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Robot-assisted radical prostatectomy vs laparoscopic and open retropubic radical prostatectomy: functional outcomes 18 months after diagnosis from a national cohort study in England

Julie Nossiter^{*,1,2}, Arunan Sujenthiran², Susan C Charman^{1,2}, Paul J Cathcart³, Ajay Aggarwal^{1,2}, Heather Payne⁴, Noel W Clarke^{5,6} and Jan van der Meulen^{1,2}

¹Department of Health Services Research & Policy, London School of Hygiene and Tropical Medicine, London WC1E 7HT, UK; ²Clinical Effectiveness Unit, Royal College of Surgeons of England, London WC2A 3PE, UK; ³Department of Urology, Guy's and St Thomas' NHS Foundation Trust, London SE1 9RT, UK; ⁴Department of Oncology, University College London Hospitals NHS Foundation Trust, London NW1 2BU, UK; ⁵Department of Urology, The Christie, Manchester M20 4BX, UK and ⁶Department of Urology, Salford Royal NHS Foundation Trusts, Manchester M6 8HD, UK

Background: Robot-assisted radical prostatectomy (RARP) has been rapidly adopted without robust evidence comparing its functional outcomes against laparoscopic radical prostatectomy (LRP) or open retropubic radical prostatectomy (ORP) approaches. This study compared patient-reported functional outcomes following RARP, LRP or ORP.

Methods: All men diagnosed with prostate cancer in England during April – October 2014 who underwent radical prostatectomy were identified from the National Prostate Cancer Audit and mailed a questionnaire 18 months after diagnosis. Group differences in patient-reported sexual, urinary, bowel and hormonal function (EPIC-26 domain scores) and generic health-related quality of life (HRQoL; EQ-5D-5L scores), with adjustment for patient and tumour characteristics, were estimated using linear regression.

Results: In all, 2219 men (77.0%) responded; 1310 (59.0%) had RARP, 487 (21.9%) LRP and 422 (19.0%) ORP. RARP was associated with slightly higher adjusted mean EPIC-26 sexual function scores compared with LRP (3.5 point difference; 95% CI: 1.1–5.9, $P=0.004$) or ORP (4.0 point difference; 95% CI: 1.5–6.5, $P=0.002$), which did not meet the threshold for a minimal clinically important difference (10–12 points). There were no significant differences in other EPIC-26 domain scores or HRQoL.

Conclusions: It is unlikely that the rapid adoption of RARP in the English NHS has produced substantial improvements in functional outcomes for patients.

Radical prostatectomy (RP) is a primary treatment option for men with localised prostate cancer (PCa) (Anandadas *et al*, 2011; Eggener *et al*, 2011; Donovan *et al*, 2016). Robot-assisted radical prostatectomy (RARP) has been rapidly adopted despite the lack of evidence demonstrating superior oncological or functional

outcomes compared with laparoscopic (LRP) or open retropubic radical prostatectomy (ORP).

Various studies have compared sexual and urinary function and health-related quality of life (HRQoL) according to RP type (Ficarra *et al*, 2012a, b; Yaxley *et al*, 2016; Herlemann *et al*, 2017).

*Correspondence: Dr J Nossiter; E-mail: jnossiter@rcseng.ac.uk

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However, many of these studies recruited patients from a single surgeon, single institution, or from tertiary medical centres. One community-based and two population-based studies from the USA and one multi-centre study from Sweden compared functional outcomes (Barry *et al*, 2012; Haglind *et al*, 2015; O'Neil *et al*, 2016; Herlemann *et al*, 2017). However, one of these studies used a predominantly historical control group (patients enrolled in 1994–1995; O'Neil *et al*, 2016) and none used fully validated measures of urinary continence and erectile function (Barry *et al*, 2012; Haglind *et al*, 2015; O'Neil *et al*, 2016; Herlemann *et al*, 2017).

