Prospective study of single-stage repair of contaminated hernias using a biologic porcine tissue matrix: The RICH Study

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Background. *In the presence of contamination, the repair of a ventral incisional hernia (VIH) is challenging. The presence of comorbidities poses an additional risk for postoperative wound events and hernia recurrence. To date, very few studies describe the outcomes of VIH repair in this high-risk population.*

Methods. *A prospective, multicenter, single-arm, the Repair of Infected or Contaminated Hernias study was performed to study the clinical outcomes of open VIH repair of contaminated abdominal defects with a non–cross-linked, porcine, acellular dermal matrix, Strattice.*

Results. *Of 85 patients who consented to participate, 80 underwent open VIH repair with Strattice. Hernia defects were 'clean-contaminated'* (n = *39), 'contaminated'* (n = *39), or 'dirty'* (n = *2), and the defects were classified as grade 3* (n = *60) or grade 4* (n = *20). The midline was restored, and primary closure was achieved in 64 patients; the defect was bridged in 16 patients. At 24 months, 53 patients (66%) experienced 95 wound events. There were 28 unique, infection-related events in 24 patients. Twenty-two patients experienced seromas, all but 5 of which were transient and required no intervention. No unanticipated adverse events occurred, and no tissue matrix required complete excision. There were 22 hernia (28%) recurrences by month 24. There was no correlation between infection-related events and hernia recurrence.*

Conclusion. *The use of the intact, non–cross-linked, porcine, acellular dermal matrix, Strattice, in the repair of contaminated VIH in high-risk patients allowed for successful, single-stage reconstruction in >70% of patients followed for 24 months after repair. (Surgery 2012;■:■-■.)*

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Hernia repair in the presence of contamination is challenging. Patients in need of such repair often have comorbidities and multiple risk factors that further contribute to the development of postoperative complications and hernia recurrence. High-risk patients requiring repair of contaminated defects or repair after the removal of infected prosthesis often undergo a planned, staged repair, sometimes with a temporary skin graft over the abdominal viscera. During a second operation, the defect is repaired definitively. This staged approach has been associated with prolonged recovery times and difficulty in achieving definitive abdominal wall reconstruction during the second stage,[1] and may contribute to a decreased quality of life. The alternative, a definitive single-stage repair often includes the use of a biologic prosthesis to reinforce or bridge the fascial defect, coupled with advanced operative techniques, such as component separation. Although the use of component separation techniques to obtain primary closure of the hernia defect is increasingly common, the outcomes when

All investigators received research support from LifeCell Corporation for the conduct of this study. Dr Butler serves as a consultant for LifeCell Corporation. Drs Butler, Rosen, Vargo, DeNoto are members of LifeCell's Speakers' Bureau.

Accepted for publication April 27, 2012.

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0039-6060/$ - see front matter

doi:10.1016/j.surg.2012.04.008

used in a contaminated operative site have not been well studied.

When used in hernia repair, biologic prostheses provide support to weak tissue or bridge areas of absent tissue and allegedly provide a biologic scaffold for native tissue in-growth. Some biologic prostheses also seem to be less likely to harbor contamination by supporting rapid neovascularization,[2] which provides access of host defense systems to the site to combat microorganisms. These tissue-based products provide an alternative to synthetic prostheses and, particularly in the face of contamination or infection, may decrease the risk of postoperative complications.[3-5]

Strattice Reconstructive Tissue Matrix (LifeCell Corporation, Branchburg, NJ) is a decellularized, intact, non–cross-linked, porcine extracellular dermal matrix designed to perform as a surgical prosthesis for soft tissue repair. At the time of study design, the investigators felt that the use of a non–cross-linked xenograft would be important to optimize tissue in-growth and neovascularization, and that it should be available in large sheets to avoid the suturing of several sheets of mesh together to perform the repair. Strattice was the only mesh available at that time that fulfilled all characteristics and its maker agreed to provide the mesh at no cost.

The Repair of Infected or Contaminated ventral incisional Hernias (RICH) study prospectively evaluated the clinical outcomes and durability of repair in patients undergoing repair of infected or contaminated ventral incisional hernias (VIHs) with Strattice. We herein have reported the 24-month results of the RICH study.

