The Preventive Surgical Site Infection Bundle in Colorectal Surgery
An Effective Approach to Surgical Site Infection Reduction and Health Care Cost Savings

Jeffrey E. Keenan, MD; Paul J. Speicher, MD; Julie K. M. Thacker, MD; Monica Walter, DNP; Maragatha Kuchibhatla, PhD; Christopher R. Mantyh, MD

IMPORTANCE Surgical site infections (SSIs) in colorectal surgery are associated with increased morbidity and health care costs.

OBJECTIVE To determine the effect of a preventive SSI bundle (hereafter bundle) on SSI rates and costs in colorectal surgery.

DESIGN Retrospective study of institutional clinical and cost data. The study period was January 1, 2008, to December 31, 2012, and outcomes were assessed and compared before and after implementation of the bundle on July 1, 2011.

SETTING AND PARTICIPANTS Academic tertiary referral center among 559 patients who underwent major elective colorectal surgery.

MAIN OUTCOMES AND MEASURES The primary outcome was the rate of superficial SSIs before and after implementation of the bundle. Secondary outcomes included deep SSIs, organ-space SSIs, wound disruption, postoperative sepsis, length of stay, 30-day readmission, and variable direct costs of the index admission.

RESULTS Of 559 patients in the study, 346 (61.9%) and 213 (38.1%) underwent their operation before and after implementation of the bundle, respectively. Groups were matched on their propensity to be treated with the bundle to account for significant differences in the preimplementation and postimplementation characteristics. Comparison of the matched groups revealed that implementation of the bundle was associated with reduced superficial SSIs (19.3% vs 5.7%, \( P < .001 \)) and postoperative sepsis (8.5% vs 2.4%, \( P = .009 \)). No significant difference was observed in deep SSIs, organ-space SSIs, wound disruption, length of stay, 30-day readmission, or variable direct costs of the index admission. However, in a subgroup analysis of the postbundle period, superficial SSI occurrence was associated with a 35.5% increase in variable direct costs ($13 253 vs $9779, \( P = .001 \)) and a 71.7% increase in length of stay (7.9 vs 4.6 days, \( P < .001 \)).

CONCLUSIONS AND RELEVANCE The preventive SSI bundle was associated with a substantial reduction in SSIs after colorectal surgery. The increased costs associated with SSIs support that the bundle represents an effective approach to reduce health care costs.
Surgical site infections (SSIs) are associated with increased morbidity, length of hospitalization, readmission rates, and health care costs. They represent a particularly important problem in colorectal surgery (CRS), for which SSI rates are disproportionately high, ranging from 15% to 30%. Therefore, reduction in SSIs in CRS has become a major target of quality improvement initiatives. To a large degree, the focus has been on improving adherence to evidence-based practices, such as those laid out by the Surgical Care Improvement Project of the Centers for Medicare and Medicaid Services. These practices include appropriate administration of prophylactic antibiotics, perioperative hair clipping, glucose control in cardiac surgery patients, and normothermia in CRS patients. However, it has become apparent that improvement in the compliance of individual Surgical Care Improvement Project measures alone is unlikely to result in effective SSI reduction. In contrast, efforts that have used systematic approaches, or bundles, directed toward the incorporation of best practices across the phases of perioperative care have been successful to varying degrees.

In addition to improved patient care, reduction in healthcare costs is commonly touted as a benefit of SSI reduction. However, few studies have attempted to quantitate the SSI-associated costs. Among these studies, significant heterogeneity exists in terms of (1) the procedures included, (2) the method for determination of costs or charges, (3) the definition of SSIs, and (4) the types of SSIs included. This heterogeneity has made assessment of the SSI-associated costs for any specific patient population difficult. As a result, the cost savings associated with successful SSI reduction are unknown.

Herein, we present our experience with a preventive SSI bundle (hereafter bundle) for CRS. The impetus for implementation of our bundle arose from our institution's participation in the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP). The ACS-NSQIP provides a prospectively maintained database designed to allow determination of 30-day postsurgical outcomes as a vehicle for quality improvement. Through involvement with the ACS-NSQIP, our institution was identified as having a significantly higher rate of SSIs in CRS compared with peer institutions. In this study, we evaluate the effect of the bundle on the CRS SSI rate and how SSIs affect health care costs associated with CRS.

