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ORIGINAL ARTICLE

A comparative study of a single-incision sling and a transobturator sling: clinical efficacy and urodynamic changes

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Abstract
Introduction In this retrospective study, a comparison is made of the clinical efficacy of two stress urinary incontinence treatment apparatuses, a single-incision sling and a transobturator sling.
Methods Eighty-five (single-incision n=43, transobturator n=42) consecutive patients were included in this study. Clinical outcomes were assessed by the cough stress test (CST), the pad test, the Impact Questionnaire-Short Form (IIQ-7), the Urogenital Distress Inventory six-item questionnaire (UDI-6), the Sexual Questionnaire-SF (PIS-Q), the pain score, and the postoperative changes in urodynamic parameters. A comparison of the 1-year follow-up data is presented.
Results Three months post-surgery, 81.8% of the single-incision sling group and 74.4% of the transobturator sling group had a negative cough test and a dry pad test. One year after surgery, significantly decreasing UDI-6, IIQ-7, and increasing PIS-Q scores were observed in both groups, while the complication rates remained similar. Postoperatively, the single-incision sling group seems to show a greater improvement in UDI-6 score, require less operation time, and experience less blood loss, less postoperative pain, and a smaller decrease in maximal urethral closure pressure (MUCP).
Conclusions These results suggest that the single-incision sling and the transobturator sling are equally as effective and safe for the treatment of stress incontinence, as evaluated during the 1-year follow-up. The insertion of a single-incision sling seems to be less painful than that of a conventional sling. One year after surgery, the MUCP and mean flow rate of the transobturator sling group had significantly decreased compared with that of the single-incision sling group.

Keywords Comparison · MiniArc · TVT-O · Efficacy · Urodynamic

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Introduction

The tension-free vaginal tape (TVT) procedure is the first generation of modern incontinence treatments that uses minimally invasive mid-urethra tape, as described by Ulmsten and Petros [1]. The long-term results are good, and registries showing low rates of complications have been established [2]. Further developments in the obturator route have resulted in second-generation mid-urethra tape placement to address the postoperative bowel, bladder, and major blood vessel injuries observed in many case reports [3, 4]. While these techniques are equally as effective in the treatment of stress urinary incontinence (SUI), the transobturator route appears safer than the classic retropubic route [5, 6].

The MiniArc single-incision sling is the third generation of the mid-urethral sling (MUSs) for female SUI, which uses a single-incision vaginal approach and self-fixating tape with anchoring tips that causes tension in the internal obturator muscles. The objective cure rate of MiniArc is described in the literature as being 90.6% after 1 year, comparable with the results for conventional mid-urethral tape [7]. Owing to its shorter insertion trajectory, it is expected to reduce complications such as bladder perforation, vascular injuries, and perineal fasciitis, as well as postoperative pain in the region of the adductor muscles [8]. However, there have been very few reports of the postoperative effects of these tense mini-tapes on the clinical outcomes and urodynamic changes. To date, sparse published data exist to support the use of the MiniArc MUS in the place of alternative, commercially available MUSs.

The aim of this retrospective study is to observe and compare the clinical outcomes between the established transobturator procedure (TVT-O) and the innovative Mini-Arc technique, characterized by the single incision and lower tension of the mid-urethral tape, with a focus on efficacy, complications, urodynamic changes, and quality of life, measured both qualitatively (Urogenital Distress Inventory-Short Form, Incontinence Impact Questionnaire-Short Form, and the Sexual Questionnaire-SF: PIS-Q short form measurements) and quantitatively (1-h pad weight test and the cough stress test).

Materials and methods

We enrolled consecutive patients with clinically and urodynamically proven SUI between January 2010 and December 2011. The two slings investigated in the study were available in Changhua Christian Hospital, a tertiary medical center situated in central Taiwan. All patients received the sling procedure only. As the MiniArc device is not yet covered by the Bureau of National Health Insurance in Taiwan, patients who underwent a MiniArc procedure signed an agreement of extra payment after the possible benefits of a smaller wound site and reduced pain and tissue injury had been explained to them. No recommendations for the MiniArc were given based on the patients' medical or physical conditions, including age, severity of incontinence, bodyweight, and medical history; thus, their selection for the MiniArc was entirely based on personal preference for the benefits of the single-incision sling. Therefore, no bias was created in the make-up of the study groups. Patients who had a neurogenic bladder, detrusor overactivity, concomitant surgical procedure, or loss of follow-up, were excluded.

