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CASE SERIES

Rod fractures and nonunions after long fusion to the sacrum for primary presentation adult spinal deformity: a comparison with and without interbody fusion in the distal lumbar spine

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Abstract

Study design Retrospective cohort study.

Objectives To investigate the prevalence and incidence rate of rod fractures (RF) in patients undergoing surgery for correction of adult spinal deformity (ASD) with or without the use of interbody fusions in the caudal levels of the fusion construct.

Background Data: Pseudarthrosis and rod fracture after long spinal fusion to the sacrum for correction of ASD remain a concern.

Methods We reviewed clinical records of patients who underwent surgery for correction of ASD between 2004 and 2014. All cases were primary (no prior spine fusion) surgeries with long fusion to the sacrum and bilateral spinopelvic fixation. Patients were dichotomized into one of two groups based on whether an interbody fusion was performed at the caudal levels of the fusion construct. The primary outcome of interest was the prevalence and incidence rate of RFs.

Results A total of 230 patients underwent a long segment fusion for correction of ASD with mean follow-up of 55 months. 117 patients had an interbody fusion (IF) while 113 patients did not (NIF). At last follow-up, there was no significant difference in the prevalence of RFs between the cohort of patients IF vs NIF (IF cohort: $n=20$, 17.9% vs NIF cohort: $n=15$, 14.2%, $p=0.49$). However, the incidence rate for bilateral rod fractures was 1.6%/year for IF group vs 1.0%/year for NIF group ($p=0.02$). Location of RF was different between the two groups; RF (unilateral and bilateral) above L4 was the most common location in the IF group ($n=17/20$; 85%) compared to L4–S1 in the NIF group ($n=11/15$; 73%) ($p=0.02$).

Conclusion Interbody fusion does not fully protect against rod failure in the lumbar spine in ASD patients with long posterior spinal fusion and may encourage failure at L2–L4, the levels above the interbody fusion.

Level of evidence III.

Keywords Adult spinal deformity · Pseudarthrosis · Rod fractures · Lumbosacral junction

Introduction

The rate of rod fractures (RFs) in the lower lumbar spine, specifically the LS junction (L4–S1), is substantial in adult spinal deformity (ASD) patients [1–4]. The addition of sacropelvic fixation techniques with iliac screws and S2AI screws has been shown to protect the S1 screws [5] and improve fusion rates in long constructs [2], but implant failure still remains high [6] and determination of nonunion is complex. [7] Other strategies include the use of recombinant bone morphogenetic protein (rhBMP-2) and interbody fusion (IF). Whether anterior column support is useful with the combination of contemporary sacropelvic fixation and

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use of rhBMP-2 in ASD with long posterior spinal fusion (PSF) remains unanswered.

The purpose of our study is to compare the rate and characteristics of RF in ASD patients who underwent long construct fusions with rhBMP-2 and sacropelvic fixation with and without IF (most commonly L4–L5 and L5–S1) in the distal lumbar spine.

Methods

Patient selection

This is a retrospective study of 230 consecutive adult patients (≥ 18 years old) with a diagnosis of ASD (adult idiopathic or degenerative scoliosis) who underwent ≥ 5 level PSF to the sacrum with sacropelvic fixation between January 2004 and December 2014 at one institution. Two-hundred twenty-seven out of 230 patients included in the study had complete baseline and 2-year full length standing radiographs and patient-reported outcomes (PROs). One IF patient and two no interbody fusion (NIF) patients with rod fractures were followed for 1 year but were then lost to follow-up by 2 years. We report RF data on 230 patients out to latest follow-up and radiographic and PRO data on 227 patients at 2 years post the index surgery. Institutional Review Board approval was obtained prior to the initiation of the study. PROs and operative details were retrieved from the center's prospective database. The primary reasons for surgery included progressive deformity, sagittal or coronal imbalance, progressive back pain or neurogenic claudication unresponsive to nonoperative treatment. All patients included in the study met at least one or more of the following radiographic criteria: [1] sagittal vertical axis (SVA) ≥ 50 mm [2], lumbar lordosis < 30°; [3] thoracic kyphosis ≥ 60°; [4] pelvic tilt ≥ 25°; or [5] pelvic incidence minus lumbar lordosis (PI − LL) mismatch over 10°. Patients were excluded if their spinal deformity resulted from active infection, trauma or tumors. Additionally, patients who underwent a 3-column osteotomy or those with multi-rod constructs (> 2 rods) were excluded. We included only primary cases, all patients who had prior fusion or spinal deformity surgery were excluded. All surgeries were performed by two surgeons. All patients were treated with pedicle screw implants and had an implant density of ≥ 1.8 fixation points/level. Bilateral sacral screws and bilateral pelvic fixation, consisting of either iliac screws or S2 alar-iliac screws, were placed in all patients. Local bone, fresh frozen allograft and rhBMP-2 were used on all patients. Patients were dichotomized into one of two groups based on whether an IF was performed. Two surgeons performed the IFs, either anterior lumbar interbody fusion (ALIF) or transforaminal lumbar interbody fusion (TLIF). One surgeon did TLIFs, the other surgeon ALIFs or no IF. Both surgeons were active SRS members, spine-fellowship trained with over 10 years of experience. TLIFs were performed with boomerang-shaped titanium mesh cages, ALIFs with polyetheretherketone (PEEK) cages.