Methods

Study Design

This retrospective cohort study was approved by the institutional review board at Duke University Medical Center. The requirement for informed consent was waived by the institutional review board. For most retrospective studies, our institutional review board will waive the requirement for informed consent so long as the only risk to patients relates to the use of patient health information and there is an appropriate plan for protecting that patient health information in place. Institutional ACS-NSQIP data files were used to identify a sample group of patients undergoing major CRS at Duke University Medical Center between January 1, 2008, and December 31, 2012. These procedures included low anterior resection, abdominoperineal resection, partial or total abdominal colectomy with or without proctectomy, proctectomy, pelvic exenteration, or Hartmann-type procedure (including Current Procedural Terminology codes 44147, 44150, 44151, 44160, 44204, 44205, 44206, 44207, 44208, 44210, 44155, 44156, 44157, 44158, 44211, 44212, 45110, 45111, 45112, 45113, 45114, 45116, 45119, 45120, 45121, 45123, 45126, 45130, 45135, 45160, 45395, 45397, 45402, and 45550). Both open and laparoscopic cases were included. The bundle was designed for and by colorectal surgeons (J.K.M.T. and C.R.M.) who used it in all of their cases from the implementation date (July 1, 2011) forward. Therefore, only procedures performed by 1 of 3 board-certified colorectal surgeons at our institution were considered throughout the study period. Emergent cases or cases that occurred more than 1 day from the date of admission were excluded. Patient demographics, preoperative comorbidities, intraoperative factors, and 30-day outcomes were determined using the ACS-NSQIP institutional data. The ACS-NSQIP data relate to a systematically sampled set of surgical procedures and are collected by a trained surgical-clinical reviewer (M.W.), ensuring an accurate data set. In addition to the ACS-NSQIP data, the variable direct costs (VDCs) for the index admission were obtained from Duke University Hospital Finance. The VDCs account for costs incurred during a hospital stay related to care provided to the patient but exclude physician fees. Examples of VDCs include operating room time and equipment use, pharmaceutical agents, and nursing, labora
tory, radiological, and other services.

The Preventive SSI Bundle

The use of the bundle involved a systematic approach to improve the use of SSI preventive measures across the phases of perioperative care. It was a multidisciplinary effort, calling on surgeons, anesthesiologists, clinic nurses, operating room staff, unit nurses, house staff, and hospital mid-level providers to enact the prescribed elements. The bundle program was led and coordinated by one of the colorectal surgeons (C.R.M.) who met monthly with designated key personnel from the various groups to review recent SSI results and address any issues with bundle delivery.

The elements of the bundle included existing evidence-based measures as well as commonsense measures that were thought to pose minimal risk and hold potential for benefit (Figure 1). Before surgery, patients were provided with educational materials on the prevention of SSIs, as well as materials and instructions to undergo a full-body chlorhexidine gluconate shower the night before surgery. A standardized polyethylene glycol 3350 bowel preparation with oral antibiotics (neomycin sulfate and erythromycin) was adopted. For preoperative antibiotic prophylaxis, all patients without an allergy received a single 1-g dose of cefazolin sodium within 1 hour of incision. Ciprofloxacin hydrochloride and metronidazole phosphate were used as an alternative when an allergy was present. The surgical field preparation was performed in a standardized fashion using a 2% chlorhexidine gluconate–70% isopropyl alcohol solution. During surgery, a wound protector was used for open incisions, operating room...
traffic was limited to essential personnel, and close attention to maintenance of normothermia and euglycemia was provided by the anesthesiologist. At the time of wound closure, surgeons and scrub staff underwent a gown and glove change, and a dedicated wound closure tray was used to close the fascia and skin. Following closure, a sterile occlusive dressing was placed over the incisions. After surgery, the dressing was removed within 48 hours from the time of surgery. The wound was then washed daily with chlorhexidine. On discharge, the patient was provided with materials and instructions to continue the chlorhexidine washes for 1 week following surgery.

