

## Voiding Dysfunction

# One-Year Outcomes of Mid-urethral Sling Procedures for Stress Urinary Incontinence According to Body Mass Index

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**Purpose:** The purpose of our study was to investigate the safety and efficacy of the suprapubic arch (SPARC) sling operation and the transobturator tape (MONARC) sling operation according to body mass index (BMI).

**Materials and Methods:** Between January 1, 2004, and July 12, 2009, a retrospective clinical trial was performed with 284 patients treated by the SPARC sling procedure and 49 patients treated by the MONARC sling procedure. The women were classified into 3 groups by BMI according to the WHO Expert Consultation: normal weight (A, BMI 18.5 to 22.9 kg/m<sup>2</sup>), overweight (B, BMI 23 to 27.5 kg/m<sup>2</sup>), and obese (C, BMI > 27.6 kg/m<sup>2</sup>). Patients' characteristics and clinical outcomes of the operation were analyzed according to BMI at 1 year after surgery via questionnaires and interviews with the patients about their voiding symptoms and medical records.

**Results:** There were 103 patients in group A, 186 in group B, and 34 in group C. The objective cure rates for groups A, B, and C after the SPARC procedure were 94.4%, 96.7%, and 96.8%, respectively (p=0.321), and the subjective cure rates were 94.4%, 96.1%, and 96.8%, respectively (p=0.222). The objective cure rates for groups A, B, and C after the MONARC procedure were 100.0%, 90.9%, and 66.7%, respectively (p=0.742), and the subjective cure rates were 92.3%, 93.9%, and 66.7%, respectively (p=0.779). The complication rates were similar among the three study groups.

**Conclusions:** Mid-urethral sling procedures for urinary incontinence result in similar objective and subjective cure rates and postoperative complications irrespective of BMI.

**Key Words:** Obesity; Surgery; Urinary incontinence, stress

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## INTRODUCTION

Stress urinary incontinence (SUI) is the most prevalent disease in middle-aged women, with an incidence of 30 to 50% [1]. Obesity is an important risk factor for the development of urinary incontinence at an old age in addition to vaginal delivery, a history of gynecological surgery, body mass index (BMI), menopausal status, smoking, and coffee and alcohol consumption [2,3]. Currently, obesity is not just a cosmetic problem. Obesity is an increasing health problem all over the world that affects as much as 25% of the adult population in many countries in Europe, in Australia, and in the United States [4]. The Third National Health and Nutrition Survey reported in 2001 announced

that the overall prevalence of obesity (BMI  $\geq$  25.0 kg/m<sup>2</sup>) in Korean adults is 30.6% (32.4% in men and 29.4% in women) [5]. SUI was proven to be the urinary incontinence type most closely associated with BMI [6]. Some have described the increase of intra-abdominal pressure in obese patients, and this phenomenon may stress the pelvic floor, possibly causing nerve and muscular injuries that may lead to a higher prevalence of SUI [7,8].

Although weight loss may be beneficial to obese patients with SUI, operative interventions remain the best options for definitive treatment [9]. A number of techniques for the correction of SUI have been described through the years. Since the description of the tension-free vaginal tape (TVT) procedure in 1996 [10], interest in minimally invasive tech-

niques for treating SUI and the attractiveness of such treatments to patients have led to a number of modifications of the TVT procedure, including transobturator vaginal tape (TOT) [11] and suprapubic arch sling (SPARC) [12]. This kind of surgery is generally considered to have the advantages of low morbidity, reduced costs, and shorter hospital stay [11,12]. However, there are not many large prospective series, and few studies have assessed the outcome of these procedures in obese women.

The purpose of this study was to assess the potential impact of obesity on the success rate of the MONARC and SPARC sling procedures, patient satisfaction, and complications at 1 year after surgery.