METHODS

Study design. This prospective, multicenter, single-arm, observational study was approved by the Institutional Review Boards of all participating institutions and all patients provided written informed consent. The study was registered (ClinicalTrials.gov number NCT00771407).

Patients aged ≥18 years with hernias ≥9 cm^2 by physical examination and reparable using a single sheet (up to 20 × 20 cm) of Strattice were recruited from 12 sites across the United States. Patients were only enrolled into the study if they were to undergo a medically necessary open repair of a ventral hernia and if the hernia was classified as 'clean-contaminated,' 'contaminated,' or 'dirty,' as per the Surgical Site Infection classification system.[6]

Patients were excluded from the study if they were nonambulatory, were to undergo laparoscopic hernia repair, had a systemic infection at the time of repair, had chronic conditions such as hepatic cirrhosis, had renal failure on hemodialysis or peritoneal dialysis, had incomplete malignancy resection or a defined collagen disorder, had a body mass index (BMI) of >40 kg/m^2, a life expectancy of <24 months, required chronic immunosuppressive therapy including steroids or cytotoxic agents, or had sensitivity to porcine products.

Reconstruction required appropriate methods of bioburden reduction, such as debridement of nonviable tissue, abdominal 'washouts,' and drainage of abscess(es) before or at the time of definitive repair. The study required Strattice to be placed in the retrorectus or intraperitoneal space (ie, as an underlay), with a 3- to 5-cm overlap of healthy, musculofascial tissue. Primary fascial closure was encouraged, but in those cases where primary closure was not possible, component separation techniques were used to obtain closure or at least minimize the size of the defect. The number, placement, and duration of drains were left to surgeon discretion. Endpoints were evaluated in interim data reviews at day 30 and months 6, 12, and 24.

Outcomes. The primary endpoint was the incidence of wound events, including clinically relevant inflammation, seroma, hematoma, dehiscence of the incision, infection of the operative wound, incidence of reoperation, and bedside debridement or removal of Strattice. Infection-related events were categorized as those with wound drainage only (requiring no intervention), cellulitis, draining pus, or requiring incision and drainage. Seromas were diagnosed clinically and described as 1 of 3 subcategories: (1) Self-limiting requiring no intervention, (2) requiring aspiration of ≤50 mL fluid, or (3) requiring aspiration of >50 mL fluid and/or placement of a drain. Events were counted only once until the event resolved.

Secondary endpoints included resumption of activities of daily living as measured by the Activities Assessment Scale (AAS), narcotic/analgesic use, antibiotic days, duration of hospital stay, resource utilization, and hernia recurrence. The AAS asks individuals to rate on a scale of 1 to 5 the level of difficulty they experience in performing various tasks of daily living, such as getting in and out of a chair, climbing stairs, and engaging in various activities of mild, moderate, or substantial exertion. Antibiotic and narcotic days were calculated as the number of days an antibiotic or narcotic was administered or taken (per patient report, if after hospital discharge). In cases of suspected hernia recurrence, the patient was seen

in follow-up by their surgeon, and hernia recurrences were diagnosed by clinician evaluation and verified by abdominal computed tomography.

Follow-up. Patients were followed prospectively from the time of repair for local inflammation, infection, and pain. Assessments were made after operation on postoperative days (POD) 7 (±3 days), 14 (±3 days), and 30 (−3 to +7 days), as well as months 3 (±2 weeks), 6 (±4 weeks), 12 (±4 weeks) and 24 (±4 weeks). At each visit, surgeons were required to assess inflammation (erythema, edema, heat, and pain) at the operative site. If a hernia recurred and needed to be repaired, study participation continued until the time of recurrence repair.

Statistical analysis. Continuous variables were summarized using means and standard deviations, and categorical variables were summarized with frequencies and percentages. A sample size of ≥75 patients was planned. The intent-to-treat population, which was defined as patients who had received Strattice reinforcement of the hernia repair and completed ≥1 postoperative visit, was used to describe the outcomes. Univariate Pearson correlation tests were performed to assess relationships between various characteristics and outcomes, Student's *t*-tests to compare to means, and Fisher's exact tests to compare proportions.