Preoperative variables and intraoperative variables

Demographic variables evaluated included age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) grade, history of smoking, alcohol use, diabetes, and osteopenia/osteoporosis. Postoperative variables included length of follow-up, extent of deformity correction achieved and rate of RF (prevalence and incidence rate). RFs were analyzed in terms of either unilateral (URF) or bilateral (BRF) as well as location. RFs were also listed according to location into two groups: fractures occurring above L4 and between L4 and the sacrum. Patients with BRFs with additional fracture of a single rod (BRF with additional URF) were considered to have BRF.

The number of patients who underwent revision surgery for RF is reported. Cobb angles, pelvic incidence, pelvic tilt, sagittal balance and coronal balance were evaluated both preoperatively and at 2-year follow-up.

Radiographic and patient-reported outcomes assessment

Radiographic assessments included measurements of sagittal imbalance (measured with SVA), thoracic kyphosis (T5–T12), lumbar lordosis (T12–S1), pelvic incidence, sacral slope and pelvic tilt. Pelvic incidence lumbar lordosis (PI–LL) mismatch was also calculated. All radiographic parameters were measured before surgery, postoperatively (prior to discharge) and at last follow-up on 227 patients by 2 independent reviewers. The independent reviewers were spine fellows who completed an orthopaedic or a neurosurgery residency.

Two-hundred twenty-seven patients completed SRS and ODI PROs at baseline and 2-year follow-up.

Management of rod fractures

Our institution's algorithm for management of RFs included a CT scan through the affected segments and evaluation of the patient's SRS domain scores. If an area of pseudarthrosis was identified on the CT scan, the patient was indicated for revision surgery. If no pseudarthrosis was identified, we only performed revision surgery if the patient either demonstrated loss of correction or deterioration of SRS pain and/or self-image domains greater than 0.2. The criteria for revision surgery were an arbitrary decision by the senior authors.

Statistical analysis

The primary aim of the study was to compare the prevalence and incidence rate of BRF and URF at final follow-up on 230 patients undergoing PSF to the sacrum for correction of ASD with or without an interbody fusion in the lumbar spine. We paid particularly close attention to the prevalence and incidence rate of BRFs as these seem to be most representative of nonunion. The secondary aim was to compare PROs and radiographic data at 2-year follow-up on 227 of the 230 patients.

Parametric data were expressed as mean ± standard deviation and compared using the Student *t* test. Nonparametric data were expressed as median (interquartile range) and compared via the Mann–Whitney *U* test. Nominal data were compared with the χ^2 test. All tests were two sided and were statistically significant if the *p* value was less than 0.05. Statistical analysis was performed using JMP, version 13 (SAS Institute Inc., Cary, North Carolina, USA).

Results

Two-hundred thirty adult patients who underwent ≥ 5 levels long fusion to the sacrum with pelvic fixation between January 2004 and 2014 were included in the study. Two-hundred twenty-seven patients were followed for a minimum 2 years after surgery. One-hundred seventeen patients had an interbody fusion at the caudal levels of the construct, while 113 patients did not have an interbody fusion (Table 1). The mean patient age for the entire cohort was 57.8 years (IF cohort: 57.3 ± 10.9 years vs NIF cohort: 58.1 ± 8.6 years; $p = 0.53$) (Table 1). There was no significant difference in BMI between cohorts. There was a difference in the mean posterior fusion levels between groups, 13.7 (± 3.6) in the IF group and 11.5 (± 3.8) in the NIF group ($p = 0.01$) (Table 1).