## MATERIALS AND METHODS

Between January 2004 and December 2003, 337 consecutive women who suffered from SUI underwent either the SPARC or the TOT procedure in our institute, and this study analyzed 323 of the patients who had been followed up for at least 1 year. The patients were classified into three groups by BMI according to the World Health Organization Expert Consultation: the normal-weight group (A, BMI 18.5 to 22.9 kg/m<sup>2</sup>), the overweight group (B, BMI 23 to 27.5 kg/m<sup>2</sup>), and the obese group (C, BMI > 27.6 kg/m<sup>2</sup>) [13]. The success rate of the procedures and the patients' satisfaction with the procedures were assessed after 1 year through questionnaires, interviews with the patients, and medical records. All the patients were preoperatively evaluated through the review of their medical history, physical examinations, and urinalysis and urodynamic studies including the measurement of Valsalva leak point pressure (VLPP). The severity of urinary incontinence was classified by the Stamey grade as grade I for women who lost urine only with coughing, sneezing, or lifting heavy objects; grade II for those who lost urine with minimal activities such as walking or arising from the sitting position; and grade III for those who were totally incontinent in the upright position [14]. Patients with previous failed anti-incontinence surgeries or treatments with bulking agent were also eligible for the study. Patients with mixed urinary incontinence were not excluded as far as their cystometrogram showed normal capacity, compliance, and no uninhibited contractions. Patients with obstructive, unstable bladder functions or neurogenic bladders were excluded from the study.

All surgeries were performed with the patient in the lithotomy position under general anesthesia or spinal anesthesia. After the bladder was voided by inserting a catheter, a median incision was made around 2.0 cm long along the mid-urethra from the lower portion of the external orifice of the urethra on the anterior vaginal wall, and tissue on both sides around the urethra was detached through the incision. In the SPARC procedure, 1-cm long skin incisions were made on both sides of the superior pubis, and SPARC needles were inserted so that the needle tip went through the posterior surface of the pubis and came out to the in-

cision on the anterior vaginal wall. In the MONARC procedure, an incision was made on the obturator foramen, and a tunnel was inserted through the rear side of the ischio-pubic ramus in the direction of 45° from the horizontal and vertical planes so that its end came out to the incision site on the vagina. The same method was applied to both sides so that the two needle ends were positioned in the incision sites on the anterior vaginal wall, and cystoscopy was performed to see if there was any injury in the bladder or the urethra. Tape was connected to the two needle tips, and Mayo scissors were hung on the tape so that tensile force was not applied. In this state, the tape was pulled from the outer area of the superior pubis and the obturator foramen so that it was positioned at around the mid-urethra. In cases in which no bladder perforations occurred during the operation, the catheter was removed on day 2 to 3 and self-voiding was tried. If bladder perforation occurred, the catheter was maintained for 7 to 10 days and was then removed and self-voiding was tried. If self-voiding failed or the quantity of residual was over 100 ml, intermittent self-catheterization was performed. If the symptoms were not improved even with intermittent self-catheterization, urethral dilatation was performed, or within 1 month from the surgery the tensile force of the tape was adjusted under local anesthesia. Postoperative cure or improvement was defined according to Stamey's criteria [10]. "Cure" meant a state without urinary incontinence at all; "improvement" meant a state in which no particular treatment was necessary because urinary incontinence was quite rare or the patient was highly satisfied with the outcome of the surgery; and "failure" meant a state in which the severity of urinary incontinence had not changed after surgery or the patient was not satisfied with the outcome of surgery. The objective success rate included both cure and improvement. The level of satisfaction with the outcome of surgery was graded as "satisfied," "fair," or "dissatisfied," and the subjective success rate included "satisfied" and "fair." In addition, we assessed the objective success rate and the subjective success rate in patients with mixed urinary incontinence, and investigated the safety of the SPARC procedure and the MONARC procedure by comparing the incidence of postoperative complications. The results of this study were processed statistically through independent-sample Student's t-tests and one-way analysis of variance, and statistical significance was considered if  $p < 0.05$ .

## RESULTS

The numbers of patients in the normal-weight group, overweight group, and obese group were 103, 186, and 34, respectively, and the patients' mean ages were 49.23±7.90, 50.42±8.14, and 52.15±6.53 years, respectively ( $p=0.873$ ). The mean numbers of childbirths were 2.17±0.85, 2.38±0.84, and 2.32±0.91 ( $p=0.138$ ); the patients' mean BMIs were 21.51±1.11 kg/m<sup>2</sup>, 24.8±1.24 kg/m<sup>2</sup>, and 29.64±2.17 kg/m<sup>2</sup> ( $p < 0.001$ ); the mean preoperative maximum urine flow rates were 28.88±10.99 ml/s, 30.30±9.96 ml/s, and 33.44±

