Usage of Positional Therapy in Adults with Obstructive Sleep Apnea

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Study Objectives: Many positional therapy (PT) strategies are available for treating positional obstructive sleep apnea (OSA). PT is primarily supplied to selected patients as a secondary treatment option when other therapies have failed. To our knowledge this is the largest study to date to assess effectiveness and long-term compliance of PT (both commercial waistband and self-made constructions, mimicking the tennis ball technique) as primary treatment in patients with different positional OSA severities.

Methods: PT was used by 53 patients, of which 40 patients underwent a follow-up polygraphic evaluation under treatment after a median time interval of 12 weeks. Patients were routinely contacted regarding their clinical status and treatment compliance.

Results: PT was successful in 27 out of 40 patients (68%). Overall AHI reduced significantly from a median (interquartile range [IQR]) AHI of 14.5 (10.7–19.6) to 5.9 (3.1–8.5), $p < 0.001$. The commercial waistband and self-made constructions were

equally effective (median (IQR) reduction in overall AHI ($\Delta 9.6$ (5.5–11.9) and $\Delta 6.8$ (3.2–11.3) respectively), $p = 0.22$). Short-term compliance was good as most patients used PT more than 7 hours/night (mean $7.2 \pm \text{SD } 1.4$) and more than 6 days/week (mean $6.5 \pm \text{SD } 1.3$). However, after mean 13 ± 5 months, 26 patients (65%) reported they no longer used PT, especially patients with moderate positional OSA (89%).

Conclusions: On the short-term, PT using the tennis ball technique, is an easy method to treat most patients with positional OSA, showing significant reductions in AHI. Unfortunately, long-term compliance is low and close follow-up of patients on PT with regard to their compliance is necessary.

Keywords: compliance, effectiveness, obstructive sleep apnea, positional therapy, sleep related breathing disorder

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Obstructive sleep apnea syndrome (OSAS) is a common sleep-related breathing disorder affecting 14% of middle-aged men and 5% of women.¹ OSAS is characterized by repetitive upper airway collapse during sleep, resulting in a complete (apnea) or partial (hypopnea) obstruction in airflow, reduced oxygen saturation levels and disruptive snoring. The increased respiratory effort to restore oxygen levels result in activation of the sympathetic nervous system, brief awakenings from sleep, leading to sleep fragmentation and excessive daytime sleepiness (EDS).^{2,3}

The collapsibility of the upper airway is increased in the supine sleeping position, possibly due to the effect of gravity and altered size and shape of the upper airway in this position.^{4–7}

As a result the total number of apneas and hypopneas per hour of sleep (i.e., apnea-hypopnea index [AHI]) and severity of the respiratory events usually increases in supine position. According to the American Academy of Sleep Medicine (AASM) definition positional obstructive sleep apnea (OSA) can be defined as a lower AHI in the non-supine position than in the supine position.⁸ In practice positional OSA is defined as an AHI at least twice as high in supine position as in other positions.^{9,10}

BRIEF SUMMARY

Current Knowledge/Study Rationale: To our knowledge this is the largest study to date to assess effectiveness and long-term compliance of positional therapy as a primary treatment option in patients with different severities of positional OSA. Furthermore, in this study both a commercial fabricated waistband and self-made constructions mimicking the tennis ball technique were assessed.

Study Impact: After reading this article, readers should be able to know the short-term effectiveness of and long-term compliance with positional therapy. Positional therapy is an effective method to treat patients with positional OSA on the short-term. Long-term compliance is low especially in patients with moderate OSA at baseline. More comfortable devices such as vibrating devices might be more useful to treat positional OSA.

When using this definition about half of all patients with OSA have positional OSA,¹⁰ while in patients with mild (AHI 5–15 events/h) to moderate (AHI 15–30 events/h) OSA this percentage is even higher.¹⁰ When using a more stringent definition, requiring an AHI that normalizes (AHI < 5 events/h) in the non-supine posture, prevalence is still 35%.¹¹

Throughout the years, many PT strategies have been designed to prevent patients from sleeping on their back,¹² such as

Figure 1—Werkmeister SnurkStop.

an alarm system,¹³ a backpack with ball,¹⁴ behavioral therapy,¹⁵ a pillow with straps,¹⁶ the so-called tennis ball technique,^{17,18} a recently developed neck-worn vibrating device,^{19,20} and a chest-worn vibrating device.^{21,22}

Oksenberg and Gadoth²³ argue that PT might be a simple solution for patients with mild to moderate positional OSA. While most devices appear effective in the beginning and compliance on a short-term (< 3 months) seems satisfactory, long-term (> 6 months) efficacy is unknown and compliance is poor.²⁴ To date most studies have a short follow-up period and in general small patient samples. Furthermore, in most studies the devices are supplied to selected patients as a secondary treatment option when continuous positive airway pressure (CPAP) and oral appliance therapy have failed.