RESULTS

Patient characteristics. A total of 85 patients consented to participate in the study, and 80 underwent ventral hernia repair with Strattice (Figure). Hernia defects were 'clean-contaminated' (n = 39; 49%), 'contaminated' (n = 39; 49%), or 'dirty' (n = 2; 2%), and the defects were classified as grade 3 (n = 60) or grade 4 (n = 20). Baseline patient characteristics are shown in Table I. The majority of patients (64%) had undergone multiple prior hernia repairs, more than one third had experienced previous abdominal wound infections, and one quarter of these patients had a body mass index of >30 kg/m^2. Additional risk factors and comorbidities in the study population are shown in Table I. Intraoperative challenges are detailed in Table II.

All hernias were midline, and at the time of repair, hernia defects were 236 ± 158 cm^2 (mean ± standard deviation; range, 8–841) with a mean length of 14.9 ± 6.7 cm (range, 3–33). Repairs were performed using 20 × 20-cm (86%), 16 × 20-cm (13%), or 10 × 20-cm (1%) sheet of Strattice. Primary fascial closure was achieved in 12 patients (15% of patients), 3 of whom received Strattice reinforcement as an on-lay (a protocol violation). Component separation techniques

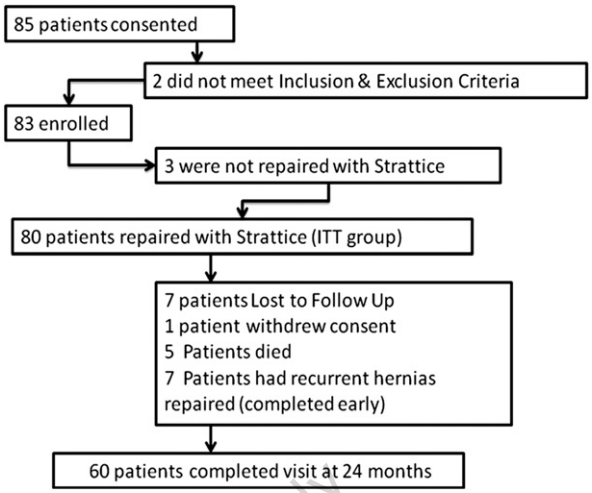

Figure. Study population. *ITT*, Intent-to-treat.

Table I. Baseline patient demographics and risk factors/comorbidities

Characteristic	*Patients* (n = *80)*
Age (yrs)	
Mean ± SD	57 ± 14
Male, *n* (%)	47 (59)
Ethnicity, *n* (%)	
Caucasian	71 (89)
African American	9 (11)
Risk factor/comorbidity, *n* (%)	
Current (or within past 2 weeks) smoker	14 (18)
Obese (BMI 35–40 kg/m^2)	18 (23)
Diabetes	17 (21)
Chronic pulmonary disease	13 (16)
Past abdominal aortic aneurysm	7 (9)
Prior ventral incisional hernia repair	51 (64)
Enterocutaneous fistula	7 (9)
Previous abdominal wound infection	27 (34)

BMI, Body mass index; *SD*, standard deviation.

were used to achieve fascial closure in 52 patients (65%). Fascial closure was not achieved in 16 defects (19%), despite the use of component separation techniques, and no musculofascial medialization procedure was possible in the last patient (1%), where fascial closure was not achieved. The tissue matrix reinforced mainly the repair in a retrorectus (36%), intraperitoneal underlay (60%) position, or as an on-lay (4%; Table III).

In 78 patients, ≥1 closed suction drain was placed before closure of the hernia repair site. Patients had 3 ± 1 (median, 3; range, 0–7) drains placed at the time of hernia repair, and these remained in place for 1–288 days postoperatively (median, 11). Over the 24-month period of this

Table II. Intraoperative challenges

Challenge	n *(%)*
Contamination at or in operative site	42 (53)
Stoma present	31 (39)
Planned entry of gastrointestinal tract	27 (34)
Infected mesh removed during procedure	15 (19)
Infection present at or in operative site	4 (5)

Table III. Operative repair

Parameter	*Patients* (n = *80)*
Mean ± SD hernia defects area, cm^2	236 ± 158
Position of repair, *n* (%)	
Retrorectus	29 (36)
Intraperitoneal underlay	48 (60)
Onlay*	3 (4)
Fascial closure achieved, *n* (%)	64 (80)

*This constituted a protocol violation.
SD, Standard deviation.

study, patients experienced a median of 12 narcotic days (range, 0–728). At follow-up, 11 patients were lost at 1 year and 20 at 2 years.