The median ASA grade was similar, not different, between both cohorts. There was no significant difference between both cohorts in the prevalence of diabetes, active smokers or osteopenia. The prevalence of osteoporosis was higher in the IF cohort (IF cohort: 21.4% vs NIF cohort: 10.6%; $p = 0.03$). Both groups had average follow-up over 4 years, but the IF group had longer average follow-up (64.3 months) compared to the NIF group (49.8 months; $p = 0.001$), as, on average, the NIF surgeries were performed more recently than the IF procedures (Table 1). We therefore calculated the incidence rate, which represents the rate of RFs per patient years of follow-up, to adjust for the longer follow-up in the IF group.

Intraoperative variables

RhBMP-2 was used in all patients in both groups. The total mean dose of rhBMP-2 from L1 to the sacrum, including

Table 1 Baseline and operative characteristics of patients undergoing operative correction of adult degenerative scoliosis and related spinal deformity with or without the use of distal interbody fusions

Characteristic	Interbody fusion cohort ($n = 117$)	No interbody fusion cohort ($n = 113$)	*p* value
Follow-up (months)	64.3 ± 29.8	49.8 ± 21.4	0.001
Male; *n* (%)	7 (6.0)	7 (6.2)	0.95
Patient age; years	57.3 ± 10.9	58.1 ± 8.6	0.53
BMI; kg/m^2	26.5 ± 4.7	26.2 ± 4.2	0.65
Diabetes; *n* (%)	4 (3.4%)	6 (5.3%)	0.49
History of smoking; *n* (%)	36 (30.8%)	35 (31.0%)	0.97
Current smoker; *n* (%)	7 (6.0%)	4 (3.5%)	0.39
Alcohol use; *n* (%)	56 (47.9%)	68 (60.2%)	0.06
Median ASA grade	2.0	2.0	0.30
Osteopenia; *n* (%)	51 (43.6%)	49 (43.4%)	0.97
Osteoporosis; *n* (%)	25 (21.4%)	12 (10.6%)	0.03
C7 SVA; cm	3.2 ± 5.3	2.9 ± 4.1	0.65
Pelvic incidence; °	55.8 ± 11.8	53.2 ± 14.1	0.14
Pelvic tilt; °	23.8 ± 9.1	22.2 ± 10.2	0.21
Sacral slope; °	31.9 ± 10.4	31.0 ± 11.5	0.51
Lumbar lordosis; °	42.2 ± 18.8	40.8 ± 16.4	0.55
Pelvic incidence–lumbar lordosis; °	13.6 ± 17.3	12.4 ± 16.5	0.61
Mean rhBMP-2 dosage (mg)			
Total L1–SI (anterior + posterior)	51.8	98.1	0.01
Total L4–S1 (anterior + posterior)	20.7	39.2	0.01
Mean number of posterior fusion levels (SD)	13.7 (± 3.6)	11.5 (± 3.8)	0.01

anterior and posterior surgeries, in the IF group was 51.8 mg compared to a total mean dose of 98.1 mg for the NIF group ($p=0.01$). The total mean dose of rhBMP-2 from L4 to the sacrum, including anterior and posterior, in the IF group was 20.7 mg compared to a total mean dose of 39.2 mg for the NIF group ($p=0.01$) (Table 1). The number of lumbar spine IFs performed per patient varied from one to three in the IF group, average slightly less than two for TLIF (1.9) and slightly more than two for ALIF (2.3). In the IF group, there were 34 patients who had ALIFs and 83 who had TLIFs performed. Cobalt chrome and stainless steel posterior implants were utilized in both groups with similar, not different, frequency. No Titanium rods were used. The NIF group utilized 5.5 mm implants and the IF group utilized 5.5, 6.0 and 6.35 mm implants, therein slightly bigger rod diameters than the IF compared to the NIF group but not statistically different. The ALIF cages were all peek cages while the TLIF cages were all boomerang-type titanium cages.

Radiographic assessment

At baseline, there was no significant difference between both cohorts in global sagittal alignment, including SVA and PI-LL mismatch (Table 1). There was no difference between the cohorts at baseline in all the lumbo-pelvic parameters, including pelvic incidence, pelvic tilt, sacral slope and lumbar lordosis (Table 1).