To our knowledge this is the largest study to date to assess effectiveness and long-term compliance of PT as a primary treatment option in patients with different severities of positional OSA. In this observational study both a commercial fabricated waistband and self-made constructions mimicking the tennis ball technique were assessed.

METHODS

This study is a retrospective observational study. Data were collected based on patient files. Therefore, there is no control group and no sample size calculation was performed. Patients were seen by a nurse practitioner at the outpatient clinic, and had follow-up visits scheduled based on usual care. The (telephone) visits followed a semi-structured protocol using structured and predefined questions including questions about the clinical status of the patient and treatment compliance.

Patients and Treatment

Patients suspected of having OSA were referred to the University Sleep Apnea Center (USAC) Groningen, University Medical Center Groningen (UMCG), Groningen, the Netherlands. All patients diagnosed with positional OSA during an overnight polygraphic or polysomnographic evaluation received information about the possible treatment modalities (PT, oral appliance therapy, CPAP or surgery if indicated). It was up to the patient which treatment option to use. When patients chose to start with PT, they were given information about the commercial waistband (Werkmeister SnurkStop, Soft Medic Veendam, the

Netherlands, **Figure 1**). As costs for the commercial waistband are not reimbursed by the health insurance companies, patients were allowed to make a self-made construction (tennis ball or other stiff product sewn into the backside of a shirt or pyjamas). All devices mimicked the so-called tennis ball technique.

A second group consisting of patients who failed on CPAP or oral appliance therapy, and had positional OSA based on their diagnostic sleep study, were advised to use PT afterwards. Patients with known significant cardiovascular diseases (heart failure, coronary disease, or severe cardiac arrhythmias) were excluded from PT as primary treatment option and received CPAP therapy.

Measurements

OSA was diagnosed by polygraphy (PG) (Embletta-GOLD Medcare) or polysomnography (PSG) (Vitaport-4 PSG, Temec Instruments BV, Kerkrade, the Netherlands) during overnight home-based monitoring. Follow-up measurement under treatment was performed by PG.

During PSG, 6-channel surface electroencephalography, left and right electrooculography, and submental electromyography were used to stage sleep. Oxygen saturation was recorded with pulse oximetry. Cardiac function was monitored by electrocardiography. Oronasal airflow was recorded with a pressure cannula. Respiratory effort was monitored with thoracic and abdominal strain gauges. Electromyography of the tibialis anterior muscle was measured to screen for periodic limb movements. Body position was measured with a position meter. During PG, the same assessments were done but without the electroencephalography. Apnea was defined as a complete obstruction resulting in a cessation in airflow (reduction of airflow $\geq 90\%$) of ≥ 10 seconds. Hypopnea was defined as a substantial ($\geq 30\%$) reduction in airflow of ≥ 10 seconds when associated with oxygen desaturation ($\geq 4\%$).²⁵ Severity of OSA was classified by AHI during the poly(somno)graphic sleep study. Accordingly, patients were classified either as suffering from mild (5–15 events/h), moderate (15–30 events/h), or severe (AHI > 30 events/h) OSA.⁸ Positional OSA was defined as an AHI at least twice as high in supine position as in other positions (usually lateral position).^{9,10}

A follow-up polygraphic evaluation (PG) under treatment was performed to assess the effectiveness of PT, including differences between baseline and follow-up percentages in supine position, AHI, minimal oxygen saturation, and maximal duration of apnoeic events. The sleep physicians scoring the PGs were not blinded on which therapy the patient was using as the sleep study was part of usual care. EDS was measured with the Epworth Sleepiness Scale (ESS), a questionnaire filled in by the patient, which assesses the propensity to fall asleep in eight different situations. ESS was scored both at baseline and follow-up.