All of the surgical procedures were performed by one senior urogynecologist with adequate experience of sling surgery (having performed more than 20 MiniArc slings and over 300 TVT-O slings) to avoid inter-surgeon variation. All of the procedures were performed in the modified dorsal lithotomy position. All of the patients were given preoperative broad-spectrum intravenous antibiotics and were operated on under intravenous general anesthesia.

The TVT-O was inserted according to De Leval [9], and the MiniArc was inserted according to the original description [10] to ensure pillow-effect tension. Cystoscopy was performed on each patient following sling insertion to verify the absence of bladder injury. A urinary catheter was inserted before the sling implantation and removed on the day after surgery. The postvoid residual was then measured before the patient was discharged from hospital. In cases of voiding difficulty (i.e., >100 mL residual urine), hospitalization was prolonged until a postvoid residual less than 100 mL was obtained.

Preoperative evaluations included a detailed history, physical examination, Q-tip test, cough stress test, and a 1-h pad test; preoperative urodynamic studies included uroflowmetry, static and dynamic urethral pressure profiles, urethrocystometry, and postvoid residual (PVR), measured using a bladder scan. Before intervention, and at the 3-month postoperative follow-up, the patients completed two validated quality-of-life questionnaires, the Urogenital Distress Inventory six-item questionnaire (UDI-6) and the Incontinence Impact seven-item short form Questionnaire (IIQ-7) [11]. The IIQ-7 and UDI-6 were scored according to the established protocols. The mean values for all completed IIQ and UDI items (range 0–3) were calculated. The Sexual Questionnaire-SF (PIS-Q short form [12]), limited to five questions, was only completed by patients with sexual activity.

Postoperative follow-up visits were scheduled at 1 week, and 3, 6, 12, and 24 months. Charts produced from the study were reviewed both subjectively and objectively, including the need for urgent medication, urinary retention, and other perioperative complications. Uroflowmetry, PVR, a 1-h pad test, and cough provocation tests were performed postoperatively at 3 months. Patients were defined as "objectively cured" when they had both negative cough stress test and dry pad test results. After 3 months, the subjective outcomes were collected via telephone interviews by an experienced nurse using the UDI-6, IIQ-7, and PIS-Q questionnaires. Patients were defined as "subjectively cured" when they responded negatively to the third question on the UDI-6. On the operation day and the following day, subjects were asked by the study coordinator to rate their pain on a ten-point numeric pain scale and describe their use of pain medication over the previous 24 h.

Statistical analysis was performed using the Student's *t* test for parametric and nonparametric continuous variables, and the Wilcoxon signed rank test or Fisher's exact test for the categorical variables. A p value of less than 0.05 was considered statistically significant.

In this study, the methods, definitions, and units used conform to the standards jointly recommended by the International Urogynecological Association (IUGA) and the International Continence Society (ICS), except where specifically noted [13]. The complications are described according to IUGA/ICS terminology and classification [14].

Results

Ninety patients were included in this study, 5 (3 TVT-O, 2 MiniArc) of which were excluded subsequently owing to a loss of follow-up data. The basic background of the study subjects is shown in Table 1. Forty-three patients underwent a MiniArc sling procedure, and 42 underwent a TVT-O sling procedure. The two groups are comparable with regard to age, parity, body weight index (BMI), history of previous hysterectomy and incontinence operation, 1-h pad test, IIQ-7, UDI-6, PIS-Q and follow-up period (Table 1).

There were few complications in either group (Table 2), with no occurrence of any major intraoperative complication (bladder and urethra injury, bleeding >500 ml, nerve lesions), immediate postoperative urinary retention (residual urine volume >100 ml over 24 h), prolonged urinary retention requiring sling release, de novo dyspareunia, or tape exposure. At 1-year post-surgery, only 2 patients in the TVT-O group and 1 in the MiniArc group had slight de novo urgency with an UDI-6 score of 1.

There were significant differences in operation time and blood loss between the two groups: the MiniArc group had a shorter operation time and less blood loss ($P<0.05$). In addition, a lower pain score ($P<0.05$) was noted in the MiniArc group on the second postoperative day (Table 3).