Wound events. At 24 months post repair, a total of 95 wound events had been experienced by 53 patients (66%). There were 23 seromas, which occurred in 22 (29%) of the 80 patients (Table IV). Most seromas were transient and resolved spontaneously, although 5 interventions were required: 3 seromas were aspirated (1 twice), and 1 was aspirated and a drain placed. All these interventions were performed within the first 30 POD. Of the 5 seromas requiring aspiration and/or drainage, only 1 was reported to have developed an infection. All but 3 seromas resolved within the first 30 PODs. Of these, 1 developed on POD 14 and persisted through month 3, another was observed on POD 30 and persisted through month 12, and the third developed in month 6 and persisted through month 12.

There were 14 superficial, single-layer separations of the wound edge reported in 14 patients (18%), which were generally treated with topical dressings and the site allowed to granulate and reepithelialize. There was no relationship between wound separation and hernia recurrence (Spearman $R = 0.133$; $P = .24$, Spearman rank correlation). No operative site events required removal of the tissue matrix.

Infection-related events. There were 28 unique, infection-related events in 24 (30%) of the 80 patients. Most of these (16/28; 57%) occurred and resolved within the first 30 POD. Of the 11 late-occurring, infection-related events, 5 were abscesses, 3 were related to chronic draining sinuses, and the others were late cellulitis and persistent wound drainage. Ten of the 28 infection-related events required 'incision and drainage,' with 3 patients undergoing minor debridement of small pieces of the tissue matrix (ie, managed operatively). No tissue matrix was completely excised or explanted. Over the 24-month period of this study, intention-to-treat patients received a median of 17 days (range, 0–693) of antibiotic therapy. There was no relationship between infection-related events and hernia recurrence ($P = .75$, Fisher's exact test).

Hernia recurrence. Hernia recurrence was based on clinical assessment. In the intention-to-treat population, there were 15 hernia recurrences (19%) by month 12 and 22 recurrences (28%) by month 24 (Table V). Of the 64 patients who had a fascia-to-fascia closure with or without component separation at the time of repair, 15 recurrences (23%) were observed by 24 months. In the 16 patients in whom fascial closure was not obtained (ie, defects were bridged), a recurrence rate of 44% (7 recurrences) was observed.

Adverse events. Reported adverse events and serious adverse events were reviewed and adjudicated by an independent Medical Events Committee. No unanticipated adverse events or effects occurred, and there were no safety concerns about the tissue matrix. There were 5 deaths (6%) that occurred over the course of the study. One patient died within 30 days of ventral hernia repair from a ruptured abdominal aortic aneurysm. Two deaths were related to infections, possibly associated with the wound in 1 and from an infected retroperitoneal hematoma in another, possibly related to the subsequent placement of a renal artery stent. The fourth death was due to progressive renal and respiratory failure, and the fifth death was secondary to a myocardial infarction.

AAS. Patients completed the AAS at baseline, POD 30, and months 6, 12, and 24 after repair. At baseline, the AAS score was 71.3 ± 22.5 ($n = 83$), which significantly improved by month 3 (score 81.9 ± 17.8; $n = 70$; $P < .001$, paired difference *t*-test). AAS scores remained greater than baseline through month 24, with the peak AAS score at month 6 post repair, with a mean score of 87.9 ± 14.8 ($n = 73$; $P < .001$, paired difference *t*-test).

Hospital stay. Patients were in hospital for a median of 8 days after the repair (range, 3–81). Twenty-six of the 80 patients (33%) spent a median of 4 days in the ICU (range, 1–44) and 4 days in "step-down" units (range, 1–9).

Table IV. Cumulative wound events up to 24 months

Repair site event	*30 days,* n *(%)*	*6 months,* n *(%)*	*12 months,* n *(%)*	*24 months,* n *(%)*
Seroma	17 (21)	17 (21)	22 (28)	23 (29)
Requiring intervention	5 (6)	5 (6)	5 (6)	5 (6)
Hematoma	6 (8)	6 (8)	7 (9)	7 (9)
Would edge separation	11 (14)	11 (14)	14 (18)	14 (18)
Infection	17 (21)	21 (26)	23 (29)	28 (35)
Managed nonoperatively	6 (8)	9 (11)	10 (13)	13 (16)
Managed operatively	11 (14)	12 (15)	13 (16)	15 (19)
Abscesses				
Abdominal wall abscess	3 (4)	3 (4)	4 (5)	5 (6)
Stitch abscess	0	2 (3)	2 (3)	2 (3)
Fistulae*	1 (1)	2 (3)	2 (3)	2 (3)
Mesh removals	0	0	0	0

*One recurrent, 1 pancreatic.

