16 women (35.6%) who had undergone the pelvic floor muscle training before, none of them received the specialist's instruction or were continuing it. Four women who dropped out had SUI, including two with slight and two with moderate UI.

Elevation of the bladder neck from wearing the shaper-research question (1)

In "at rest" position, the bladder neck in women wearing the shaper was significantly higher than those without ($P < 0.008$). The extent of elevation was 11.5 mm (median; 95% CI, 10.0–12.9; Table 2). Moreover, wearing the shaper elevated the bladder neck in all 45 women (100%). Likewise, the bladder neck position was significantly different between with and without the shaper for the other two motions, "at PFM contraction" and "at pelvic strain" ($P < 0.008$). Interestingly, the bladder neck position showed no difference (difference, 0.5 mm; 95% CI, –2.1 to 3.3; $P > 0.008$) between "at rest" without the shaper (median, 0.0 mm) and "at pelvic strain" with the shaper (median, 0.9 mm) (A vs. F). In other words, the results showed that the bladder neck position on wearing the shaper is maintained at the same height as "at rest" without the shaper, if the abdominal pressure is added. In addition, the bladder neck position "at rest" while wearing the shaper (median, 11.7 mm) was significantly higher than the position "at PFM contraction" (median, 6.9 mm) without the shaper (difference, 4.4 mm; 95% CI, 1.8–6.6; $P < 0.008$) (B vs. D). In other words, the results showed that the bladder neck position was elevated to a higher level than by performing voluntary PFM contraction by wearing the shaper. Figure 2 shows an example of MRI.

Decrease in symptoms of UI by wearing the shaper-research question (2)

Outcome measures were compared over the entire study period (Table 3). Compared to baseline, the 1-h pad test, the ICIQ-SF and the number of incontinence episodes per week were significantly decreased after 6 weeks of wearing the shaper ($P < 0.003$). In addition,

compared to baseline, at 12 weeks the 1-h pad test and the ICIQ-SF indicated a further decrease ($P < 0.003$) and the frequency of voiding per day was also decreased significantly ($P < 0.016$). Moreover, the bladder neck position without the shaper was more elevated than baseline after 12 weeks (difference, 4.7 mm; 95% CI, 2.8–6.6; $P < 0.003$). Next, compared to 12 weeks, there was no significant change in any of the four outcome measures related to UI, and no change in the bladder neck position after the one week follow-up, during which the participants did not wear the shaper (difference, 1.7 mm; 95% CI, -0.5 to 4.3; $P > 0.016$). In other words, these results showed that wearing the shaper in daytime for 12 weeks reduced symptoms of UI, and this effect was sustained for at least one week after stopping wearing the shaper.

The symptoms of UI decreased or disappeared after 12 weeks in 35 of 41 women (85.4%). In addition, both MUI as well as SUI improved (Table 4). Moreover, this improvement did not relate to the severity of the UI symptoms; UI symptoms disappeared in two of three women with moderate UI, and in all three women with severe UI. The average steps as counted by pedometer for 12 weeks was 8713 steps/day (25th–75th percentile, 6650–10 247; $n = 41$). The number of steps did not correlate with the reduction of UI and elevation of the bladder neck position after 12 weeks.

Safety and adherence of wearing the shaper

No participant reported side-effects such as skin trouble or changes in voiding function on wearing the shaper for 12 weeks. These were confirmed from the notes of the participants in the free space of the incontinence diary, and by oral questioning. In addition,

when inquired at the end of the study, all participants wished to continue wearing the shaper even after the study. Further, all participants graded the comfort of wearing the shaper as "good" or "very good".