Treatment was considered successful when AHI was < 5 events/h or reduced $\geq 50\%$ from the baseline value to an absolute value < 20 events/h in patients without subjective OSA symptoms.²⁶ Patients were routinely contacted by the nurse practitioner about their clinical status and their compliance with the treatment. We considered 3 months results as short-term and results after 6 months as long-term.

Statistical Analysis

Descriptive statistics are presented as mean $\pm$ standard deviation or median and interquartile range (IQR) for continuous

Figure 2—Patients with positional obstructive sleep apnea syndrome.

AHI, apnea-hypopnea index; CPAP, continuous positive airway pressure; OSA, obstructive sleep apnea.

Figure 3—Patients using positional therapy.

CPAP, continuous positive airway pressure; OSA, obstructive sleep apnea.

variables (depending on the distribution of the variables). Categorical variables are presented in terms of proportions. To test for normality Kolmogorov-Smirnov tests were performed. Paired t-tests and Wilcoxon signed-rank tests were performed to assess the difference between baseline and follow-up values. Independent t-tests and Mann-Whitney U-tests were performed to assess baseline differences between groups, and to compare changes from baseline between groups. Data were analyzed with SPSS 18.0 statistical software. A value of $p < 0.05$ was considered statistically significant. As this was a retrospective observational study not deviating from standard medical care approval from the ethics committee was not obligatory. Patient confidentiality was warranted. All patients gave informed consent for using their data for this study and publication.

RESULTS

Between April 2009 and April 2011, 89 patients were diagnosed with positional OSA (Figure 2). Forty-six used PT as primary treatment option, while 43 chose a different treatment: CPAP $n = 19$, oral appliance $n = 5$, ear nose and throat surgery $n = 6$, other/no therapy $n = 13$. Seven patients used

PT as secondary treatment option after another treatment had failed (Figure 2). In total 53 patients used PT (Figure 3).

Forty patients (32 polygraphic (PG) and 8 polysomnographic (PSG) evaluations at baseline) underwent follow-up PG (20 mild, 18 moderate, 2 severe OSA; 85% men, mean age 51.1 ± 8.3 years) to assess the effectiveness of PT. The PG under treatment was scheduled in consultation with the patient with a median (IQR) time interval of 12 (9–16) weeks.

Thirteen patients had no follow-up PG: $n = 6$ cancelled the sleep study or did not show up and were lost to follow-up (4 mild, 2 moderate OSA), $n = 7$ stopped using PT before the follow-up PG (dissatisfied with PT $n = 6$, no specific reason mentioned for stopping PT $n = 1$) and received other treatment (CPAP $n = 3$; oral appliance $n = 2$, ear nose and throat surgery $n = 2$). There were no baseline differences in overall AHI, ESS score, and percentage supine position between these 13 patients and the 40 patients with follow-up PG.

Effectiveness

Table 1 shows the baseline and follow-up data and the results of the statistical analysis for the total group ($n = 40$) and for both kinds of PT (commercial waistband $n = 20$; and self-made

Table 1—Baseline and follow-up data of patients using positional therapy.

	Baseline	Follow-up			p value [‡]
	(n = 40)	Total Group (n = 40)	Commercial Device (n = 20)	Self-Made Construction (n = 20)	
BMI (kg/m ²) [*]	28.0 ± 4.1	27.9 ± 4.0	28.5 ± 4.8	27.2 ± 3.1	0.29
Analyzed time (min) [*]	452.4 ± 59.1	443.6 ± 81.2	428.6 ± 56.5	458.6 ± 99.4	0.45
Time spent in supine posture (min) [†]	155.3 (97.8–193.7)	33.5 (0.5–66.9)	30.5 (0.5–48.8)	35.6 (0.3–75.2)	< 0.001
Time spent in supine posture (%) [†]	32.4 (23.2–43.9)	8.7 (0.1–15.2)	7.0 (0.1–10.9)	9.1 (0.1–15.9)	< 0.001
Overall AHI (events/h) [†]	14.5 (10.7–19.6)	5.9 (3.1–8.5)	5.8 (3.3–7.8)	5.9 (2.5–13.5)	< 0.001
Supine AHI (events/h) [†]	38.0 (24.0–52.4)	8.5 (0–21.5)	12.0 (0–32.4)	6.3 (0–14.6)	< 0.001
Non-supine AHI (events/h) [†]	3.9 (2.2–7.1)	4.3 (1.4–8.9)	3.6 (1.2–7.0)	5.9 (1.7–17.2)	0.21
Minimal oxygen saturation (%) [†]	86 (82–87)	87 (84–89)	87 (80–89)	88 (85–90)	0.01
Maximal duration event (sec) [*]	63.0 ± 23.8	52.0 ± 25.3	50.7 ± 20.9	53.6 ± 28.7	0.02
Epworth sleepiness scale (0–24) [*]	12.2 ± 5.4	10.2 ± 5.5	9.1 ± 4.9	11.3 ± 6.0	< 0.01