There was a significant improvement in all radiographic parameters at last follow-up. The C7 SVA and lumbopelvic parameters, including mean lumbar lordosis, as well as mean pelvic tilt and PI-LL mismatch, for both groups improved postoperatively with no significant difference at 2 years between groups (Table 2).

There were 20 total (URF and BFR) RFs (17.9%) in the IF cohort and 15 total RFs (14.2%) in the NIF cohort, which were not different ($p=0.49$). The IF group had 10 (8.5%) URFs and 10 (8.5%) BRFs. The NIF group had nine (8.0%) URFs and six (5.3%) BRFs. There was no difference in the prevalence of RF in both groups ($p=0.87$ for URF, $p=0.33$ for BRF). The combined incidence rate (rod fracture/patient follow-up years) for URF and BRF in the IF group was 3.7%/year compared to 3.7%/year for the NIF group ($p=0.91$). There was no difference in the incidence rate (rod fracture/patient follow-up years) for URF in the IF group 2.1%/year compared to 1.8%/year for the NIF group ($p=0.25$). Of note, there was a difference in the incidence rate for BRF, with a lower incidence rate for the NIF group of 1.0%/year compared to 1.6%/year in the IF group ($p=0.02$). When

Table 2 Postoperative variables comparison between the interbody and no-interbody cohorts; the rod fracture incidence is the rate of rod fracture per year of follow-up

Characteristic	Interbody fusion ($n=117$)	No interbody fusion ($n=113$)	p value
Rod fracture; n (%)	20 (17.9)	15 (14.2)	0.49
Unilateral rod fracture (URF); n (%)	10 (8.5)	9 (8.0)	0.87
Bilateral rod fracture (BRF); n (%)	10 (8.5)	6 (5.3)	0.33
Revision surgery for rod fracture; n (%)	12 (9 BRF, 3 URF) (10.3)	4 (3 BRF,1 URF) (3.5)	0.06
Duration from surgery to rod fracture; months	46.2 ± 28.6	40.4 ± 18.6	0.44
Location of RFs	Interbody fusion ($n=20$)	No interbody fusion ($n=15$)	p value
Above L4 URF; n (%)	9 (45%)	4 (26%)	0.06
Above L4 BRF; n (%)	8 (40%)	0	0.02
Below L4 URF; n (%)	1 (5%)	5 (34%)	0.69
Below L4 BRF; n (%)	2 (10%)	6 (40%)	0.10
Rod fracture incidence rate	Interbody fusion ($n=117$)	No interbody fusion ($n=113$)	p value
Combined rod fracture incidence; %/year	3.7	3.7	0.91
Unilateral rod fracture incidence; %/year	2.1	1.8	0.25
Bilateral rod fracture incidence; %/year	1.6	1.0	0.02
Lumbar-pelvic parameters at 2-year postop	$n=116$	$n=111$	p value
Mean C7 SVA; mm	2.9 ± 4.0	2.4 ± 3.8	0.33
Mean pelvic incidence; °	55.8 ± 11.7	53.1 ± 14.4	0.12
Mean pelvic tilt; °	22.7 ± 8.6	21.3 ± 10.6	0.27
Mean sacral slope; °	33.1 ± 8.4	32.2 ± 10.3	0.43
Mean lumbar lordosis; °	47.9 ± 11.7	46.3 ± 13.6	0.34
Mean pelvic incidence – lumbar lordosis; °	8.1 ± 12.4	6.8 ± 15.8	0.51

comparing the prevalence of combined RF and BRF for short (T9, T10, T11 to the sacrum) vs long (T2, T3, T4, T5 to the sacrum) fusions, there were no significant differences between groups. BRF rates for long (T2, T3, T4, T5 to the sacrum) fusions were 7.7% for IF vs 3.5% for NIF patients (Table 3).

In terms of location of RFs, the most common location in both groups combined was above L4 with 21/35 RF (60%). There were five RFs (three in IF and two in the NIF group) below S1 (between S1 and iliac screws) that were considered not clinically relevant as there is continued motion through the SI joints, so those RFs were not included in the number of RFs. The location of RF was different between the two groups, as RF (unilateral and bilateral) above L4 was the most common location in IF group ($n=17/20$; 85%) compared to NIF group where the most common location for RF was L4–S1 ($n=11/15$; 73%; $p=0.02$) (Table 2).