Table 1 Comparison of baseline patient characteristics

	TVT-O (n=42)	MiniArc (n=43)	P
Age (years) mean ± SD	54.4±10.7	55.0±9.7	0.766
BMI (kg/h^2) mean ± SD	26.5±4.1	24.6±3.1	0.015
Parity mean ± SD	3.2±1.3	3.1±1.2	0.621
Prior hysterectomy n (%)	12 (26.7)	7 (15.9)	0.216
Prior incontinence procedure n (%)	5 (11.1)	4 (9.1)	1.000
Intrinsic sphincter deficiency n (%)	2 (4.76)	3 (6.98)	0.998
1-h pad test (g)	18.4±15.8	22.9±19.4	0.239
Mean period of follow up (months)	13.5±8.9	13.1±7.5	0.823

Intrinsic sphincter deficiency: maximum urethral closure pressure <20 cm H_2O or Valsalva leak point pressure <60 cm H_2O

The objective cure rate (negative cough test and dry pad test) was not significantly different (TVT-O 74.4% vs MiniArc 81.8%, P=0.607). Subjective outcomes were recorded 3 months postsurgery and during the most recent postoperative telephone interview (mean follow-up 13.1±7.5 months in MiniArc, 13.5±8.9 in TVT-O; Table 4). The Median Urogenital Distress Inventory-Short Form and the Incontinence Impact Questionnaire-Short Form scores showed statistically significant improvements ($P<0.001$) in both groups. The MiniArc group had a lower UDI-6 score than the TVT-O group at both the 3-month and 1-year follow-up ($P<0.001$). The subjective efficacy rate was determined by patient responses to the UDI-6 question #3, "Do you experience urine leakage related to physical activity, coughing, or sneezing?" No statistically significant difference was noted between the TVT-O and MiniArc group at the 3-month (80.0%, 88.6% respectively) and 1-year follow-up (71.4%, 81.8% respectively).

The UDI-6 subscores for urge (Q2), stress (Q3), and obstructive symptoms (Q5) indicated significant improvements ($P<0.05$) in both groups at 1 year after treatment. Using a score of 2 or 3 to define symptomatic conditions, we found that the percentage of patients with urge incontinence decreased from 60.5 to 4.8% and 46.5 to 0% for the TVT-O and MiniArc groups respectively; 24 of the 26 TVT-O group patients with pre-treatment urge incontinence with a pre-treatment score of 2 or 3 had resolved urge leakage post-treatment with a score of 0 or 1, while all 20 patients of the MiniArc group with pre-treatment urge incontinence had similar improvement post-treatment. On the other hand, none of the patients in either group went from a score of 0 or 1 to 2 or 3. Patients with stress incontinence decreased from 100 to 7.1%, and 100 to 0% in the TVT-O and MiniArc groups respectively, and those with obstructive symptoms decreased from 14 to 7.1%, and 7.0 to 0% respectively. However, no significant difference in improvements was found between the two groups.

The preoperative and postoperative urodynamic changes (Table 5) revealed a statistically significant decrease in the maximal flow rate (MAX) in the TVT-O group, and in the average flow rate (AVG) in both groups ($P<0.05$). More importantly, there was a decrease in the maximal urethral closure pressure (MUCP) in both groups, but only the TVT-O group revealed a statistically significant decrease, while the MiniArc group did not.

Discussion

Mid-urethral slings result in bothersome complications that should not be overlooked. The complication rates ranged from 4.3 to 75.1% for retropubic and 10.5–31.3% for transobturator mid-urethral slings, including bladder perforation,

Table 2 Comparison of operative and postoperative complications

	TVT-O (n=42)			MiniArc (n=43)		
	Intra and postoperative immediate	Postoperative 3 months	Postoperative 1 year	Intra- and postoperative immediate	Postoperative 3 months	Postoperative 1 year
Urinary tract infection	6.8%	0	0	4.5%	0	0
Pain (VAS>3 day 1 or day 2)	0	0	0	0	0	0
Urinary retention	0	0	0	0	0	0
De novo urgency, n (%)	0	2 (4.8)	2 (4.8)	0	2 (4.7)	1 (2.3)
Bladder perforation	0			0		
Urethra injury	0			0		
De novo dyspareunia (n=23)		0	0		0	0
Tape exposure		0	0		0	0

No significant difference in complications between the two groups (p>0.05)

hemorrhage, bowel injury, vaginal extrusion, de novo urgency and urge incontinence, urinary tract infections, and voiding dysfunction [15].