Table V. Hernia recurrence

	Incidence of recurrences, % (n/N)	
Type of repair	*12 months*	*24 months*
Fascial closure with and without CST (defect area: 203 ± 150 cm^2)	14 (9/64)	23 (15/64)
With CST (defect area: 220 ± 150 cm^2)	17 (9/52)	27 (14/52)
Without CST (defect area: 126 ± 121 cm^2)	0 (0/12)	8 (1/12)
No fascial closure with and without CST (defect area: 355 ± 141 cm^2)	38 (6/16)	44 (7/16)
All intent-to-treat patients	19 (15/80)	28 (22/80)

CST, Component separation technique.

DISCUSSION

This study demonstrated that in the repair of contaminated or infected ventral hernias in high-risk patients, the use of the intact, non–cross-linked, porcine, acellular dermal matrix, Strattice, allowed for successful single-stage reconstruction. Additionally, of the 22 recurrences in this complex, high-risk group, only 7 had recurrences of such clinical importance to undergo repair within the study period.

This study enrolled patients who belong to a very difficult treatment group; all of those enrolled had hernia defects that were classified as grades 3 or 4, according to the Ventral Hernia Working Group system.[7] Furthermore, these patients often had considerable comorbidities and risk factors that would be expected to increase the occurrence of wound- and infection-related events, as well as hernia recurrence. Factors such as preoperative wound infection, smoking, and chronic pulmonary conditions have been shown to be associated with increased wound infection rates,[8] and studies have shown that postoperative wound infection after single-stage repair using a synthetic prosthesis of infected or contaminated ventral hernias is a consistent risk factor for hernia recurrence.[9] In this series, despite the occurrence rate of wound events after repair of infected and contaminated hernias, most events were managed nonoperatively and required minimal operative intervention.

It is worth noting that comparison of the RICH study with other studies has its limitations as there are no published studies that have the same characteristics and methodology. Most studies lack standardized methods, are retrospective,[10,11] single-center,[10,11] have small sample sizes (n = 20 in Ueno et al[12]), involve mixed surgical techniques, have heterogeneous patient populations, vary widely in the range of follow-up periods (from 9.1 months in Diaz et al[11] to 15.7 months in Ueno et al[12]) and use different types of prostheses (small intestinal submucosa in Ueno et al[12] and Helton et al,[10] acellular human dermis in Diaz et al[11]). Although it is difficult to compare those outcomes reported from retrospective studies with those observed in the RICH study, in the absence of other prospective studies, such comparisons are inevitable. Wound-related events observed in this study occurred at a rate similar to those reported in the literature in studies of comparable patient populations.[10-12] The rate of infection reported in this analysis was 35%. The type, frequency, and severity of adverse events in our study are comparable to those reported in a segment of patients with clean VIH, carefully selected and prospectively randomized to open repair.[13] Rates of infection in other studies of

relatively comparable patient groups were reported at 33% by Diaz et al[11] and 23% by Helton et al.[10] Moreover, whereas 19% and 7% of patients in the Helton et al[10] and Diaz et al[11] studies, respectively, required removal of the prosthesis, none of the patients in this study required complete excision of the tissue matrix, although 3 underwent minor debridement of small sections of the matrix.

Hernia recurrence rates after Strattice-reinforced repairs of infected or contaminated hernias (RICH) study patients are comparable with or better than those reported in the literature for biologic prosthesis repairs in comparable patient groups.[10,11] Fascia-to-fascia closure (reinforced repair) was achieved in the majority of patients in our study; however, patients who had inadequate abdominal wall muscle or fascia to obtain fascial closure were bridged, and such patients experienced a greater rate of hernia recurrence.