Discussion

This study verified the effectiveness of the shaper to elevate the bladder neck and to reduce the symptoms of UI in parous women. The major findings of this study revealed that wearing the shaper elevated the bladder neck in all participants; that even on adding an abdominal pressure, the bladder neck was maintained at the same position as that at rest without wearing the shaper; and that the bladder neck position was higher than that at voluntary PFM contractions without wearing the shaper. In addition, this study showed that wearing the shaper for 12 weeks led to significant improvements in symptoms of UI, and these symptoms did not recur immediately even when the participants stopped wearing the shaper for one week. The effect was found to be valid not only in women with SUI but also in those with MUI. Wearing the shaper was also found to be effective even against severe UI, and 85.4% of the participants showed an improvement in the symptoms. The strengths of this study include the low dropout rate, high adherence rate, and the fact that the assessment of the bladder neck position was conducted using MRI in a sitting posture, which was close to the posture subject to vertical gravity in which urinary leakage was likely to occur.

By wearing the shaper, since all participants accepted elevation of the bladder neck, the

shaper could potentially have an effect of reducing the symptoms of SUI in all participants. The participants included in this study showed a large range of age, and time since last delivery. However, since the effect of wearing the shaper to elevate the bladder neck was large, it is thought that these two variables did not affect the outcome.

In a previous study, Fielding and his group¹³ reported that the bladder neck position of eight women with SUI (years of age; 45–69) was an average of 22 mm below the PC line in sitting posture. The discrepancy in this and our study may be attributed to the differences in sample size and characteristics of the study population. Although the normal position of the bladder neck was not well-defined for the participants in this study, urinary leakage did not occur "at rest", but occurred "at pelvic strain" in women with SUI, therefore it was based on position "at rest". When wearing the shaper, the bladder neck position "at pelvic strain" was maintained at the same position as "at rest" without the shaper, thus it could have prevented the urinary leakage. In addition, the bladder neck was open "at pelvic strain" without wearing the shaper, but it was flat "at pelvic strain" with wearing the shaper. Miller and his group¹⁴ reported that no urinary leakage occurs when a contraction of the PFM is performed at the moment of a sneezing or a cough (the Knack maneuver). In this study, simply wearing the shaper allowed the bladder neck to reach an elevation higher than that "at PFM contraction" without wearing the shaper.

The reasons why the shaper could have led to the elevation of the bladder neck could be as follows: it did not have strong support power for the abdomen, and it led to the elevation of not only the bladder neck but also the fundus of the bladder, suggesting that it was

effective to lift the gluteal region from behind. According to the integral theory of female UI¹⁵, the normal pelvic floor function is considered analogous to a suspension bridge, and structure and function of pelvic floor are related mutually. The supportive power of underwear is believed to complement the strength of internal muscles, fascia and ligaments, and keep the structure of the pelvic floor in a balanced state. We estimate that this balanced state will be a mechanism effective in improving UI by the shaper.

After wearing the shaper for 12 weeks, the bladder neck position was found to be elevated even without wearing the shaper, and the symptoms of UI did not immediately recur after the use of the shaper was discontinued. Braekken and his group¹⁶ previously reported having achieved a 4.3 mm (95% CI, 2.1–6.5) elevation of the position of the bladder through 6 months of PFM training. The shaper used in this study is designed to strengthen the muscles of buttocks. Possibly, wearing the shaper for 12 weeks might have influenced not only these muscles, but also the muscles of PFM. This might be associated with the fact that the shape of the bladder "at rest" while wearing the shaper resembled that "at PFM contraction" without the shaper, and also with the fact that merely by wearing the shaper, the bladder neck position can be elevated higher than "at PFM contraction" without the shaper. However, although the patent of buttocks muscles strengthening by wearing the shaper and walking was acquired, there is no report that shows the scientific evidence of it. In addition, the number of steps did not correlate with the reduction of UI and elevation of the bladder neck position after 12 weeks.

In this study, we were not able to show clearly why wearing the shaper could have led to

the elevation of the bladder neck, and which parts of the support power of the shaper led to the elevation of the bladder neck, which was more effective in reducing the symptoms of UI between the elevation of the bladder neck or the PFM strengthening. It is important to elucidate these mechanisms in the future.