**TABLE 1.** Characteristics of patients undergoing the mid-urethral sling procedure according to body mass index

Characteristics	Normal group	Overweight group	Obese group	p-value
Number	103	186	34	-
Mean age (yr)	49.23±7.90	50.42±8.14	52.15±6.53	0.156
Mean body weight (kg)	53.22±4.23	60.87±4.85	72.49±6.27	<0.001
Mean height (m)	1.57±0.05	1.57±0.05	1.56±0.46	0.455
Mean BMI (kg/m <sup>2</sup> )	21.52±1.14	24.8±1.24	29.64±2.17	<0.001
Mean parity (no.)	2.17±0.85	2.38±0.84	2.32±0.91	0.138
Mean preoperative Qmax (ml/s)	28.88±10.99	30.30±9.96	33.44±14.94	0.106
Mean preoperative residual urine (ml)	18.84±19.41	20.91±33.72	22.71±34.27	0.767
Mean preoperative VLPP (cm/H <sub>2</sub> O)	70.90±27.14	68.81±29.80	64.97±23.70	0.562
Preoperative symptom severity				0.088
Stamey grade (%)				
I	79 (76.7)	120 (64.5)	22 (64.7)	
II	22 (21.4)	58 (31.2)	11 (32.4)	
III	2 (1.9)	8 (4.3)	1 (2.9)	
Presence of cystocele	9 (8.7)	21 (11.3)	3 (8.8)	0.761
Chronic disease				
Hypertension (%)	16 (15.5)	30 (16.1)	14 (41.2)	0.002 <sup>a</sup>
DM (%)	7 (6.8)	11 (5.9)	7 (20.6)	0.012 <sup>a</sup>
Previous pelvic surgery (%)	12 (11.7)	36 (19.4)	7 (20.6)	0.149
Previous anti-incontinence surgery (%)	2 (1.9)	4 (2.2)	2 (5.9)	0.402
Type of procedure				0.283
SPARC (%)	90 (87.4)	153 (82.3)	31 (91.2)	
MONARC (%)	13 (12.6)	33 (17.7)	3 (8.8)	

BMI, body mass index; Qmax, maximum urinary flow rate; VLPP, Valsalva leakage point pressure; DM, diabetic mellitus; SPARC, suprapubic arch sling procedure; MONARC, transobturator tape procedure.

<sup>a</sup>: p < 0.05, statistically significant.

14.94 ml/s (p=0.106); and the mean preoperative VLPPs were 70.90±27.14 cm/H<sub>2</sub>O, 68.81±29.80 cm/H<sub>2</sub>O, and 64.97±23.70 cm/H<sub>2</sub>O (p=0.562). Concerning the history of hypertension and diabetes in the groups, the normal-weight, overweight, and obese groups had, respectively, 16, 30, and 14 hypertensive patients (p=0.002) and 7, 11, and 7 patients with diabetes (p=0.012). In addition, there were, respectively, 12, 36, and 7 patients with a history of pelvic surgery and 2, 4, and 2 patients with a history of surgery for urinary incontinence. When preoperative patient characteristics were compared among the groups, no statistically significant differences were observed except for the history of hypertension and diabetes (Table 1). When the postoperative objective success rate and subjective success rate were compared among the groups, the objective success rates of the sling operation were 95.1% (98/103), 95.7% (178/186), and 94.1% (32/34), respectively, in the normal-weight, overweight, and obese groups (p=0.288), and the subjective success rates were 94.2% (97/103), 95.7% (178/186), and 94.1% (32/34) (p=0.163). The objective success rates of the SPARC procedure were 94.4% (85/90), 96.7% (148/153), and 96.8% (30/31) (p=0.321), and the subjective success rates were 94.4% (85/90), 96.1% (147/153), and 96.8% (30/31) (p=0.222). The objective success rates of the MONARC procedure were, respectively, 100.0% (13/13), 90.9% (30/33), and 66.7% (2/3) (p=0.742), and the subjective success rates were 92.3% (12/13), 93.9%

(31/33), and 66.7% (2/3) (p=0.779). The differences in the success rates according to BMI were not statistically significant (Tables 2-4). In addition, 34, 70, and 16 patients in each group, respectively, had mixed incontinence and the objective success rates and subjective success rates were, respectively, 91.2% (31/34), 90.0% (63/70), and 100.0% (16/16) (p=0.183) and 91.2% (31/34), 88.6% (62/70), and 100.0% (16/16) (p=0.139). These differences among the groups were not statistically significant (Table 5).

