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The effect of apical tensioning and suburethral support on stress and urgency urinary incontinence

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ABSTRACT

Objectives: In the present study, we evaluated the effect of apical suspension of the vagina on urinary incontinence by replacing both uterosacral ligaments with polyvinylidene-fluoride (PVDF) structures.

Materials and Methods: All patients had stress and urgency urinary incontinence (mixed urinary incontinence). These PVDF-structures were sutured to the cervical stump (after supracervical hysterectomy) or to the vaginal vault according to the standardized cervicosacropexy (CESA) or vaginosacropexy (VASA) technique. The length of PVDF-structures in patients who underwent CESA and VASA was 8.8 cm and 9.3 cm, respectively.

Results: In total 39% and 33% of the patients who underwent CESA or VASA became continent, respectively. Stress-related and urgency symptoms disappeared in all patients. The number of patients who became continent with these suspensions decreased with the increasing age, particularly in those aged >60 years. The age-dependent decrease in continence rates was significant among patients who underwent CESA. The percentage of patients in the <60-years and >60-years-of-age groups who became continent after CESA was 50% and 26%, respectively (p=0.002). In patients who underwent VASA, the respective continence rates were 41.5% (<60-years-of-age group) and 28.9% (>60-years-of-age group) (p=0.100).

Conclusion: Patients who still exhibited mixed urinary incontinent were then offered a transobturator tape (TOT) procedure, following which the continence rates ranged between 40.4% and 43.3%.

Patients with mixed urinary incontinence are usually treated with different medical methods, which provide a limited success rate. The results of our study demonstrated that a bilateral apical fixation of the vaginal apex either alone or in combination with a suburethral TOT procedure was effective in treating and restoring urinary continence in 56% and 87% of patients aged >60 and <60 years, respectively.

Keywords: Urinary incontinence; urgency; cervicosacropexy; vaginosacropexy; transobturator tape; bilateral apical fixation

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INTRODUCTION

Urinary incontinence is a chronic disorder associated with a progressive increase in symptoms of uncontrolled urine leakage over the lifetime of an individual (X). In the early stage, the leakage of urine occurs only with a sudden increase in the pressure on the bladder outlet, for example, in case of coughing or sneezing. This phase is called "stress-urinary incontinence".[1]

In the later stage of the disease, urinary leakage occurs with even a low pressure on the bladder. Eventually, patients lose bladder control while rising from a chair or walking. This later stage of urinary incontinence is accompanied by a sudden feeling of urgency; hence, it has been termed "urgency urinary incontinence".[2]

The treatment of urinary incontinence depends on the symptoms. Incontinence caused by coughing or sneezing can be cured with a suburethral tape that compresses the urethra when the vertical pressure on the bladder increases.[3] The association between urgency and incontinence led to the formulation of a hypothesis, which suggests that this form of urinary incontinence is the consequence of a neurological dysfunction in the closing musculature.[2] Based on this hypothesis different neurological treatment modalities were developed that led to a reduction in symptoms.[4] However, these treatments are not effective in the long run because the patients often exhibit urinary incontinence upon discontinuation of the treatment.

But there is a way to help these patients!

Urgency urinary incontinence is often seen in patients with pelvic organ prolapse.[5,6] Petros and Ulmsten[7] hypothesized in their "integral theory" that both stress and urgency urinary incontinence are commonly caused by laxity of the anterior vaginal wall. This hypothesis was supported by observations that the surgical repair of pelvic organ prolapse led to permanent continence, as well as complete disappearance of the feeling of urgency in 14-45% of patients.[8-11]

For visualization purpose, the vagina is separated into three levels.[12] An apical fixation is usually performed at the apical end of the vaginal stump (level 1) or at the bladder-urethral junction (level 2) according to the Burch procedure. Colporrhaphy involves repair of the lax anterior vaginal wall at level 2.[13] These procedures employed to increase tension on the anterior vaginal wall can lead to urinary continence and the disappearance of urgency; however, the reasons for large differences observed in continence rates following these procedures are unknown.

Sacrocolpopexy (apical fixation) involves tensioning of the vagina on the longitudinal axis. The stump of the apical vagina (colpo) is anchored at the sacral bone.[14] Surgical textbooks do not mention the most appropriate degree of tensioning of the vagina, that is, the optimal length of the anchor chain,[15] and this parameter is determined by surgeons. To evaluate whether the extent of tensioning could be responsible for different continence rates, the apical suspension of the vagina was standardized in the present study.