In terms of revision surgery for RFs, there were 12 patients (10.3%), 9 with BRF and 3 with URF, in the IF group who came to revision surgery versus 4 patients (3.5%), 3 with BRF and 1 URF, in the NIF group who underwent revision surgery for RFs ($p=0.06$) (Table 2). In all cases, BRFs were associated with pseudarthrosis on CT scan, loss of radiographic correction and deterioration of SRS domains. In most cases, URFs did not demonstrate pseudarthrosis on CT scan and were not associated with deterioration of SRS pain and/or self-image domains.

Patient-reported outcomes assessment

Baseline health-related quality of life (HRQoL) scores were similar, not different, between both groups, except for the SRS mental health score which was slightly higher (less pathologic) in the NIF cohort (Table 4). At 2 years after surgery, both groups reported similar, not different, improvement in most HRQoL measures. The SRS pain domain scores were higher (less pathologic) in the NIF group (3.7 ± 1.0 for IF vs 4.0 ± 0.8 for NIF; $p=0.01$) at 2 years (Table 4).

Table 3 Rod fracture rate for long (T2, T3, T4, T5 to the sacrum) and short (T9, T10, T11 to the sacrum) fusions for the IF vs. NIF groups

Characteristic	Interbody fusion ($n=117$)	No interbody fusion ($n=113$)	p value
Combined rod fracture T9, T10, T11-sacrum	4.0%	3.3%	0.78
Bilateral rod fracture T9, T10, T11-sacrum	0.9%	1.8%	0.55
Combined rod fracture T2, T3, T4, T5-sacrum	14.0%	10.8%	0.39
Bilateral rod fracture T2, T3, T4, T5-sacrum	7.7%	3.5%	0.17

Prevalence (percent of rod fracture out of total cases in that group) is reported in this table

Table 4 Preoperative and 2-year postoperative health-related quality of life measures

Characteristic	Interbody fusion cohort ($n=116$)	No interbody fusion cohort ($n=111$)	p value
Preoperative HRQOL scores			
Scoliosis Research Society (SRS) pain	2.9 ± 0.9	2.9 ± 0.7	0.80
SRS function	3.0 ± 0.8	3.1 ± 0.6	0.30
SRS self-image	2.8 ± 0.7	2.80 ± 0.7	0.90
SRS mental health	3.4 ± 0.8	3.7 ± 0.8	0.01
SRS satisfaction	2.8 ± 1.1	2.8 ± 1.1	0.90
SRS subscore	2.9 ± 0.8	3.0 ± 0.7	0.40
Oswestry disability index (ODI)	35.7 ± 16.8	35.9 ± 14.8	0.90
2-year postoperative HRQOL scores			
SRS pain	3.7 ± 1.0	4.0 ± 0.8	0.01
SRS function	3.7 ± 0.8	3.6 ± 0.6	0.10
SRS self-image	3.9 ± 0.8	3.9 ± 0.7	0.50
SRS mental health	4.1 ± 0.8	4.3 ± 0.7	0.30
SRS satisfaction	4.2 ± 0.8	4.4 ± 0.8	0.20
SRS subscore	3.9 ± 1.3	4.0 ± 1.3	0.63
ODI	21.7 ± 17.8	18.3 ± 14.3	0.10

Discussion

In this study, we compare two groups of ASD patients to determine whether interbody fusion of the lower lumbar spine was protective against RFs in long construct fusions to the sacrum. We found no significant difference in the prevalence of RFs between groups. However, in all comparisons the RF rate was numerically higher in the IF group than the NIF group and the incidence rate was significantly higher in the IF group than the NIF group for BRFs, which are most indicative of pseudarthrosis. We found the addition of anterior column support in the lower lumbar spine at levels from L4–S1 changed the location of RFs. The most common location for implant failure for the IF group was above L4 compared to lumbosacral junction, L4–S1, the most common in the NIF group. There were numerically more patients who came to revision surgery in the IF group compared to the NIF group.

Most RFs in both groups were unilateral, which are often clinically inconsequential. Our experience has been that BRFs are more problematic and represent a nonunion compared to URFs, which usually do not.