**Statistical Analysis**

Patients were stratified by the use of the bundle at the time of surgery, which was our main predictor of interest. The primary outcome measure for our analysis was the rate of superficial SSIs. Secondary outcomes included deep SSIs, organ-space SSIs, wound disruption, postoperative sepsis, length of stay, 30-day readmission, and VDCs of the index admission. For categorical and continuous variables, proportions and measures of central tendency were assessed, respectively. Comparisons of baseline and procedure-specific characteristics for patients before vs after implementation of the bundle were performed using Pearson χ² test or Fisher exact test for categorical variables and t test for continuous variables.

As a confirmatory analysis and to control for fundamental, nonrandom differences between patients treated with vs without the bundle, we performed a propensity analysis. Variables chosen for inclusion were those most likely to act as confounders and included patient age, sex, body mass index, diabetes mellitus, recent chemotherapy, recent radiation therapy, total operative time, use of laparoscopy, and whether the procedure comprised rectal resection or not. These variables were entered into a logistic regression model to calculate propensity scores, and an optimized nearest-neighbor algorithm was used to find the most appropriate matched pairs. After propensity score matching to create 2 identically sized groups with balanced covariates, baseline characteristics and postoperative end points were compared between the 2 groups using Pearson χ² test or Fisher exact test for categorical variables and t test for continuous variables.

A subgroup analysis was performed among all patients who underwent an operation using the SSI bundle to capture the cost effect of any potential reduction in SSI rates by comparing costs for patients who developed an SSI vs those who did not. A multivariable linear regression model was used to control for the same potentially confounding variables mentioned previously. In all linear models, the continuous end points of interest (length of stay and VDCs) were log transformed to address issues of normalcy.

Model diagnostics and balance were assessed, and no major model assumptions were violated. An affirmative decision was made to control for type I error at the level of comparison. P ≤ 0.05 indicated statistical significance for all comparisons and analyses of primary and secondary outcomes. Statistical analyses were performed with statistical software (R, version 3.0.1; R Foundation for Statistical Computing).

**Results**

During the study period, 559 CRS cases meeting the study criteria were sampled by the ACS-NSQIP at our institution (Table 1). These included 346 (61.9%) and 213 (38.1%) cases before and after implementation of the bundle, respectively. The median age was older in the prebundle group (62.2 vs 58.7 years, P = .04). In addition, a higher percentage of patients in the prebundle group received preoperative radiation therapy (19.1% vs 12.2%, P = .04). In contrast, a lower percentage of patients in the prebundle group had received recent chemotherapy (5.5% vs 14.6%, P < .001). The proportion of laparoscopic cases was lower in the prebundle group (38.4% vs 58.7%, P < .001) as well. Other factors evaluated did not differ significantly between the 2 groups.
Comparison of the unadjusted outcomes between the prebundle and postbundle groups demonstrated a significant reduction in superficial SSIs (24.9% vs 5.6%, \( P < .001 \)), postoperative sepsis (10.4% vs 2.3%, \( P < .001 \)), and length of stay (6.0 vs 5.0 days, \( P = .001 \)). No significant difference was observed in 30-day readmissions (15.9% vs 9.9%, \( P = .06 \)) or VDCs ($8422 vs $9700, \( P = .85 \)) between the prebundle and postbundle groups.

Because of several important differences that might affect the rate of SSIs between the prebundle and postbundle groups, propensity matching for the SSI bundle was performed (Table 2). Matched prebundle and postbundle groups were generated containing 212 patients each. No significant difference was observed in patient demographics, baseline characteristics, or procedure-specific factors between the matched groups. Evaluation of outcomes indicated a significant reduction in superficial SSIs (19.3% vs 5.7%, \( P < .001 \)) and postoperative sepsis (8.5% vs 2.4%, \( P = .009 \)) in the postbundle period (Table 3). In contrast, no significant difference was found in deep SSIs, organ-space SSIs, wound disruption, median length of stay, 30-day readmission, or VDCs between the matched groups.