The limitations of this study were that it was the first trial, and it was not a randomized controlled trial but a before-after design without any control groups. Therefore, the result of this study cannot deny the placebo effect. Moreover, MRIs were analyzed by one researcher who was not blinded. In addition, the changes in the strength of PFM were not directly evaluated. However, the effect of elevating the bladder neck and in reducing symptoms of UI was enough to cover these imperfections.

In the participants of this study, although urination was stopped for an hour before MRI, bladder volume was not fixed. However, since there was no clear difference in the bladder volume of the same participant, probably, it has very little influence on the result.

The treatment of SUI often imposes a number of burdens on women. Although PFM training can achieve a 35–80% improvement rate¹⁷, adherence decreases in the long-term¹⁸. In addition, since 30% of women cannot contract their PFM correctly, PFM training is ineffective in such women¹⁹. For biofeedback and functional electrical stimulation, regular hospital visits are necessary. In contrast, wearing the shaper is easy, and does not interfere with daily life. The improvement rate of the symptoms of UI by wearing the shaper was 85.4%, and it was effective not only in mild SUI, but also in MUI and severe UI. Wearing the shaper may expand the possibility of the treatment of UI.

In conclusion, wearing the shaper elevated the bladder neck in all participants, and use of the shaper for 12 weeks led to significant improvements in symptoms of UI. In addition, symptoms of UI did not recur immediately even when the participants stopped wearing the shaper. Although a randomized controlled trial, short or long-term evaluation, and the elucidation of mechanism to elevate the bladder neck and to reduce the symptoms of UI will be required, this pilot study has demonstrated that the use of underwear might be a promising treatment option for management of UI symptoms.

Acknowledgements

The authors would like to acknowledge the contributions of Wacoal Corporation. This was a joint study conducted by Wacoal Corporation in collaboration with the Shiga University of Medical Science. The shapers were provided by Wacoal Corporation. This study received a Grant in Aid for Promotion of Faculty Development from Shiga University of Medical Science (2008), and a Grant in Aid for Challenging Exploratory Research (No. 21659518).

Disclosure

This study was carried out properly on the basis of the conflict of interest management policy adopted by the Shiga University of Medical Science. We have no other conflict of interest.

References

1. Hampel C, Weinhold D, Eggersmann C, Thüroff JW. Definition of overactive bladder and epidemiology of urinary incontinence. *Urology* 1997; 50: 4–14.
2. Lasserre A, Pelat C, Guérault V *et al.* Urinary incontinence in French women: prevalence, risk factors, and impact on quality of life. *Eur Urol* 2009; 56: 177–83.
3. Berger MB, Patel DA, Miller JM, Delancey JO, Fenner DE. Racial differences in self-reported healthcare seeking and treatment for urinary incontinence in community-dwelling women from the EPI study. *Neurourol Urodyn* 2011; 30: 1442–7.
4. Luber KM. The definition, prevalence, and risk factors for stress urinary incontinence. *Rev Urol* 2004; 6: S3–9.
5. Bump RC, Norton PA. Epidemiology and natural history of pelvic floor dysfunction. *Obstet Gynecol Clin North Am* 1998; 25: 723–46.
6. Dmochowski RR, Blaivas JM, Gormley EA *et al.* Update of AUA guideline on female stress urinary incontinence. *J Urol* 2010; 183: 1906–14.
7. Abrams P, Cardozo L, Fall M *et al.* The standardization of terminology of lower urinary tract function: report from the Standardization Sub-committee of the International Continence Society. *Neurourol Urodyn* 2002; 21: 167–78.
8. Rortveit G, Daltveit AK, Hannestad YS, Hunskaar S, Norwegian EPINCONT Study. Urinary incontinence after vaginal delivery or cesarean section. *N Engl J Med* 2003; 348: 900–7.
9. Armillotta M, Casillo A, Bonetti MG, Morcaldi M. Stress urinary incontinence in