The table does not include the 13 patients who started on PT but who did not have follow-up PG. Data are presented as mean ± SD or median (IQR).

^{*} Paired t-test. [†] Wilcoxon signed-rank test. [‡] Baseline vs. follow-up total group. BMI; body mass index; AHI; apnea-hypopnea index.

Table 2—Comparing the commercial device with self-made constructions.

	Commercial Device (n = 20)	Self-Made Construction (n = 20)	p value
Δ BMI (kg/m ²) [†]	0.0 (0.0–0.3)	0.0 (–0.2–0.1)	0.61
Δ Analyzed time (min) [*]	9.6 ± 53.7	8.2 ± 91.4	0.95
Δ Time spent in supine posture (min) [*]	127.5 ± 102.0	121.7 ± 95.8	0.86
Δ Time spent in supine posture (%) [*]	28.1 ± 23.0	24.7 ± 20.8	0.63
Δ Overall AHI (events/h) [†]	9.6 (5.5–11.9)	6.8 (3.2–11.3)	0.22
Δ Supine AHI (events/h) [*]	18.7 ± 30.5	27.8 ± 28.6	0.35
Δ Non-supine AHI (events/h) [†]	–1.0 (–3.0–2.4)	–0.7 (–11.3–1.2)	0.41
Δ Minimal oxygen saturation (%) [*]	–0.7 ± 6.1	–3.0 ± 4.1	0.19
Δ Maximal duration event (sec) [*]	10.8 ± 23.7	11.1 ± 31.9	0.98
Δ Epworth sleepiness scale (0–24) [*]	2.8 ± 4.1	1.3 ± 2.8	0.19

The table does not include the 13 patients who started on PT but who did not have follow-up PG. Data are presented as mean ± SD or median (IQR).

^{*} Independent t-test. [†] Mann-Whitney U-test. BMI; body mass index; AHI; apnea-hypopnea index.

construction n = 20). The cost of a commercial waistband not being reimbursed was the reason for 20 patients to make their own waistband.

PT effectively reduced the time spent in supine sleeping position from median (IQR) 155.3 (97.8–193.7) minutes at baseline to 33.5 (0.5–66.9) minutes, $p < 0.001$. At baseline all patients spent at least 30 minutes in both the supine and non-supine position. Overall AHI reduced from a median (IQR) AHI of 14.5 (10.7–19.6) events/h to 5.9 (3.1–8.5) events/h, $p < 0.001$. Baseline overall AHI was not significantly different between both groups ($p = 0.99$). Furthermore, supine AHI, maximal duration of the respiratory events, and ESS score significantly reduced when using PT (**Table 1**). Also oxygen saturation increased significantly under treatment.

PT for the short-term was successful in 27 (commercial waistband n = 14; and self-made construction n = 13) of 40 patients (68%); these 27 patients showed a reduction in AHI of $\geq 50\%$ from the baseline value to a value < 20 events/h; of these 16 patients showed an AHI < 5 events/h. Results per patient on overall AHI are shown in **Figures 4A, 4B, and 4C**. PT was comparably effective in mild (n = 20; 65% successful) and moderate OSA (n = 18; 67% successful). In severe OSA all patients (n = 2; 100% successful) were treated effectively.

In 2 patients with mild and 2 with moderate OSA, AHI worsened despite using PT. All those patients made their own PT construction, of which 3 were successful in reducing the time spent in supine position (2 completely eliminated the supine position) without leading to a reduction in AHI.