To assess the cost effect from reduced superficial SSIs following implementation of the bundle, a subgroup analysis was performed on the VDCs incurred by patients with vs without

### Table 1. Baseline Characteristics of the ACS-NSQIP Sampled Colorectal Surgical Procedures Subdivided by the Use of the Bundle

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (N = 559)</th>
<th>Prebundle Period (n = 346)</th>
<th>Postbundle Period (n = 213)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (Q1-Q3), y</td>
<td>60.8</td>
<td>62.2 (50.7-69.9)</td>
<td>58.7 (46.2-69.2)</td>
<td>.04</td>
</tr>
<tr>
<td>Male sex, No. (%)</td>
<td>258</td>
<td>156 (45.1)</td>
<td>102 (47.9)</td>
<td>.58</td>
</tr>
<tr>
<td>Race/ethnicity, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td>.80</td>
</tr>
<tr>
<td>White</td>
<td>428</td>
<td>267 (77.2)</td>
<td>161 (75.6)</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>118</td>
<td>72 (20.8)</td>
<td>46 (21.6)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>13</td>
<td>7 (2.0)</td>
<td>6 (2.8)</td>
<td></td>
</tr>
<tr>
<td>BMI, median (Q1-Q3)</td>
<td>27.6</td>
<td>27.8 (23.9-31.7)</td>
<td>27 (23.7-31.6)</td>
<td>.28</td>
</tr>
<tr>
<td>ASA classification, No. (%)(^\text{a})</td>
<td></td>
<td></td>
<td></td>
<td>.10</td>
</tr>
<tr>
<td>1. No disturbance</td>
<td>5</td>
<td>1 (0.3)</td>
<td>4 (1.9)</td>
<td></td>
</tr>
<tr>
<td>2. Mild disturbance</td>
<td>219</td>
<td>138 (39.9)</td>
<td>81 (38.2)</td>
<td></td>
</tr>
<tr>
<td>3. Severe disturbance</td>
<td>318</td>
<td>200 (57.8)</td>
<td>118 (55.7)</td>
<td></td>
</tr>
<tr>
<td>4. Life threatening</td>
<td>16</td>
<td>7 (2.0)</td>
<td>9 (4.2)</td>
<td></td>
</tr>
<tr>
<td>Procedure type, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td>.11</td>
</tr>
<tr>
<td>Partial colectomy</td>
<td>194</td>
<td>109 (31.5)</td>
<td>85 (39.9)</td>
<td></td>
</tr>
<tr>
<td>Low anterior resection</td>
<td>197</td>
<td>129 (37.3)</td>
<td>68 (31.9)</td>
<td></td>
</tr>
<tr>
<td>Abdominoperineal resection</td>
<td>50</td>
<td>37 (10.7)</td>
<td>13 (6.1)</td>
<td></td>
</tr>
<tr>
<td>TAC with proctectomy</td>
<td>45</td>
<td>25 (7.2)</td>
<td>20 (9.4)</td>
<td></td>
</tr>
<tr>
<td>TAC without proctectomy</td>
<td>31</td>
<td>20 (5.8)</td>
<td>11 (5.2)</td>
<td></td>
</tr>
<tr>
<td>Partial proctectomy</td>
<td>31</td>
<td>22 (6.4)</td>
<td>9 (4.2)</td>
<td></td>
</tr>
<tr>
<td>Hartmann-type procedure</td>
<td>8</td>
<td>3 (0.9)</td>
<td>5 (2.3)</td>
<td></td>
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<tr>
<td>Pelvic exenteration</td>
<td>3</td>
<td>1 (0.3)</td>
<td>2 (0.9)</td>
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<tr>
<td>Laparoscopic case, No. (%)</td>
<td>258</td>
<td>133 (38.4)</td>
<td>125 (58.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Wound classification, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td>.11</td>
</tr>
<tr>
<td>Clean or contaminated</td>
<td>481</td>
<td>305 (88.2)</td>
<td>176 (82.6)</td>
<td></td>
</tr>
<tr>
<td>Contaminated</td>
<td>51</td>
<td>29 (8.4)</td>
<td>22 (10.3)</td>
<td></td>
</tr>
<tr>
<td>Dirty or infected</td>
<td>27</td>
<td>12 (3.5)</td>
<td>15 (7.0)</td>
<td></td>
</tr>
<tr>
<td>Preoperative sepsis, No. (%)(^\text{a})</td>
<td></td>
<td></td>
<td></td>
<td>.47</td>
</tr>
<tr>
<td>None</td>
<td>553</td>
<td>342 (99.7)</td>
<td>211 (99.1)</td>
<td></td>
</tr>
<tr>
<td>Sepsis</td>
<td>1</td>
<td>0</td>
<td>1 (0.5)</td>
<td></td>
</tr>
<tr>
<td>SIRS</td>
<td>2</td>
<td>1 (0.3)</td>
<td>1 (0.5)</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus, No. (%)</td>
<td>483</td>
<td>297 (85.8)</td>
<td>186 (87.3)</td>
<td>.05</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease, No. (%)</td>
<td>20</td>
<td>15 (4.3)</td>
<td>5 (2.3)</td>
<td>.25</td>
</tr>
<tr>
<td>Smoker, No. (%)</td>
<td>102</td>
<td>67 (19.4)</td>
<td>35 (16.4)</td>
<td>.45</td>
</tr>
<tr>
<td>Functional status, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td>.18</td>
</tr>
<tr>
<td>Independent</td>
<td>550</td>
<td>338 (97.7)</td>
<td>212 (99.5)</td>
<td></td>
</tr>
<tr>
<td>Partially dependent</td>
<td>9</td>
<td>8 (2.3)</td>
<td>1 (0.5)</td>
<td></td>
</tr>
<tr>
<td>Recent chemotherapy in last 30 d, No. (%)</td>
<td>50</td>
<td>19 (5.5)</td>
<td>31 (14.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Radiation therapy in last 90 d, No. (%)</td>
<td>92</td>
<td>66 (19.1)</td>
<td>26 (12.2)</td>
<td>.04</td>
</tr>
</tbody>
</table>