- women: magnetic resonance assessment. *Radiol Med* 1995; 89: 112–16.
10. Fielding JR. Practical MR imaging of female pelvic floor weakness. *Radiographics* 2002; 22: 295–304.
 11. Gotoh M, Donovan J, Corcos J *et al*. Symptom and QOL questionnaire for urinary incontinence, scored ICIQ-SF (International Consultation on Incontinence Questionnaire: Short Form). *JNBS* 2001; 12: 227–31. (In Japanese).
 12. Abrams P, Khoury S, Wein A. Incontinence, 1st International Consultation on Incontinence. Plymouth, UK: *Plymbridge Distributors Ltd*, 1998.
 13. Fielding JR, Griffiths DJ, Versi E, Mulkern RV, Lee ML, Jolesz FA. MR imaging of pelvic floor continence mechanisms in the supine and sitting positions. *AJR Am J Roentgenol* 1998; 171: 1607–10.
 14. Miller JM, Sampsel C, Ashton-Miller J, Hong GR, DeLancey JO. Clarification and confirmation of the Knack maneuver: the effect of volitional pelvic floor muscle contraction to preempt expected stress incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2008; 19: 773–82.
 15. Petros PE, Ulmsten UI. An integral theory of female urinary incontinence . Experimental and clinical considerations. *Acta Obstet Gynecol Scand Suppl* 1990; 153: 7–31.
 16. Braekken IH, Majida M, Engh ME, Bø K. Morphological changes after pelvic floor muscle training measured by 3-dimensional ultrasonography: a randomized controlled trial. *Obstet Gynecol* 2010; 115: 317–24.

17. Bø K. Pelvic floor muscle training in treatment of female stress urinary incontinence, pelvic organ prolapse and sexual dysfunction. *World J Urol* 2012; 30: 437–43.
18. Agur WI, Steggles P, Waterfield M, Freeman RM. The long-term effectiveness of antenatal pelvic floor muscle training: eight-year follow up of a randomized controlled trial. *BJOG* 2008; 115: 985–90.
19. Bø K, Mørkved S. Motor learning. In: Bø K, Berghmans B, Mørkved S *et al.* (eds.), Evidence-based Physical Therapy for the Pelvic Floor. Bridging Science and Clinical Practice. Edinburgh, Scotland: *Churchill Livingstone Elsevier*, 2007; 113–19.