The National Prostate Cancer Audit (NPCA) collects the data prospectively on the diagnosis, management and outcomes of every newly diagnosed man with PCa from all providers of PCa services in the National Health Service (NHS) in England and Wales. The patient-reported outcomes collected by the NPCA provide important and unique evidence. First, it is a national study that includes a truly representative sample – all patients in all surgical centres in the English NHS are invited to participate. Second, it is the only population-based study that uses the same validated instruments throughout the study to capture outcomes for patients who had radical treatment. Third, all participating patients were diagnosed in 2014, providing contemporary results. We used this evidence to compare the functional outcomes after RARP, LRP or ORP reported by patients 18 months after diagnosis.

MATERIALS AND METHODS

Study design and participants. All patients diagnosed with PCa in England between 1 April 2014 and 30 September 2014 as recorded in the NPCA database and who subsequently underwent RP were eligible for inclusion (ICD-10 and OPCS-4). This database includes relevant data items from the English National Cancer Registration and Analysis Service (www.ncras.nhs.uk) and the data items specific to the NPCA (The National Prostate Cancer Audit, 2016a).

This study was exempt from NHS Research Ethics Committee approval because it involved analysis of pseudonymised linked data collected for the purpose of service evaluation as part of the National Clinical Audit and Patient Outcomes Programme.

Survey design, administration and data handling. The NPCA patient questionnaire was designed to determine patients' views of their functional outcomes and their HRQoL following radical treatment. The questionnaire includes the EPIC-26, a validated instrument comprising 26 items to measure patient function and bother in five domains (urinary incontinence; urinary irritation/obstruction; bowel function; sexual function; hormonal disturbance). Each domain has 4–7 items. The validated summary score for each domain ranges from 0 to 100 with higher scores representing better function (Szymanski *et al*, 2010). Thresholds for a minimal clinically important difference (MCID) have been estimated for each EPIC-26 domain, representing changes considered to be meaningful for patients (Skolarus *et al*, 2015).

The EuroQol (EQ-5D-5L) describes generic HRQoL based on five domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with responses at five levels ('no problems', 'slight problems', 'moderate problems', 'severe problems', and 'unable to/extreme problems'). An index score, expressed on a scale with 0 representing 'death' and 1 'perfect health', is calculated by matching the pattern of the five responses against a set of utilities derived from the general UK population (Herdman *et al*, 2011).

Questionnaires were mailed to the homes of all identified men 18 months after they were diagnosed. Two reminders were sent to non-responders 3 and 6 weeks after the first mail out.

The survey response data were linked to records from the NPCA prospective audit database and Hospital Episodes Statistics (HES), an administrative database of all admissions to the English NHS (<http://content.digital.nhs.uk/hes>). The ICD-10 system classifies diseases and other health conditions and the OPCS-4 classifies interventions and surgical procedures (ICD-10 and OPCS-4).

The survey questionnaire provided the data on ethnicity and comorbidities. The NPCA database was the data source for age at diagnosis, tumour characteristics according to TNM scores, Gleason biopsy score, serum PSA and additional treatments (adjuvant/salvage external beam radiotherapy and androgen deprivation therapy [ADT]). Hospital Episodes Statistics was used to determine socioeconomic deprivation and type of RP (OPCS-4 Classification of Diseases codes for RARP: Y753, Y765; ORP: Y508, Y751, Y752, Y763, Y768).

Socioeconomic deprivation was measured with the Index of Multiple Deprivation (IMD) for lower super output areas (small geographic areas with population of ~1500 people) (Noble *et al*, 2008). Areas were grouped into five categories according to national quintiles of the IMD ranking with higher scores indicating more deprivation.

Men were classified as having low-risk localised, intermediate-risk localised, locally advanced or advanced cancer based on their TNM stage, Gleason score, and PSA level, according to a previously developed algorithm (The National Prostate Cancer Audit, 2016b).