Because the dimensions of the bony pelvis are nearly identical in women of different ethnicities standardization of colposuspension (apical fixation) was possible.[16] Apical prolapse is caused by a defect of the holding apparatus, especially of the uterosacral (USL) and laterally (cardinal) ligaments. As a first step in surgical standardization the author decided to replace both USL as a repair of level 1.[10,17]

The fixation sides of the USL were known; however, the length of the ligaments was unknown. Based on literature of pelvic anatomy, the physiological length of the USL was calculated to be approximately 9 cm, which is in accordance to anatomical studies.[18] In patients with uterine prolapse, the USLs were replaced with polyvinylidene-fluoride (PVDF) structures of defined length.[10,17,19-21] The tapes were fixed at the promontory, placed retroperitoneally in the peritoneal folds of the USLs, and sutured to the implantation sides of the USLs at the cervix. This standardized method of cervicosacropexy performed using an 8.8 cm long PVDF structure in every patient was termed CESA. In vaginosacropexy, these PVDF structures used were 9.3 cm long and were sutured to the lateral ends of the vaginal vault. This standardized method for placement of the PVDF structures was referred to as VASA.[22] Thus, every patient was operated on in the same way. We deliberately decided to replace the USL with an 8.8 cm long PVDF structure in CESA, and because of the length of the resected cervix, a 9.3 cm long structure was used in VASA (Figure 1).[10,17,20-22]

CESA and VASA procedures were originally developed as surgical treatments for patients with uterine or vaginal (apical) prolapse; however, we observed that several patients with either stress urinary incontinence or urgency urinary incontinence became continent after undergoing CESA or VASA.[10,17] Therefore, in the URGE 1 study, patients with urgency urinary incontinence were randomized to receive either medical treatment with solifenacin or surgical treatment with CESA/VASA. In the solifenacin treatment group 10% of patients experienced a relief from their symptoms, whereas in the CESA/VASA surgical treatment group, 42% of the patients became continent.[19] However, upon completion of the treatment, the patients in the solifenacin treatment group became incontinent, whereas those in the CESA/VASA surgical treatment group remained continent.

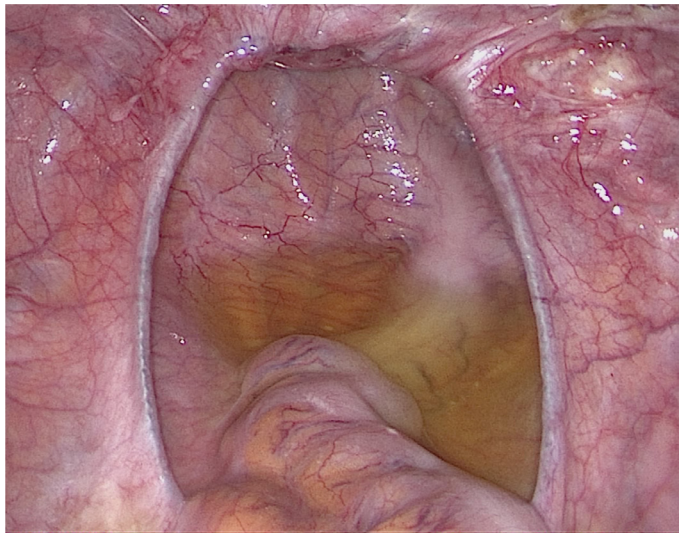

Figure 1. The small pelvis with a cervicosacropexy structure (DynaMesh CESA® FEG Textiltechnik Aachen, Germany) placed between the cut surface of the cervix and promontory in the run of both uterosacral ligaments.

According to the integral theory, patients who remained incontinent after replacement of the USL would require support of the urethra.[7,13,23] Therefore, these patients received an additional suburethral tape. This led to continence in 76% of the patients with urgency urinary incontinence.[10,11]

However, the reason for incontinence among some patients even after the treatment remained unclear. After standardization of the CESA/VASA procedure and placement of the suburethral tape (TOT 8/4), addressing this question was feasible.

MATERIALS AND METHODS

Patients with urinary incontinence who presented to the Department of Gynecology at the University of Cologne between 2012 and 2020 were included in this study. The study was approved by the Ethical Committee of the University of Cologne (approval no: 20-176).