In order to avoid complications due to blind needle passage through the retropubic space (TVT sling) or transobturator foramen (TOT), new single-incision slings were introduced, aiming to obtain the same suburethral support with less invasivity and anchor the two arms in the obturator internus muscle while avoiding passage through the obturator foramen. The following improvements are possible: eliminate external incisions, eliminate mesh lateral to the obturator, reduce anesthesia use, further reduce the procedure time, and allow patients a quicker return to normal activities.

Unlike retropubic or transobturator slings, the MiniArc is a mini-sling that requires tension, causing the sling to lie directly against the urethra with no intervening space. The first evaluation of the recent literature shows equal cure rates, and fewer complications with the use of mini-slings. Two years' follow-up of the MiniArc system indicate that 82–93% of subjects were continent [16], with no severe side effects.

Table 3 Comparison of operation blood loss, time and postoperative pain score

	TVT-O	MiniArc	P value
Operation blood loss	45.4±96.6	13.6±26.1	0.040
Operation time (min)	32.7±43.9	15.3±13.2	0.010
Pain score, operation day (day 1)	1.7±0.6	1.6±1.0	0.484
Pain score, 1 day post-operation (day 2)	1.2±0.6	0.7±0.7	0.003

Pain score: ten-point numeric scale recorded by the nurse

Comparisons between the conventional MUS and Mini-Arc are still sparse. In order to focus on the outcomes and safety of the sling alone, combined operations or concomitant procedures were excluded from this study.

The evidence of the equivalent effectiveness of TOT and TVT-O is established over the short term. Bladder injuries and voiding difficulties appear less prevalent when using inside-out tapes, based on an indirect comparison [17]. The inside-out transobturator sling TVT-O was chosen as the standard device because of its resemblance to the Mini-Arc techniques. The results of our retrospective study indicated an objective cure rate of 81.8% for the Mini-Arc group as measured by the negative cough and dry pad test 3 months post-operation. Personal and highly subjective patient satisfaction after urinary incontinence surgery indicated a subjective cure rate of over 80% (88.6% at 3 months, 81.8% at 1 year). These cure rates were slightly lower than those observed in other studies, which may be due to the more rigorous definition of subjective cure used in this study: an answer of "no" is required for Q3 of the UDI-6 questionnaire, while other studies have used a score of 0 or 1 to indicate subjective cure. Nevertheless, postoperative cure rates indicated a significant improvement in our patients' quality of life, as determined by three validated questionnaires, the IIQ-7, UDI-6, and PIS-Q, at a mean follow-up of 13.1±7.5 months, confirming good short-term results with mini-sling systems comparable to that of the conventional systems using transobturator tape. Our results were also comparable with the results of De Ridder et al., who compared the Mini-Arc (n=75) with the Monarc (American Medical Systems, Minnetonka, MN, USA; n=56) in a retrospective study that showed an 85% objective cure rate at 13 months for both MUSs [8]. Although the patients completed a mean follow-up of 13 months, a longer term follow-

Table 4 Comparison of objective and subjective outcomes pre-operation, and 3 months and 1 year post-operation

	TVT-O				MiniArc			
	Preoperatively *n*=42	Postoperatively 3 months *n*=42	Postoperatively 1 year *n*=42	*P*	Preoperatively *n*=43	Postoperatively 3 months *n*=43	Postoperatively 1 year *n*=43	*P*
1- h pad test (g)	18.4±15.8	2.0±6.2 (*n*=27)	–	<0.001	22.9±19.4	1.9±8.4 (*n*=28)	–	<0.001
Negative stress test	0	74.4% (*n*=27)	–	<0.001	0	81.8% (*n*=28)	–	<0.001
UDI-6 Q3 answer is "No"	0%	80.0%	71.4%	<0.001	0%	88.6%	81.8%	<0.001
IIQ-7 (mean ± SD)	49.8±28.1	6.5±17.4	8.0±19.7	<0.001	60.6±19.2	4.7±12.0	6.7±13.0	<0.001
UDI-6 (mean ± SD)	52.4±2.5	13.8±17.7	14.4±19.5	<0.001	50.6±16.2	7.1±10.0**	7.7±10.2**	<0.001
PISQ (mean ± SD)	33.0±8.0 (*n*=33)	35.9±8.0 (*n*=27)	37.3±7.9 (*n*=29)	0.001	34.7±5.0 (*n*=24)	39.5±2.1 (*n*=28)	39.4±1.9 (*n*=18)	0.005