Abbreviations: ACS-NSQIP, American College of Surgeons National Surgical Quality Improvement Program; ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); Q, quartile; SIRS, systemic inflammatory response syndrome; TAC, total abdominal colectomy.

\(^{a}\) Because of missing data, the totals for ASA classification and preoperative sepsis are less than the total cohort (\( n = 558 \) and \( n = 556 \), respectively).

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superficial SSIs in the postbundle period. After multivariable adjustment, superficial SSI occurrence during the postbundle period was associated with a 35.5% increase in VDCs ($13,253 vs $9,779, P = .001, R^2 = 0.504) (Figure 2). In addition, superficial SSI occurrence was associated with a 71.7% increase in length of stay (7.9 vs 4.6 days, P < .001, R^2 = 0.359) for the index admission.

Discussion
In this study, we determined the effect of the bundle on SSI rates in elective CRS and examined the costs associated with superficial SSIs in CRS at a single institution. The absolute reduction in the rate of superficial SSIs following implementation of the bundle was 19.3% (24.9% vs 5.6%, P < .001) in the unadjusted analysis and 13.6% (19.3% vs 5.7%, P < .001) after propensity adjustment. Implementation of the bundle was also associated with a reduced rate of postoperative sepsis. In total, these findings support the bundle as an effective tool for improving the quality of patient care.

This study also demonstrates that substantial SSI reduction can be achieved at an institution having a preexisting problem with high SSI rates in CRS. After joining the ACS-NSQIP in 2006, our institution was identified as a high outlier for the CRS SSI rate among peer ACS-NSQIP institutions.
from 2007 to 2011. This was the impetus for the formation of the bundle. However, while our initial SSI rate was high, it was still within the range commonly reported in the literature for CRS, indicating that our situation was not unique; many institutions struggle to keep the CRS SSI rates at an acceptable level. We suspect that the predominant factor underlying the high SSI rate at the start of the study was the inability to provide all optimal preventive SSI measures.