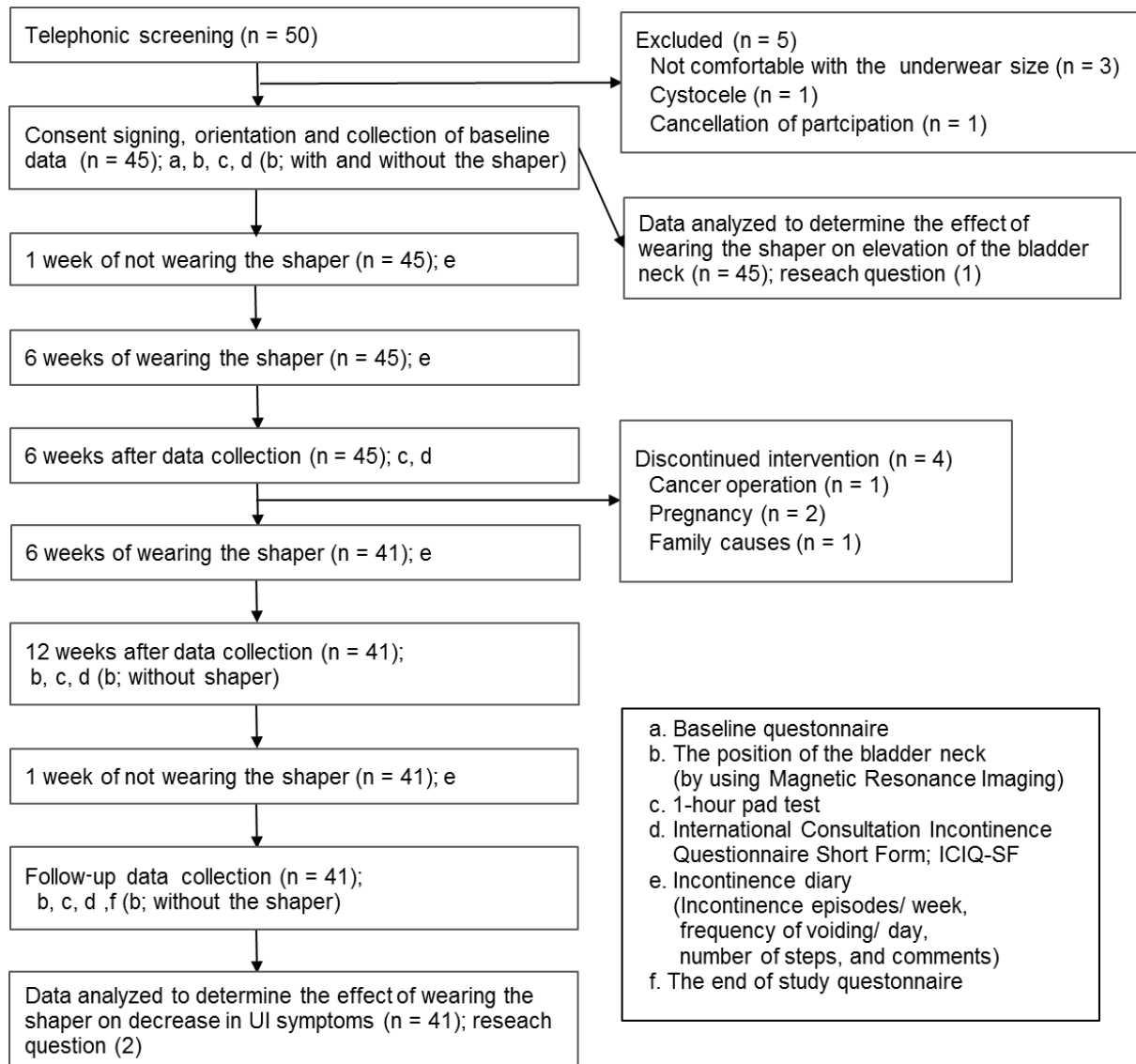


Figure 1. Flow diagram of the study.