UDI- 6 Urogenital Distress Inventory Q3: UDI-6 question #3, "Do you experience urine leakage related to physical activity, coughing, or sneezing?"; *IIQ- 7* Impact Questionnaire; *PISQ* sexual questionnaire-SF, short form, limited to five questions, only for patients with sexual activity

*Intra-group analysis of preoperatively vs 3 months and 1 year postoperatively

**Significantly different between the two groups ($P<0.01$)

up is needed to determine the durability of the procedure's outcome.

Urinary incontinence surgery with a mini-sling system is not free of complications. Alvarez-Bandrés et al. found a complication rate of 20% (22% TVT-Secur, 17% MiniArc), although most of the complications were mild and could be successfully treated conservatively [18].

Adverse events were relatively uncommon in both of our groups, with little blood loss and no bladder or urethra injury, hematoma, or vaginal erosions. There were no episodes of urinary retention in either group immediately post-surgery or in the long-term follow-ups. In addition, the 3-month postoperative uroflowmetry showed a significant decrease in the average flow rate in both groups, while the TVT-O revealed a more significant decrease in the maximal flow rate ($P<0.05$). De novo urgency showed a wide variation of 0–36%. High de novo urgency (over 30%) was reported by Gauruder-Burmester [19], while only 6.45% was reported by Alvarez-Bandrés et al. [18]. In this study, only a very few of such cases (<5%) occurred in both groups. Placing the sling correctly in the mid-urethra right position rather than in the proximal urethra by an experienced surgeon may avoid urinary retention and de novo urgency.

Another possible advantage of a minimally invasive approach could be the reduced risk of postoperative groin pain due to transobturator passage. Laurikainen et al. reported significant groin pain in 16% of patients ($n=131$) following an inside-to-outside transobturator sling procedure [20]. Groin pain after a TVT-O procedure can occur, but in most cases disappears within 4 weeks. Persistent groin pain is extremely rare and there is a lack of literature on the diagnosis and management of this adverse event [21]. Owing to the shorter insertion trajectory, thereby eliminating the tape lateral to the obturator and the external incisions, the visual analog scale pain scores of the MiniArc were significantly lower than those for the TVT-O on the day following surgery ($P<0.05$) in our study. A larger study is needed to validate these significant differences.

Table 5 Comparison of urodynamic parameter changes pre-operation and post-operation

	TVT-O			MiniArc		
	Preoperatively, *n*=42	Postoperatively 3 months, *n*=27	*P* value	Preoperatively, *n*=43	Postoperatively, 3 months, *n*=28	*P* value
MAX (ml/s)	20.9±9.2	17.8±6.3	0.037	18.2±7.1	17.5±6.8	0.187
AVG (ml/s)	10.5±4.5	8.3±3.2	0.003	10.0±3.9	8.4±3.7	0.017
VVOL (ml)	283.8±147.0	251.6±114.3	0.121	278.9±151.5	302.5±142.2	0.543
PVR (ml)	38.0±45.2	40.0±61.0	0.630	32.0±62.2	25.4±39.4	0.766
MUCP (cm H_2O)	59.5±27.5	48.1±19.9	0.028	64.6±29.4	58.7±28.0	0.699

MAX maximal flow rate; *AVG* average flow rate; *VVOL* total voiding volume; *PVR* postvoid residual volume; *MUCP* maximum urethral closure pressure

Urodynamics testing is often performed to assess postoperative failure; it is rarely performed in the setting of postoperative success. Postsurgical urodynamic evaluation can measure alterations in bladder storage and voiding function, and may provide insights into the urodynamic parameters associated with surgical success, failure, and complications. Analysis of urodynamic parameters after SUI surgery, with a stratification of the data based on the outcome's success or failure, may help to clarify which urodynamic parameter(s), if any, are associated with continence. Prior studies on urodynamic changes following SUI surgery are limited by a small single-institution case series, as well as a lack of standardization of the urodynamic protocols, surgical procedures, and outcome measures. Investigators have measured increased urethral resistance after successful Burch colposuspension while observing no such change in the Burch failure group [22]. After pubovaginal sling insertion, some investigators have reported decreased non-invasive urine flow rates and elevated residual urine volume and detrusor pressure at the maximum flow rate, whereas others have observed no significant changes in these variables post-sling insertion [23–25].