Another possibility is that the costs of the bundle negated any cost savings provided through reduction in SSIs and other complications; however, this seems unlikely. The dedicated wound closure tray had a one-time capital cost of approximately $10,000, and the costs of the other bundle elements are almost certainly nominal in comparison with the VDCs for the CARES admission. Therefore, based on the widely accepted assumption that SSIs increase the costs of care, it is reasonable to suspect that the lack of an observed reduction in VDCs following implementation of the bundle is largely the result of health care cost inflation and costs associated with concurrent changes in the care of CRS patients.

To circumvent the issues that arise in comparing costs over time, a subgroup analysis was performed to evaluate the costs associated with SSIs during the postbundle period. After multivariable adjustment, a 35.5% (P = .001) increase was seen in VDCs for the care of CRS patients who developed superficial SSIs compared with those who did not during the postbundle period. This amounted to a marginal increase in the cost of care in the postbundle period. This amounted to a marginal
VDC increase of $3474. It is less than what might be expected based on estimates previously reported in the literature,2,6 which have been on the order $20 000. We suspect that this arises from 2 main factors. First, we have relied on the conservative but reliable metric of VDCs, as opposed to charges or including aspects of costs that are fixed. Second, we have included only superficial SSIs in our cost analysis, while other investigators have also included deep or organ-space infections,7 which are more expensive. Our result aligns with a body of literature16,27 arguing that most cost estimates for SSIs and other hospital-acquired infections are overstated for various reasons, including those mentioned above.

Although our estimate of SSI-associated costs is low relative to previous studies,7,6 it is consequential and supports that substantial savings may be realized by an effective SSI reduction program. In addition, our estimate does not include indirect costs such as those incurred from discharge with home health services, discharge to a skilled nursing facility, opportunity costs, or long-term complications stemming from SSIs such as incisional hernia. It is reasonable to suspect that these indirect costs were increased in patients who developed SSIs in this study compared with those who did not. Therefore, although the cost estimate based on VDCs provides an important reference point for quantifying the savings realized through SSI reduction, it likely represents only a fraction of SSI-associated costs.

Our study has several limitations. First, the cohort is specific in its focus on elective colorectal surgical procedures performed at a single institution. To what extent similar results could be obtained with the application of the bundle in other patient populations, specialties, and institutions is uncertain. Second, because we have focused on the effect of a bundle or system of care with simultaneous initiation of multiple interventions, it is impossible to say which specific aspects of the bundle were beneficial. Third, an inherent problem with studies examining outcomes during a period is that concurrent changes in medical practice over time serve as potential founders. For instance, a change in CRS practice at our institution during the study period was the advent of an enhanced recovery pathway (ERP),43–44 which began in 2010. The propensity match performed in this study was intended to limit the effect of confounding variables brought about by the ERP and other changes in clinical practice. Nonetheless, confounding variables not included in our propensity analysis may exist. At least with regard to lowering the SSI rate, we expect that any contribution from the ERP was small because the ERP does not include specific preventive SSI measures. This is supported by the fact that the CRS SSI rate in 2010 (a prebundle year in which the ERP was in place) was 20.2%. In contrast, the ERP was likely a significant confounder for length of stay and 30-day readmission. Therefore, the trends toward reduction in these outcomes should not be solely attributed to the use of the bundle.

Conclusions

Despite these limitations, we conclude that the preventive SSI bundle effectively reduces the SSI rate in elective CRS. Furthermore, the increased costs associated with SSIs support that the bundle represents an effective approach to reduce health care costs. Further study is needed to assess whether the bundle can be effective with wider application and what level of compliance with bundle measures is needed to achieve good results.

ARTICLE INFORMATION

Accepted for Publication: January 7, 2014.
Published Online: August 27, 2014.

Author Contributions: Drs Keenan and Speicher had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Keenan, Speicher, Walter, Manthy.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Keenan, Speicher. Critical revision of the manuscript for important intellectual content: All authors.
Conflict of Interest Disclosures: None reported.

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