Concerning postoperative complications, the normal-weight group had one case of bladder injury, three of acute urinary retention, and two of urinary urgency; the overweight group had one case of bladder injury, two of urinary retention, and one of urinary urgency; and the obese group had one case of urinary retention and one of urinary urgency. On the whole, no significant differences were observed in the incidence of complications among the groups (p=0.441) (Table 6).

## DISCUSSION

Obesity is a well-established risk factor for the development of SUI and may impact the voiding pattern, but the exact mechanism of this effect is not clear. Higher intra-abdominal pressure has been observed in patients with higher BMI, and this may stress the pelvic floor secondary to a chronic state of increased pressure [7]. Mommsen and

**TABLE 2.** Objective and subjective success rates after the sling operation according to BMI group

	Normal group (n=103)	Overweight group (n=186)	Obese group (n=34)	p-value
Cure rate (objective)				
Total (%)	98 (95.1)	178 (95.7)	32 (94.1)	
SPARC (%)	85 (94.4)	148 (96.7)	30 (95.8)	0.321
MONARC (%)	13 (100)	30 (90.9)	2 (66.7)	0.742
Cure rate (subjective)				
Total (%)	97 (94.2)	178 (95.7)	32 (94.1)	
SPARC (%)	85 (94.4)	147 (96.1)	30 (95.8)	0.222
MONARC (%)	12 (91.3)	31 (93.9)	2 (66.7)	0.779

BMI, body mass index; SPARC, suprapubic arch sling procedure; MONARC, transobturator tape procedure.

<sup>a</sup>: p < 0.05, statistically significant.

**TABLE 3.** Objective and subjective success rates after SPARC according to BMI group

Outcome	Normal group (n=90)	Overweight group (n=153)	Obese group (n=31)	p-value
Objective				
Success	85 (94.4)	148 (96.7)	30 (95.8)	0.321
Cure (%)	68 (75.5)	127 (83.0)	26 (83.9)	
Improvement (%)	17 (18.9)	21 (13.7)	4 (12.9)	
Failure (%)	5 (5.6)	5 (3.3)	1 (3.2)	
Subjective				
Success (%)	85 (94.4)	147 (96.1)	30 (95.8)	0.222
Satisfied (%)	62 (68.8)	118 (77.1)	26 (83.9)	
Fair (%)	23 (25.6)	29 (19.0)	4 (12.9)	
Dissatisfied (%)	5 (5.6)	6 (3.9)	1 (3.2)	

BMI, body mass index; SPARC, suprapubic arch sling procedure.

<sup>a</sup>: p < 0.05, statistically significant.

**TABLE 4.** Objective and subjective success rates after MONARC according to BMI group

Outcome	Normal group (n=13)	Overweight group (n=33)	Obese group (n=3)	p-value
Objective				
Success (%)	13 (100)	30 (90.9)	2 (66.7)	0.742
Cure (%)	8 (61.5)	24 (72.7)	1 (33.3)	
Improvement (%)	5 (38.5)	6 (18.2)	1 (33.3)	
Failure (%)	0	3 (9.1)	1 (33.3)	
Subjective				
Success (%)	12 (91.3)	31 (93.9)	2 (66.7)	0.779
Satisfied (%)	9 (69.2)	22 (66.7)	1 (33.3)	
Fair (%)	3 (23.1)	9 (27.2)	1 (33.3)	
Dissatisfied (%)	1 (7.7)	2 (6.1)	1 (33.3)	

BMI, body mass index; MONARC, transobturator tape procedure.

<sup>a</sup>: p < 0.05, statistically significant.