Mixed urinary incontinence (MUI) was defined as a combination of stress urinary incontinence and urgency urinary incontinence. Continence was defined as no loss of urine on any occasion and the absence of a feeling of urgency. Patients with symptoms of both urgency and stress urinary incontinence were included in the study. Patients who had undergone colporrhaphy or colposuspension or a transvaginal tape (TVT) or transobturator tape (TOT) procedure were excluded from the study. Patients with a clinical prolapse of the uterus or vaginal stump (> stage 1) and those with a clinical cystocele or rectocele who required an additional colporrhaphy were also excluded from the study.

The patients underwent either CESA or VASA, which was performed as described previously.[17] For suspension, specially designed PVDF structures were used (DynaMesh CESA®, DynaMesh VASA®, FEG, Aachen, Germany). In CESA, the cervix was dissected below the side where the uterine vessels reach the uterus, and the bladder attachment at the cervix remained untouched. In VASA, the sutures were secured to the furthest lateral edges of the vaginal vault. Since 2016, CESA and VASA have been performed laparoscopically.[20,24]

Patients who became continent after CESA or VASA did not receive further treatment. Patients who remained incontinent were offered a TOT procedure. The placement of the TOT had also previously been standardized. Before tensioning the tape, a Hegar pin 8 was placed in the urethra, and a Hegar pin 4 was placed between the tape and the urethra (TOT 8/4).[25]

The CESA, VASA and TOT 8/4 procedures were performed by the same surgeons (WJ and SL).

The patients provided information about their symptoms of urinary incontinence by completing a modified LUTS questionnaire of the ICS before surgery and again between 4 and 6 weeks after surgery. Patients experiencing continence were asked to contact the department, in case of incontinence relapse.

Statistical Analysis

Patient data were registered in a computer databank on the day of surgery. Statistical analysis was performed in collaboration with the Institute of Medical Statistics at the University of Cologne.

RESULTS

In total, 1033 women with urinary incontinence were treated at our institution during the study period. Two hundred-fifteen patients underwent a CESA or VASA plus a TOT procedure simultaneously. In addition, 135 patients underwent a colporrhaphy at the time of CESA or VASA. These patients, as well as 43 patients with incomplete data were excluded. In addition, 45 patients were operated on for different indications. After identifying the patients with only urgency urinary incontinence or stress urinary incontinence, 326 patients with MUI were included in the study to evaluate the effects of the surgical treatment (Figure 2).

Of the total, 159 patients underwent CESA, and 167 patients underwent VASA. Sixty-two of 159 patients (39%) and 55 of 167 patients (32.9%) who underwent CESA and VASA, respectively, became continent; however, the difference in the continence rates was not significant (p=0.300).

The enrolled patients were further subdivided into two groups based on their age: One group comprised patients aged <60 years, and the other group comprised patients aged >60 years.

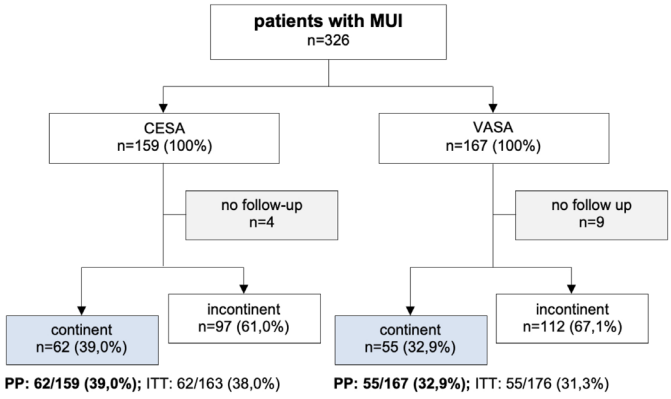

Figure 2. Distribution of evaluable patients with mixed urinary incontinence (MUI) according to the type of operation.

Pp: per protocol treated patient; ITT: intention to treat; CESA: cervicosacropexy; VASA: vaginosacropexy

In the <60-years-of-age group, 46.8% patients became continent after undergoing CESA or VASA compared with 27.8% in the >60-years-of-age group (p=0.001).