Our study shows the location of RF is different with IFs in the lower lumbar spine. Interbody fusion was protective against implant failure across those levels but did not change the overall rate of RFs observed. A large registry of ASD patients reported that L5–S1 was the most common location of most BRFs (10/21, 47.7% of patients with BRFs), while L3–L4 segment was as common as L4–L5 for URFs [4]. Adding more rods in the lumbar spine would likely increase stability [8], but no clinical data have been published on 4-year or longer follow-up with that strategy.

To our knowledge, this is the largest case series of ASD patients undergoing long spinal fusions to the sacrum for deformity correction comparing RF for IF vs NIF. We recognize the limitations of the study being retrospective in nature, surgeries performed by two different surgeons, which introduces performance bias, and a difference in follow-up between groups. However, we addressed the difference in follow-up by reporting the incidence rate, defined as rod fracture cases over patient years, as well as the prevalence. Our report of the incidence rates is to address the different treatment group follow-ups, but this is still a confounding variable. Longer follow-up than 2 years is needed to capture late fractures and both groups have well over 2 years of follow-up. The IF group had more patients with osteoporosis which represents a potential confounder though osteoporosis per se has not been shown to increase nonunion or rod fracture. Also, the NIF group had somewhat more rhBMP-2 utilized at L1 and L4 to the sacrum than the IF group and that may have had influence on the numerically lower RF prevalence and incidence in the NIF group. Also, we used a higher dose of rhBMP-2 in both groups than most centers, many of which limit use of the product due to its high cost. It is unclear whether a higher dose of rhBMP-2 represents more expense versus the expense of two or more TLIFs/ALIFs when one factors in more operative time, the price of those implants and the added surgeon charges. At least one study suggested the cost of added rhBMP-2 was less than the total cost of the interbodies [9]. Multiple studies reported on rhBMP-2 safety in higher doses, including risk of cancer [10], local and systemic effects [11]. Also, on average, 2.2 more posterior levels were fused in the IF group than the NIF group, which may predispose to more nonunion and RF risk for the IF group. However, long (T2, T3, T4, T5 to the sacrum) fusions had a numerically higher combined RF and BRF prevalence in the IF than the NIF group, although not statistically different.

Conclusion

Bilateral rod fractures were more problematic and seem more likely to represent a nonunion than unilateral rod fractures. The addition of anterior column support was not associated with a significant difference in the total rate of rod fractures in the two groups, but rod fracture was numerically higher in the IF group. Interbody fusion at L4–S1 changed the location of rod fractures to the level above the interbody fusion. For the NIF group, which utilized somewhat more rhBMP-2 in the lumbar spine, the prevalence of bilateral rod fractures was numerically, but not significantly, lower than the IF group. However, the NIF group had a statistically lower incidence rate for bilateral rod fracture. Surgeons generally accept that distal interbody fusion is needed for long fusion to the sacrum or else unacceptable nonunion rates will be seen. This paper should call into question whether that dictum is the case, especially if rhBMP-2 is used.

Key points

- Rod fracture was more common above L4 for the interbody fusion patients.
- Total rod fracture prevalence (rate of occurrence per patients studied) at final follow-up was not different for the interbody fusion vs no interbody fusion groups.
- The incidence rate (rate of occurrence per patient follow-up years) for bilateral rod fractures was higher in the IF than the NIF group.

Author contributions MED: (1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work; (2) drafted the work or revised it critically for important intellectual content; (3) approved the version to be published; and (4) agree to be accountable

for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. KB: (1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work; (2) drafted the work or revised it critically for important intellectual content; (3) approved the version to be published; and (4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. OA: (1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work; (2) drafted the work or revised it critically for important intellectual content; (3) approved the version to be published; and (4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. MS: (1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work; (2) drafted the work or revised it critically for important intellectual content; (3) approved the version to be published; and (4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. JK: (1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work; (2) drafted the work or revised it critically for important intellectual content; (3) approved the version to be published; and (4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. LGL: (1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work; (2) drafted the work or revised it critically for important intellectual content; (3) approved the version to be published; and (4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. TL: (1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work; (2) drafted the work or revised it critically for important intellectual content; (3) approved the version to be published; and (4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. MPK: (1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work; (2) drafted the work or revised it critically for important intellectual content; (3) approved the version to be published; and (4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. MG: (1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work; (2) drafted the work or revised it critically for important intellectual content; (3) approved the version to be published; and (4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Compliance with ethical standards

Ethical approval IRB approval statement: Institutional review board approval was received for this study.

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