The commercial waistband and self-made constructions showed no significant difference in overall AHI reduction, median (IQR) $\Delta 9.6$ (5.5–11.9 events/h) and $\Delta 6.8$ (3.2–11.3 events/h), respectively, $p = 0.22$. Patients using the commercial waistband had larger reductions in the time spent in supine position and had larger reductions in ESS scores than patients using a self-made construction, but these differences were not significant (**Table 2**). There were no baseline differences in demographic characteristics between patients using the commercial waistband and patients using a self-made construction.

Compliance

During the first weeks compliance was considered good, as most patients used their device > 7 h/night (mean 7.2 ± 1.4) and > 6 days/week (mean 6.5 ± 1.3). However, 13 ± 5 months after starting PT, 26 patients (65%, commercial waistband n = 15, self-made construction n = 11) reported that they had stopped using PT (**Figure 3**). In mild positional OSA patients,

9 of 20 stopped, in moderate 16 out of 18, and in severe 1 of the 2 patients. Of the patients, who were effectively treated, 60% had stopped using PT, whereas of the patients not effectively treated 77% had stopped. However, this difference was not statistically significant. In total 16 patients received other treatment after PT, such as CPAP ($n = 8$), an oral appliance ($n = 4$) or ear nose and throat surgery ($n = 4$) (**Figure 3**). Two patients who initially stopped PT restarted using the device. Three patients started other treatment in addition to their PT.

DISCUSSION

To our knowledge this is the largest study to date to assess effectiveness and long-term compliance of PT (both commercial waistband and self-made constructions) as a primary treatment option in patients with different severities of positional OSA. The largest study sample so far was by Oksenberg et al. ($n = 78$).¹⁸ This was however a questionnaire study, and only 12 patients had a follow-up sleep study to assess effectiveness.

Effectiveness

Our short-term results show that PT with the so-called tennis ball technique (both commercial waistband and self-made constructions) effectively reduces the time spent in supine sleeping position in patients with positional OSA. Furthermore, AHI, severity of the respiratory events, and EDS were significantly reduced when using PT.

PT was successful in 27 of 40 patients (68%). Body mass index (BMI) was stable during treatment, which indicates that the positive findings are not the result of weight loss, but can be ascribed to PT.

In four patients, AHI worsened despite using PT. Although we saw that in three patients the self-made constructions were effective in reducing time spent in supine position, AHI was not improved, which can be ascribed to the increased number of apneas and/or hypopneas in the non-supine position during the follow-up PG. Several factors could have influenced non-supine AHI, such as alcohol use, cigarette smoking,²⁷ and medication use. Unfortunately we have no reliable data about these factors on the specific day/evening of the sleep study.

Our short-term results are in accordance with other studies assessing PT. Most studies report positive results on the time spent in supine sleeping position, severity of the respiratory events, and a significant reduction in AHI.^{14,16,18,19,21,28–30}

In our study, a commercial waistband or a self-made construction was used by patients. As far as we know, there are no other studies comparing self-made constructions with commercially fabricated devices. Although the commercial waistband showed a slightly larger reduction in overall AHI, a larger reduction in the time spent in the supine position and a larger reduction in ESS score at the follow-up PG, these differences were not statistically significant and we conclude that both types of PT can be considered equally effective.

Compliance

In our study short-term compliance was good as most patients used their device more than 7 hours/night (mean 7.2 ± 1.4) and more than 6 days/week (mean 6.5 ± 1.3). Short-term compliance was assessed subjectively which could mean

Figure 4

Dotted lines represent commercial waistbands, straight lines self-made constructions. (A) Overall apnea-hypopnea index per patient with mild obstructive sleep apnea at baseline. (B) Overall apnea-hypopnea index per patient with moderate obstructive sleep apnea at baseline. (C) Overall apnea-hypopnea index per patient with severe obstructive sleep apnea at baseline.

that treatment use was over- or underestimated. Though, our results are comparable with the compliance rates reported by Heinzer et al.²⁸ who assessed compliance with their device objectively by placing an actigraphic recorder inside. Long-term results regarding compliance were considered disappointing,

as only 14 of 40 patients were still using their device 13 ± 5 months after starting PT. Compliance was also low in the 13 patients without follow-up PG. Of these 13 patients, 7 stopped using PT before the follow-up PG. This means that in total, 33 of the initial 53 patients (62%) who started PT stopped using this treatment modality.