The difference in the continence rates (the number of patients who became continent after surgery per 100 patients) of the patients who underwent CESA or VASA was statistically significant between the two age groups. The number of patients who became continent was higher in the <60-years-of-age group than in the >60-years-of-age group.

Among the patients who underwent CESA, the continence rates were 43/85 (50%) in the <60-years-of-age group and 19/73 (26%) in the >60-years-of-age group (p=0.002) (Figure 3).

The respective continence rates for patients who underwent VASA in the two age groups were 22/53 (41.5%) and 33/114 (28.9%); however, this difference was not significant (p=0.100) (Figure 4).

The patients who remained incontinent after CESA or VASA were offered a TOT procedure. The observed continence rates among patients who underwent CESA or VASA after the TOT procedure were comparable (i.e., 40.4% after CESA and 43.3% after VASA; p=0.700).

However, the effects of the TOT procedure after CESA or VASA varied between the two age groups (Figure 5).

The continence rates (pp) for patients who underwent CESA were 55/63 (87%) and 26/46 (56%) in the <60- and >60- years-of-age groups, respectively. Among patients who underwent VASA, the continence rates in the <60- and >60- years-of-age groups (pp) were 29/38 (76%) and 52/77 (67%), respectively.

The continence rate after the TOT procedure in patients who underwent VASA was 43% irrespective of the age. However, the continence rate after TOT in patients who underwent CESA varied depending on the age, with the rates in the <60-years and >60-years-of-age groups being 60% and 25.9%, respectively (p=0.02).

1) Materials and Methods

The merit of this study is the homogeneity of patients' symptoms and the treatment administered to them. All the patients exhibited MUI, and none of them had previously received a colposuspension (apical suspension), colporrhaphy, TVT, or TOT.

All patients underwent standardized CESA/VASA with or without a subsequent TOT 8/4 operation, and these operations were performed by the same surgeons using identical surgical techniques in every patient.[10,20,24,26-28]

2) The Effect of Apical Suspension

The results of this study confirmed that apical suspension of the vagina can lead to restoration of urinary continence. Presence of continence or incontinence is confirmed at the uterovesical junction (UVJ) (level 2). The CESA and VASA structures are placed at level 1. Therefore, when patients became continent, the effect

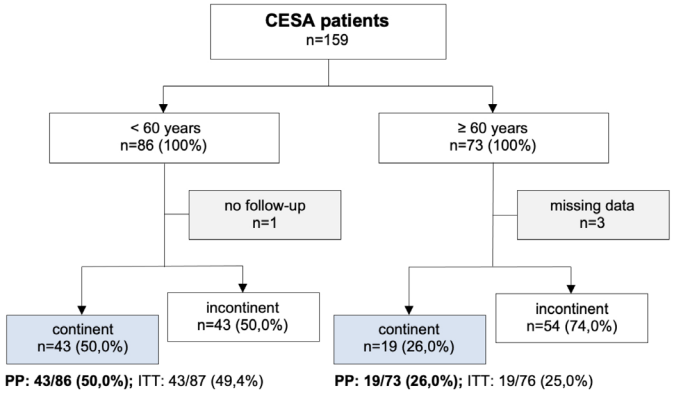

Figure 3. Distribution of evaluable patients who underwent cervicosacropexy (CESA) according to the age at surgery.

Pp: per protocol treated patient; ITT: intention to treat

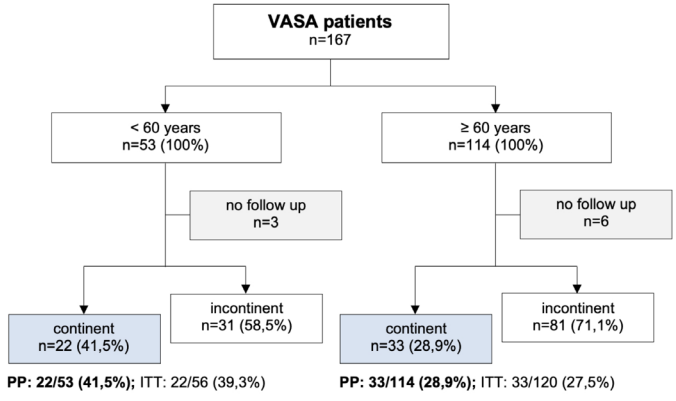

Figure 4. Distribution of evaluable patients who underwent vaginosacropexy (VASA) according to age at surgery.