Outcomes. Primary outcome measures were the five EPIC-26 domain scores and the EQ-5D-5L index score according to RP technique. Missing patient response data to individual questions were handled in accordance with respective guidelines for EPIC-26 and EQ-5D-5L (The University of Michigan, 2002; The EuroQoL Group, 2015).

Statistical analysis. We used multivariable linear regression to estimate differences in outcomes with adjustment for patient characteristics, including age, patient-reported number of comorbidities and ethnicity, cancer risk group according to NPCA data (determined on the basis of TNM stage, Gleason score and PSA level), and socioeconomic status according to HES. All *P*-values were based on the Wald test.

Multiple imputation by chained equations accounted for missing values of the adjustment variables and outcomes so that regression models included all 2219 patients (White *et al*, 2011). Missing values were replaced with 50 sets of plausible values and Rubin's rules were used to combine estimates and obtain adjusted differences with 95% confidence intervals (95% CI).

All reported *P*-values are two-sided and $P < 0.05$ was considered statistically significant without adjustment for multiple comparisons. Adjusted differences in EPIC-26 domain scores were considered to be clinically relevant if the differences reached the threshold for a MCID (Skolarus *et al*, 2015). The data analysis was undertaken using Stata version 14 (StataCorp. 2015. Stata Statistical Software (College Station, TX, USA).

RESULTS

Response rate and data completeness. Of the 2883 eligible men who underwent RP at all prostatectomy centres ($n = 55$) in England and received a questionnaire, 2219 (77.0%) responded. Compared with non-responders, responders tended to be older, were more commonly of white ethnicity, reported fewer comorbidities, and were less likely to live in more socioeconomically deprived areas (Supplementary Table 1). The missing data levels were low, typically $< 5\%$ for the majority of fields in the questionnaire.

Patient characteristics. Of the 2219 responders, 1310 (59.0%) had RARP, 487 (21.9%) LRP, and 422 (19.0%) ORP. Most responders, 1954 men (91.4%), underwent surgery within 6 months from diagnosis and 1714 men (80.1%) completed the surveys 12–18 months from surgery. There was no evidence that timing of surgery was related to RP type.

Patient characteristics are presented in Table 1. The majority of men were ≤70 years (89.2%) and of white ethnicity (93.9%). Overall, men from more socio-economically deprived backgrounds were under-represented. About one-third of men reported no comorbidities. In all, 7.6% of men also received radiotherapy and 4.6% ADT. There were only small differences in patient characteristics across RP group. For example, men who underwent ORP tended to be slightly older, and more often of white ethnicity. Men who underwent LRP were less likely to be in the most socio-economically deprived national quintile.

Tumour characteristics. Tumour characteristics were very similar across surgical groups (Table 2). Overall, 59.6% of men had tumour stage T2 and 38.2% stage T3/T4. However, men having ORP slightly more often had positive nodal stage N1, a Gleason score ≥8, and PSA levels ≥10. Consequently, the cancer risk profiles for men undergoing RARP or LRP were similar, but slightly more men undergoing ORP had locally advanced or advanced disease.

Patient-reported outcomes according to RP type. Robot-assisted radical prostatectomy was associated with slightly higher adjusted mean EPIC-26 sexual function scores (Table 3) compared with LRP (adjusted mean difference 3.5 points; 95% CI: 1.1–5.9, *P* = 0.004) or ORP (adjusted mean difference 4.0 points; 95% CI: 1.5–6.5, *P* = 0.002). These differences were smaller than the

established threshold for a MCID of 10–12 points (Skolarus *et al*, 2015).

There was no significant difference in EPIC-26 urinary incontinence, urinary irritation, bowel and hormonal function scores or EQ5D-5L index scores between RARP and LRP or ORP (Table 3).