This was particularly notable in patients with moderate positional OSA at baseline, as 16 of 18 patients (89%) stopped using PT. Patients were classified as “moderate” due to the fact that they spent more time in supine sleeping position, thereby increasing the overall AHI. Despite PT effectively correcting supine sleeping position for both mild and moderate OSA groups, residual overall AHI (due to an increase in the non-supine component of the AHI) stayed higher at follow-up only in patients with initial moderate OSA. Factors other than position might have influenced AHI, such as anatomical factors or a central component of the apneas and/or hypopneas. Sleep endoscopy is not a standard procedure for these patients in our medical center. Therefore, we cannot confirm anatomical differences between patients with initial mild and moderate positional OSA. Finally, it is possible that patients experienced insufficient reduction in AHI to feel better, resulting in the higher percentage of compliance failures in patients with moderate positional OSA.

It could be expected that successful treatment increases compliance. This was, however, not the case in our study, as 60% of patients who were successfully treated, stopped using PT. Apparently, compliance is independent of treatment effectiveness; more behavioral factors and comfort might play an important role in continued PT use.

While short-term non-compliance with therapy is a common and well-known problem, as with CPAP, there is little known about long-term compliance with PT. Bignold et al.²⁴ assessed long-term compliance with the tennis ball technique through a questionnaire study. They found that compliance after 2.5 ± 0 years was poor, as 81% of the patients no longer used the device. However, as a large proportion did not return the questionnaire (non-responders) there is a possible responder bias. In the study by Oksenberg et al.,¹⁸ 62% of the patients stopped using the device. Also in this study a large proportion of the patients did not respond (36%) to the questionnaire.

Van Maanen et al.¹⁹ tried to develop a more comfortable device not disturbing sleep architecture and sleep quality. However, the total sleep time of the patients significantly decreased when using the neck-worn vibrating device. Furthermore, the number of awakenings increased and sleep efficiency decreased with the particular device. Compliance was unfortunately not assessed in this study. In another study by van Maanen et al.,²¹ compliance with a chest-worn vibrating device was very high with 92.7% after 29 ± 2 days of usage. After 6 months, compliance was 64.4%.²² This type of device, a chest- or neck-worn vibrator, could be a solution for positional OSA as this device might be more comfortable to wear than a device using the tennis ball technique. Compliance with PT using the tennis ball technique could, for example, be limited as a result of the bulkiness of the device resulting in back pain and discomfort, which could lead to disruption of sleep and low sleep quality.

A weakness of the present study is that PG was used at follow-up instead of PSG, and we cannot state with certainty if

the patients were sleeping or not. However, in our study, analyzed bedtime remained unchanged, indicating that all parameters were assessed during the same length of time with and without the device. In future studies it would be preferred to use PSG for both baseline and follow-up measurement to compare sleep quality with and without therapy.

Unfortunately, 13 patients did not undergo follow-up PG, and therefore we cannot compare effectiveness in these patients with the patients who did attend their follow-up sleep study. This possible responder bias could have influenced our results, but it is unlikely that these patients react differently in terms of AHI reduction compared to the patients who underwent follow-up PG.

In conclusion, this study shows that on the short-term PT (both self-made construction and commercial band), is an easy and effective method in most patients with positional OSA. However, as long-term compliance is low, close follow-up of patients with regard to their compliance is necessary, especially in patients with moderate-to-severe OSA, as these patients are more prone to stop using PT. Otherwise, PT using the tennis ball technique might not be the best solution in treating patients with OSA.

More comfortable devices such as vibrating devices might be more useful in the treatment of positional OSA, but long-term compliance and effectiveness of these devices is unknown. As it was stressed recently,³¹ high-quality long-term research on this topic is needed as PT still provides a promising treatment option.

ABBREVIATIONS

AASM, American Academy of Sleep Medicine
 AHI, apnea-hypopnea index
 BMI, body mass index
 CPAP, continuous positive airway pressure
 EDS, excessive daytime sleepiness
 ESS, Epworth Sleepiness Scale
 IQR, interquartile range
 OSA, obstructive sleep apnea
 OSAS, obstructive sleep apnea syndrome
 PG, polygraphy
 PSG, polysomnography
 PT, positional therapy

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