Foldspang investigated 2,589 women aged 30 to 59 years and reported that, independently of other risk factors, BMI and the incidence of urinary incontinence in women were positively correlated with each other and, among the types of urinary incontinence, BMI was most closely related to SUI [15]. Increased intra-abdominal pressure elevates pressure at the maximum cystometric capacity and decreases cough pressure transmission from the bladder to the urethra, in addition to decreasing VLPP, which may

contribute to the development of SUI in obese patients [16]. On the other hand, obesity-induced neurogenic effects on the pelvic floor may also contribute to the development of urgency or urge incontinence [16]. However, in our data, we found no significant differences in VLPP, the grade of SUI, and urgency and urge incontinence. The results of a study of a Korean population by Ku et al. [17] agree with our data. We believe that obesity was defined by a BMI of 30 or higher in the Western population studied in the pre-

**TABLE 5.** Objective and subjective success rates in patients with mixed urinary incontinence patients according to BMI group

Operation	Outcome	Normal group (n=34)	Overweight group (n=70)	Obese group (n=16)	p-value
SPARC+MONARC	Success (%)	31 (91.2)	63 (90.0)	16 (100.0)	0.183
	Satisfaction (%)	31 (91.2)	62 (88.6)	16 (100.0)	0.139
SPARC	Success (%)	26 (89.7)	51 (91.1)	15 (100.0)	0.291
	Satisfaction (%)	58 (95.1)	50 (89.3)	15 (100.0)	0.189
MONARC	Success (%)	5 (100.0)	12 (85.7)	1 (100.0)	0.733
	Satisfaction (%)	4 (80.0)	12 (85.7)	1 (100.0)	0.539

BMI, body mass index; SPARC, suprapubic arch sling procedure; MONARC, transobturator tape procedure.

<sup>a</sup>: p < 0.05, statistically significant.

**TABLE 6.** Postoperative complications according to BMI group

Complications	Normal group (n=103)	Overweight group (n=186)	Obese group (n=34)	p-value
Bladder perforation	1	1	0	
Urinary retention	3	2	1	
Urinary urgency	2	1	1	
Bleeding	0	0	0	
Vaginal erosion	0	0	0	
Total (%)	6 (3.9)	4 (2.2)	2 (5.9)	0.441

BMI, body mass index.

<sup>a</sup>: p < 0.05, statistically significant.

vious report, and this may make a difference in the results.

The treatments of SUI are largely divided into non-surgical and surgical treatments. Nonsurgical treatments include drug therapy and physical therapies such as pelvic floor exercise, biofeedback therapy, and electrical stimulation therapy. These treatments are applicable when symptoms are mild or the patient cannot endure surgery and are less invasive and less costly than surgical ones. However, these treatments have a low cure rate and require the patient's high compliance and, in this sense, their expected effect is lower than that of surgical treatments. For this reason, surgical treatments are commonly used for SUI. It is generally known that, for obese patients, surgery through the incision of the abdominal pelvic part increases the incidence of complications and is difficult to perform [18,19]. This is also the case in surgical treatment for obese women with SUI. For example, Burch vaginal suspension and Marshall-Marchetti-Krantz cystourethropexy are invasive procedures with a large incision site. According to the report of O'Sullivan et al. [20] when obese women who had bladder neck suspension were followed up for 5 years, the failure rate was significantly higher than that in normal-weight women. Moreover, Varner reported that among SUI patients who underwent retropubic bladder neck suspension, 3 patients experienced recurrence after the surgery and all of them were obese [21]. Those authors suggested that the result was evidence that obesity may increase intraabdominal and pelvic pressure and cause the failure of surgery [21]. On the other hand, however, Parnell et al. [18] reported that 2 obese patients were cured among 151 SUI patients treated through the Marshall-Marchet-

ti-Krantz procedure, and Harris et al. [19] reported that they performed anterior colpopexy or retropubic urethropexy for SUI patients and that obesity did not affect the outcome of the procedures. In these ways, reports are not consistent on the outcomes of invasive procedures for urinary incontinence in obese patients.

In 1996, Ulmsten et al. [10] described TVT, a kind of modified sling procedure, which has since been applied to many patients with SUI with long-term follow-up results that have been reported to be satisfactory. The modified sling procedure began to be used for obese women as a substitute for previous invasive surgery, and several reports have been made on the postoperative success rates of the procedure. Cummings et al. [22] performed transvaginal bladder neck suspension in 4 of 16 obese women and the sling procedure in the other 12. Failure occurred in two of the patients who underwent transvaginal bladder neck suspension but in none of the patients who underwent the sling procedure. When addressing this result, the authors explained that the sling procedure supports the tissue around the urethra without suturing, and because this tissue is already weak and easily torn, it is more durable to correction by the sling procedure than by transvaginal bladder neck suspension. On the basis of this explanation, those authors argued that the sling procedure is the best treatment for SUI in obese women [22]. Later, the SPARC procedure was developed and has been used since 2001. The basic principle of the SPARC procedure is the same, but the approach used is opposite to that of the TVT procedure, with the anterior vaginal wall being accessed from the superior pubis. Kim et al. [23] reported this procedure