Pp: per protocol treated patient; ITT: intention to treat

of the apical suspension must have extended to the UVJ region. Tensioning of the vagina probably supports the bladder base. Therefore, when a slight pressure is applied on the bladder, such as when a patient stands up, the UVJ will not open. With the re-establishment of continence, the feeling of urgency also disappears. The causal relation between the anatomical suspension of the UVJ and continence is demonstrated by the observation that patients with incontinence do not lose urine in the sitting position.[10,11,21] Continence or incontinence is a result of pressure and counterpressure on the UVJ, respectively.[29]

The symptom of urgency is independent of incontinence. Patients with continence also experience urgency when the bladder is filled to a particular level. Urgency can even be experienced by patients while sitting when the UVJ is closed by compression. The reason for the disappearance of the feeling of urgency after surgery irrespective of whether the patient undergoes CESA, VASA, or TOT cannot be explained. Urgency is definitively a neurological sensation that originates in the brain; however, it is not the cause of rather a symptom associated with incontinence.[10]

3) Aging

In this study, the clinical results of CESA and VASA in terms of urinary incontinence were found to be critically dependent on patients' age. In the <60-years-of-age group, 50% and 41% of all patients became continent after CESA and VASA, respectively. In the >60-years-of-age group, the continence rates after surgery were 26% for patients who underwent CESA and 28% for those who underwent VASA.

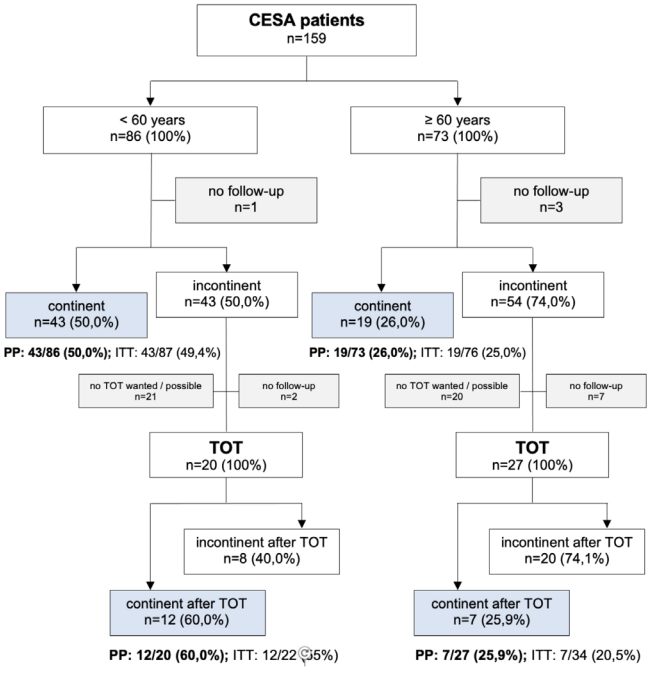

Figure 5. Continence rates after cervicosacropexy (CESA) and vaginosacropexy (VASA) and a transobturator tape (TOT) procedure according to patients' age at surgery.

Pp: per protocol treated patient; ITT: intention to treat

The cut-off of 60 years of age was chosen and implemented in the present study protocol based on the results of previous studies.[30] However, the final results suggest that patients who were most adversely affected in terms of their continence rates after surgery were aged ≥70 years. In this group of patients >70 years, the continence rates for those who underwent CESA and VASA were 16% and 20%, respectively.

The age of patient plays a critical role in urinary incontinence, which follows a consistent pattern. Urinary incontinence often starts around the age of 40 years with leakage of urine on coughing or sneezing.[31] The urgency phase begins at approximately 60 years of age with urine loss while standing or walking. Initially, the patients remain continent until they go to the toilet immediately upon experiencing the sensation of urgency; however, within a few years, the patients begin losing bladder control while on their way to the toilet. In our series, this phase developed between the ages of 60 and 65 years.

The etiology of urinary incontinence remains unknown. The course of symptoms is identical in all patients, which is an indication that urinary incontinence is a single disorder that intensifies over time. Considering that urinary incontinence is caused by the events associated with aging, the reason for incontinence only in some but not in all patients with increasing age remains to be investigated.