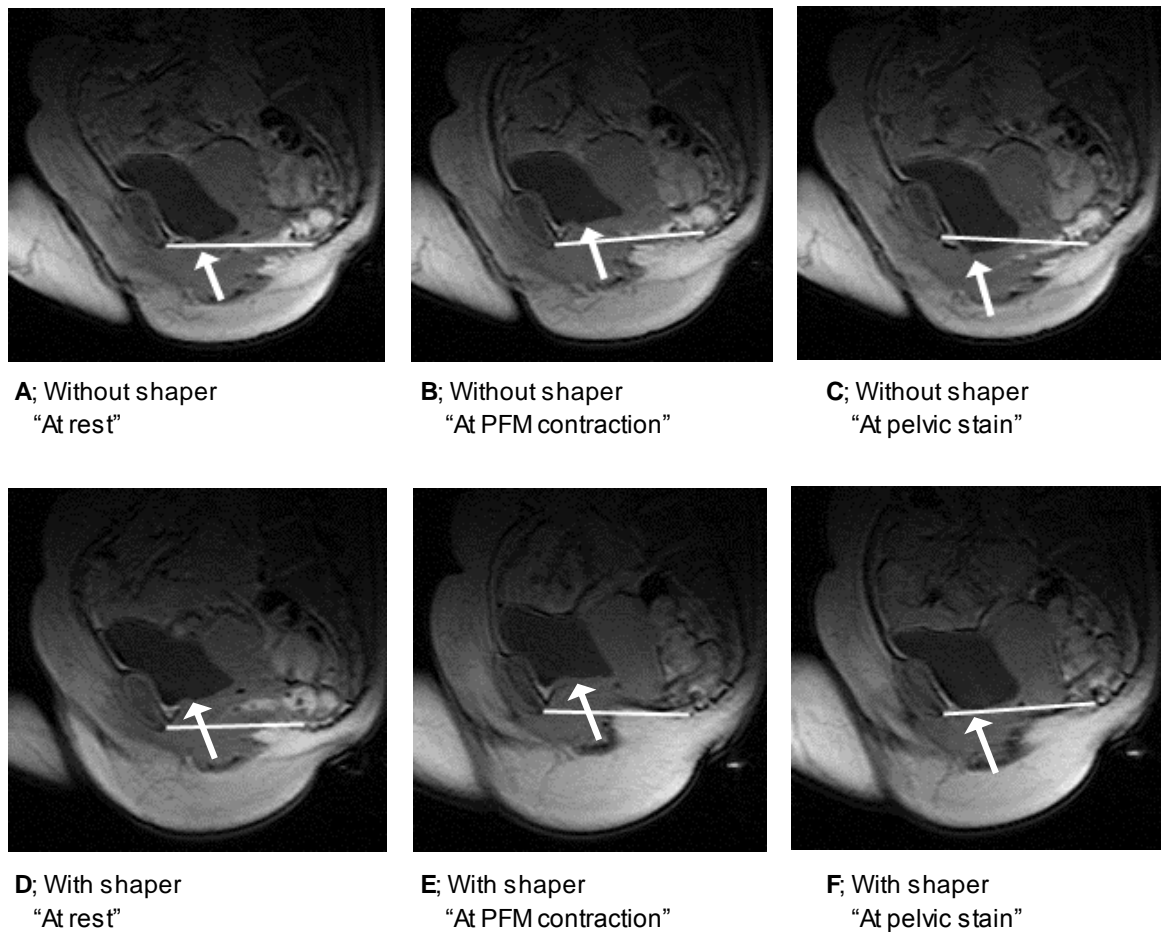


Figure 2. Sagittal T₁-weighted pelvic magnetic resonance images of a 34-year-old woman.

A, B, C (top panel) show the images without the shaper, and D, E, F (bottom panel) show the images with the shaper. Arrows point to the bladder neck positions; white line indicates the pubococcygeal line. “At rest,” the bladder neck was clearly higher with than without the shaper (A vs. D, 14.2 mm). “At pelvic floor muscle (PFM) contraction” without the shaper, the position and shape of the bladder were similar to “at rest” with the shaper (B vs. D). “At pelvic strain” with the shaper, the bladder neck was flat (C vs. F), and the position was similar to “at rest” without shaper (A vs. F).

Table 1. Baseline characteristics of participants (n = 45)

	Median [25th–75th percentile]
Age (years)	43.0 [35.5, 51.5]
Body mass index (kg/m ²)	21.4 [19.8, 22.9]
Parity (no. of childbirths)	2.0 [2.0, 2.0]
Time since last delivery (years)	8.0 [2.0, 22.5]
Type of urinary incontinence (UI), <i>n</i> (%)	
Stress urinary incontinence (SUI)	29 (64.4%)
Mixed urinary incontinence (MUI)	16 (35.6%)
Severity of UI (based on the 1-hour pad test), <i>n</i> (%)	
Slight, < 2 g	26 (57.8%)
Mild, ≥ 2–5 g	11 (24.4%)
Moderate, ≥ 5–10 g	5 (11.1%)
Severe, ≥ 10 g	3 (6.7%)
The experience of pelvic floor muscle training, <i>n</i> (%)	16 (35.6%)