to be equally effective and safe for the surgical treatment of female SUI. In addition, the TOT procedure had been developed, in which the anterior vaginal wall is accessed through the obturator foramen, which differs from the TVT procedure, which uses the retropubic route [11,24]. This procedure is a safe and effective treatment for women with SUI, and is comparable with TVT. Lee et al. [25] noted that the cure rate of the TOT procedure was 92% and the satisfaction rate was 98%. These new procedures reduce surgery-induced wounds because the incision and the detachment of the vaginal wall are not large; consequently, hospital stay is shortened and management after discharge is simple. For obese patients, the minimal size of the incision reduces the risk and simplifies the surgical technique. There have been a number of reports about the success rate of TVT surgery in obese patients, and the consensus is that obesity does not influence the outcomes of TVT.

Recently, the SPARC procedure and the TOT procedure are producing good results in the treatment SUI patients, but not many reports have been made on their effect in obese patients. Ku et al. [17] performed the TVT and SPARC sling procedures and confirmed the feasibility and safety of the SPARC procedure when applied to obese women who suffer from SUI. In addition, Rechberger et al. [26] conducted 269 retropubic and 268 transobturator sling procedures and demonstrated that BMI does not influence the clinical effectiveness of SUI treatment. In our study as well, the difference in the success rate according to BMI was not statistically significant, and the success rate differed little among the different types of surgery conducted in our hospital. However, to evaluate the exact influence of obesity on sling operation outcomes, long-term follow-up is needed. Moreover, it was reported recently that the success rate was high not only in obese patients with SUI but also in those with mixed urinary incontinence. In 1998, Ulms-ten et al. [27] reported a cure rate of 91% and an improvement rate of 7% among 131 SUI patients. In 2000, Moran et al. [28] reported an objective cure rate of 95% and a subjective cure rate of 80% in 40 patients. In our study as well, the objective cure rate and the subjective cure rate were 91.6% and 90.8%, respectively, in patients with mixed urinary incontinence, and the differences in the rates according to BMI were not statistically significant. This suggests that both the SPARC procedure and the TOT procedure are sufficiently effective also for patients with mixed urinary incontinence.

Various postoperative complications have been reported including bladder perforation, intestinal perforation, urinary tract infection, bleeding, hematoma, transient urinary retention, and newly developed *de novo* urgency, but the incidence of such complications is known to be low. According to recent reports on postoperative complications, however, Rafii et al. [8] reported that they performed the TVT procedure for 147 normal-weight or overweight patients and 38 obese patients and found no significant difference in the cure rate among the patient groups according to BMI, although the incidence of *de novo* urgency was high-

er in the obese group than in the normal-weight group. Also, Sung et al. [29] performed a meta-analysis of TVT and transobturator approach studies and concluded that the transobturator sling operation had a lower risk (odds ratio: 0.54) of *de novo* bladder voiding symptoms than did the TVT procedure. In our study, 2 cases of bladder perforation, 6 of transient urinary retention, and 4 of *de novo* urgency occurred among 323 patients, but the differences in the incidence of complications according to operative procedure or BMI were not statistically significant. Moreover, there were no major complications that required laparotomy or massive transfusion, and the complications that occurred were all improved through conservative treatment or the administration of anticholinergics. Accordingly, both of the two procedures are believed to be effective and safe regardless of BMI.

## CONCLUSIONS

In this study, the SPARC sling operation and the MONARC sling operation showed similar subjective cure rates, patient satisfaction, and incidence of postoperative complications regardless of BMI and were also effective for patients with mixed urinary incontinence at the 1-year follow-up. Accordingly, these sling procedures are believed to be safely applicable to overweight and obese women, although longer-term follow-up is needed. Moreover, efforts should be made to choose an operative procedure suitable for the condition of the patients through continuous large-scale studies.

## CONFLICTS OF INTEREST

The authors have nothing to disclose.

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