Comparing the two inside-out procedures, the tension-free TVT-O resulted in a more significant decrease in the maximal and average flow rates than the shorter tension-sling MiniArc, even though none of the patients experienced urinary retention immediately or 1 year after the operation. Urethral pressure measurements, including the measurement of the maximum urethral closure pressure (MUCP), have been investigated prior to SUI surgery. Some studies have suggested that women with higher MUCP may have a better surgical outcome. Most of the data demonstrate that women with higher preoperative MUCP do not have a better surgical outcome following stress incontinence surgery [25]. Multiple regression analysis shows that previous hysterectomy, anti-incontinence surgery, and old age were risk factors for lower MUCP in women with mixed urinary incontinence and detrusor over-activity incontinence [25, 26]. Only a few studies have identified the changes in MUCP post-sling insertion. The results of Martan's study [27] imply that the tape in a TVT operation, if properly placed and relatively slack, changes the MUCP neither at rest nor at Valsalva. The operation slightly shortens the functional urethral length at rest and causes a minor shift in the MUCP, pointing to the outer urethral orifice. Other investigators found a slight increase in the MUCP [28] post-sling insertion. In this study, compared with the preoperative measures, the postoperative MUCP decreased significantly in the TVT-O group ($P<0.05$), which is consistent with another study that found lower MUCP in women who had undergone anti-incontinence surgery [26]. In contrast, no significant decrease was observed in the MiniArc group ($P=0.699$). The less invasive nature of the MiniArc, which has a pillow-effect tape tension in the urethra, may explain this sustained postoperative MUCP. This implies another potential advantage of the MiniArc over conventional SUI surgery; a lower decrease in the MUCP may preserve urethral continence function and prevent recurrent incontinence. More cases and longer follow-ups are needed to validate the clinical impacts of these important findings about MUCP changes.

This study has some limitations. First, since patients who underwent MiniArc surgery could be identified from their self-payment for the treatment, the enrolled subjects were not randomized in a double-blinded, random fashion that would ensure an unbiased study design. This methodology is used because the group assignment is dependent on the patients' preference for the MiniArc procedure, even though they incurred extra costs not covered by insurance; thus, a completely randomized group assignment was unattainable without MiniArc being covered by the Bureau of National Health Insurance in Taiwan. However, the patients' health-related characteristics were randomized; no bias was present based on their age, medical history, body weight, incontinence severity, etc.

Second, ethics approval does not apply because this was a retrospective study that was aimed at comparing clinical outcomes. The MiniArc device has been approved for urinary incontinence treatment by the National Department of Health since September 2008; thus, it can be freely selected for use in Taiwan, just like TVT-O. Thus, this study is a clinical retrospective audit for the evaluation of the safety and efficiency of the two different incontinence surgeries, and so no ethics approval was required.

In addition, with the follow-up period set at 1 year, this study does not present a long-term comparison or the implications of the different surgical techniques. Further investigation using more cases and longer follow-ups is needed to validate the findings of the present study and determine if the postoperative improvements extend beyond the 1-year follow-up.

Conclusions

Based on the objective and subjective measures observed in this 1-year study, both surgical techniques appear to be equally as effective and safe for the treatment of SUI during the 1-year follow-up. The use of the MiniArc appears to show a greater improvement in UDI-6 score, requires a shorter operation time, and causes less blood loss, postoperative pain, and a decrease in MUCP. Thus, this study shows encouraging results for the use of the MiniArc sling as a first-line treatment for female patients with SUI.

However, further randomized, controlled trials and long-term results are still required to define the role of the new sling system in comparison to the more established mid-urethral tape techniques for treating female stress urinary incontinence.

Conflicts of interest None.

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