Table 2. Effect of wearing the shaper on the bladder neck position from pubococygeal line in women at baseline (n = 45)

	I: Without the shaper (mm)	II: With the shaper	Difference between I and II [†]	<i>P</i> -value [‡]
	Median [25th–75th percentile]	Median [25th–75th percentile]	Median (95% CI)	
At rest	A: 0.0 [-5.0, 7.1]	D: 11.7 [6.3, 17.8]	11.5 (10.0, 12.9)	< 0.001*
At PFM contraction	B: 6.9 [2.3, 14.0]	E: 14.2 [10.4, 21.8]	7.3 (6.0, 8.8)	< 0.001*
At pelvic strain	C: -10.9 [-18.0, -2.2]	F: 0.9 [-9.9, 8.9]	8.7 (6.6, 10.7)	< 0.001*
A vs. F			0.5 (-2.1, 3.3)	0.710
B vs. D			4.4 (1.8, 6.6)	0.002*

[†] Hodges-Lehmann estimator.

[‡] Wilcoxon signed-ranks test and Bonferroni correction: **P* < 0.008 (= 0.05/6).

PFM, Pelvic Floor Muscle.

Table 3. Effects of wearing the shaper on symptoms of urinary incontinence and the bladder neck position (n = 41)

	A: baseline	B: 6 week	C: 12 week	D: follow-up	Difference [†] between A and C	A Vs. B.	A Vs. C	B Vs. C	Difference [†] between C and D	C Vs. D
Outcome measure	Median [25th–75th percentile]				Median (95% CI)	P-value [‡]			Median (95% CI)	P-value [§]
The symptoms of UI										
1-hour pad test (g)	1.0 [0.0, 3.0]	0.0 [0.0, 1.5]	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]		0.002**	<0.001**	0.007*		0.589
ICIQ-SF	7.0 [5.0, 11.0]	5.0 [3.5, 7.0]	4.0 [0.0, 6.0]	4.0 [0.0, 5.0]		<0.001**	<0.001**	<0.001**		0.928
Incontinence episodes/week	4.0 [1.5, 7.0]	0.0 [0.0, 1.0]	0.0 [0.0, 1.0]	0.0 [0.0, 1.0]		<0.001**	<0.001**	0.018		0.103
Frequency of voiding/day	7.7 [6.7, 9.0]	7.4 [6.3, 8.5]	7.0 [6.2, 8.0]	7.0 [6.1, 8.4]		0.204	0.003*	0.044		0.512
Bladder neck position (mm)	0.0 [-5.0, 7.8]	NA	4.7[-2.8,11.1]	7.6 [1.8, 13.2]	4.7 (2.8, 6.6)	NA	<0.001**	NA	1.7 (-0.5, 4.3)	0.141

[†]Hodges-Lehmann estimator.

[‡]Wilcoxon signed-rank test and Bonferroni correction: * $P < 0.016$ (= 0.05/3), ** $P < 0.003$ (= 0.01/3).

[§]Wilcoxon signed-ranks test.

UI, urinary incontinence, ICIQ-SF, International Consultation Incontinence Questionnaire Short Form

Table 4. The decrease in the rate of symptoms of UI after 12 weeks

Decrease of symptoms	Overall (n = 41)	SUI (n = 25)	MUI (n = 16)
Disappearance [†]	27 (65.9%)	16 (64.0%)	11 (68.8%)
Reduction [‡]	8 (19.5%)	6 (24.0%)	2 (12.5%)
No change	6 (14.6%)	3 (12.0%)	3 (18.8%)
Aggravation	0 (0.0%)	0 (0.0%)	0 (0.0%)

[†]Disappearance; both 1-hour pad test and incontinence episodes/week showed 0.

[‡]Reduction; both 1-hour pad test and incontinence episodes/week showed less than 50% decreases from baseline.

MUI, Mixed Urinary Incontinence. *SUI*, Stress Urinary Incontinence.