In our study, we asked the patients whether their mother was also incontinent. Approximately 90% of the patients reported that their mother was also incontinent. However, we abstained from interpretating these data because of the lack of a control group (i.e., mother incontinent-daughter continent). Therefore, the suspected genomic relation remains to be studied further.

4) Caveat

The effects of patients' age on treatment results in the present study can explain the heterogeneity of the results reported in previous studies. Treatment was significantly less effective in patients aged more than 60 years. Therefore, future studies on patients with urinary incontinence should consider patients' stratification based on the age.

5) Suburethral Suspension

For the interpretation of the effects of the TOT procedure, clinicians should consider that only 51% of the patients who remained incontinent after CESA or VASA were willing to undergo a TOT procedure. The reasons for patients' refusal to undergo a

TOT procedure remain unknown. Therefore, the clinical results in the present study must be interpreted while considering this aspect.

The TOT procedure led to continence in approximately 53% of the patients who were experiencing incontinence and urgency even after undergoing CESA or VASA. This effect was not dependent on patients' age.

The effects on continence can be explained by the compression of the urethra by the TOT. However, the reason for the disappearance of the feeling of urgency in these patients remains to be explored.

We could not identify the reason for the presence of incontinence among 47% of the patients who underwent a TOT procedure. We also attempted to eliminate inter-patient differences in the placement of the tape by standardizing the TOT procedure.

One interpretation could be that the placement of the TOT was not correct in relation to the UVJ. A study reported that incontinence after the placement of a suburethral tape was caused by a displacement of the tape over time.[32] However, all the patients in our study reported that they were incontinent immediately after the first spontaneous micturition following surgery, and the placement of the tape did not show any signs of displacement.

It can be assumed that the persistent incontinence among these patients was contributed by another factor.

6) Considerations

The etiology of urinary incontinence is unknown. In the present study, its symptoms were effectively treated through CESA or VASA and TOT 8/4. CESA or VASA cured the symptoms of incontinence in approximately 45% of our patients, while the TOT procedure cured nearly 50% of the remaining patients having incontinence. Overall, these treatments could cure urinary incontinence in nearly 75% of patients.

In our study the continence rate following surgery was dependent on patients' age. The overall continence rates for patients who were treated according to the treatment protocol (pp-rates) were between 87% (in patients aged <60 years) and 56% (in patients aged >60 years).

CONCLUSION

The anatomical effects of CESA/VASA and TOT on the anterior vaginal wall vary. CESA and VASA exert a longitudinal tension not only at level 1 but also, in part, at level 2. The suburethral tapes have no effect in that respect; they do not exert tension on any part of the vagina but support the urethra in the area in front of the UVJ. This effect is evident when the patient is in the upright position. Therefore, the surgical treatment must be targeted at level two-the level of the UVJ. In the future, the additional lateral suspension of the vagina at level 2 must also be standardized to better evaluate the effect on urinary incontinence.

The scientific principle of monocausality states that each individual effect is based on an individual cause. Therefore, incontinence as an effect must have an individual cause, which remains unknown. It can be hypothesized that aging is accompanied by changes at the DNA level that leads to the decreased production of specific enzymes or proteins. In some patients, this may lead to a laxity of the anterior vaginal wall at the level of the UVJ. Additionally, considering a neurological reason for incontinence seems unreasonable.

So far, no causative treatment for urgency urinary incontinence or MUI has been found. Medical treatment does not help these patients effectively. However, surgery can be used as the mainstay treatment to re-establish continence in about 70% of these patients who otherwise have no chance for continence. By the standardization of CESA, VASA and the TOT 8/4 every surgeon can reproduce our findings.

ETHICS

Ethics Committee Approval: Patients with urinary incontinence who presented to the Department of Gynecology at the University of Cologne between 2012 and 2020 were included in this study. The study was approved by the Ethical Committee of the University of Cologne.

Informed Consent: Retrospective study.

Peer-review: Internally and externally peer-reviewed.

Contributions

Surgical and Medical Practices: W.J., S.L., Concept: W.J., E.N., P.M., S.L., Design: W.J., A.P., E.N., P.M., S.L., Data Collection or Processing: W.J., A.P., A.H., S.L., Analysis or Interpretation: W.J., A.P., A.H., S.L., Literature Search: A.P., E.N., S.L., Writing: W.J., A.P., S.L.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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