Although the use of a synthetic prosthesis to reinforce or bridge autologous tissue in hernia repair can significantly decrease the incidence of hernia recurrence,[9,14-16] its use is contraindicated typically in patients where contamination is present, because it lacks an endogenous vascular network and is thus unable to clear bacteria.[17] As a result of the complications associated with synthetic prostheses, biologically based materials have been developed. Theoretically, biologic prostheses allow the penetration of host immune cells and antibiotics to the site of infection.[18] Studies have shown that some biologic prostheses are more resistant to infection in the presence of a contaminated field and have not required removal during an infectious episode.[3-5] In the absence of data to suggest the different performance characteristics of the various biologic prostheses, however, careful consideration should be made when selecting an appropriate material for the repair.

Discussion continues regarding appropriate operative techniques to repair abdominal wall hernias.[1,19] Although the use of component separation is increasingly common in hernia repair, the use of this technique results in a contaminated field are questionable. Currently, there are few alternatives for hernia repair in a complicated patient group, such as this study population. The surgical site is often closed in a 2-stage 'planned hernia,' for which synthetic prosthesis is inappropriate because of the high risk of postoperative infection, bowel erosion, and fistula formation.

Identifying factors associated with wound infection for ventral hernia repair can provide an opportunity to improve outcomes. The risk of infection and operative site occurrences can be assessed initially by taking into account the characteristics of individual patients and hernia defects using the hernia grading system.[7] There are numerous factors to consider when deciding on the best approach for hernia repair, such as operative techniques and materials, as well as patient comorbidities and risk of infection, with the goal being to minimize hernia recurrence and postoperative complications. This study has shown that with appropriate reduction of preoperative and intraoperative bioburden, reconstruction with Strattice may be used in a single-stage approach in a high-risk patient population with contaminated ventral hernias or those associated with tissue infection.

It is important to point that there may be differences in outcomes with different prostheses, because their cross-linking or collagen damage may alter how the body interacts with the prosthesis. Orenstein et al[20] demonstrated differences in in vitro cytokine induction, a marker for monocyte/macrophage activity, which plays important roles in integration and remodeling of the prosthesis. These differences were observed in non–cross-linked human acellular dermal matrices, as well as in 4 different porcine prostheses.[21] Further differences between various prosthetic products are likely to result from different methods of processing, decellularization, and sterilization. It is likely that disparate processing alters the collagen matrix, inducing lasting biochemical and biomolecular changes which, in turn, may influence foreign body recognition and antigen presentation. These various biologic grafts should be evaluated in future comparative trials in infected and contaminated ventral hernia repairs.

Patient-centered outcomes are also important to consider after operations and should not be limited to the measurement of pain perception and requirements for pain medication. Various tools have been used to measure patient-centered outcomes. In the case of open hernia repair, McCarthy et al[22] proposed that the AAS was more sensitive to change than the SF-36 and suggested that the scale be used to establish the trajectory of recovery after these operations. In this study, AAS improved over baseline by 3 months, peaked at 6 months, and remained significantly improved over baseline by 24 months.

The strengths of our study are numerous. This study is the first in which the design is prospective, includes patients with a similar severity of defect, uses a standardized repair technique, and has relatively long follow-up period that adhered to

scheduled follow-up times. Several limitations of our study, however, should be recognized. The sample size is small, although it is the largest reported. It should also be noted that during repair, 3 patients had the tissue matrix placed as an on-lay, which constituted a protocol deviation. This study also lacks a comparison arm owing to the difficulty of identifying an appropriate control. This is the first prospective study to provide evidenced-based outcomes in the use of a biologic prosthesis over a 24-month period of follow-up. Because of the differing inherent risks of materials (synthetic, autologous, and reconstructive tissue matrix), it was considered more important to establish the outcomes of using a single type of biologic matrix in this difficult hernia population rather than to randomize patients to different types of bioprosthetic repair. We acknowledge, however, that these comparative trials need to be completed based on the preliminary data gathered from the current study.

In conclusion, the use of the Strattice reconstructive tissue matrix, a non–cross-linked, acellular, porcine dermal matrix, for the repair of contaminated ventral hernias or with tissue infection has allowed for single-stage definitive reconstruction of >70% of study patients at 2 years post repair. Despite many operative site events in this complicated patient population, no Strattice required complete excision.

Editorial assistance for this article was provided by Betty Thompson, PhD, from Excerpta Medica. The authors had full access to the data and are fully responsible for content.

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