DISCUSSION

In this contemporary, observational study of all men diagnosed with PCa in the English NHS between 01 April 2014 and 31 October 2014 who underwent RP in prostatectomy centres nationwide, RARP was associated with better sexual function than LRP or ORP, 18 months after diagnosis. However, the difference in EPIC-26 sexual function scores (3.5 point difference for RARP compared with LRP and 4 point difference for RARP compared with ORP on a scale ranging from 0 to 100) is considerably smaller than the established threshold for a clinically meaningful change (10–12 points) (Skolarus *et al*, 2015). This suggests that most patients would not identify this difference in sexual function as important. There was no significant difference in other measured functional parameters, including continence or HRQoL.

Our results concur with a recent phase 3 randomised controlled trial (RCT) comparing 163 men undergoing RARP with 163 men having ORP (Yaxley *et al*, 2016). This, to our knowledge, the largest RCT to date, found no significant differences in the EPIC sexual and urinary function scores 12 weeks after surgery. However, this RCT included a young cohort of patients (mean

Table 1. Patient characteristics by type of radical prostatectomy

	RARP n (%)	LRP n (%)	ORP n (%)	Total n (%)
No. of patients	1310 (59.0%)	487 (21.9%)	422 (19.0%)	2,219
Age at diagnosis (years)				
≤60	368 (29.2%)	121 (25.9%)	88 (22.0%)	577 (27.1%)
61–70	780 (61.9%)	284 (60.7%)	256 (63.8%)	1320 (62.1%)
>70	111 (8.8%)	62 (13.2%)	57 (14.2%)	230 (10.8%)
Missing	51	20	21	92
Ethnicity				
White	1180 (92.5%)	453 (94.0%)	399 (97.6%)	2,032 (93.9%)
Non-white	94 (7.8%)	28 (5.8%)	10 (2.4%)	132 (6.1%)
Missing	36	6	13	55
Socioeconomic deprivation				
Least deprived quintile	339 (26.3%)	131 (27.0%)	119 (28.2%)	589 (26.8%)
2nd	311 (24.1%)	122 (25.2%)	99 (23.5%)	532 (24.2%)
3rd	292 (22.9%)	117 (24.3%)	87 (20.6%)	496 (22.6%)
4th	186 (14.5%)	78 (16.1%)	57 (13.5%)	321 (14.7%)
Most deprived quintile	161 (12.5%)	36 (7.4%)	60 (14.2%)	257 (11.7%)
Missing	21	3	0	24
Comorbidities				
0	465 (35.5%)	149 (30.7%)	136 (32.2%)	750 (33.8%)
≥1	845 (64.5%)	338 (69.3%)	286 (67.8%)	1469 (66.2%)
Additional treatments				
Radiotherapy (EBRT)	97 (7.4%)	35 (7.2%)	38 (9.0%)	170 (7.6%)
Androgen deprivation	51 (3.9%)	22 (4.5%)	28 (2.8%)	101 (4.6%)

Abbreviations: LRP = laparoscopic radical prostatectomy; ORP = open retropubic radical prostatectomy; RARP = robot-assisted radical prostatectomy.

Table 2. Tumour characteristics by type of radical prostatectomy

	RARP n (%)	LRP n (%)	ORP n (%)	Total n (%)
No. of patients	1310 (59.0%)	487 (21.9%)	422 (19.0%)	2,219
Tumour stage				
T stage				
T1	28 (2.4%)	10 (2.3%)	8 (2.0%)	46 (2.3%)
T2	713 (60.3%)	256 (58.5%)	236 (58.7%)	1205 (59.6%)
T3/T4 ^a	441 (37.2%)	173 (39.3%)	158 (39%)	772 (38.2%)
Missing	128	48	20	196
N stage				
N0	1057 (96.7%)	389 (98.2%)	370 (94.9%)	1816 (96.5%)
N1	36 (3.3%)	7 (1.8%)	19 (4.9%)	62 (3.3%)
Missing	217	91	33	341
Gleason score				
≤6	217 (20.6%)	108 (24.9%)	68 (19.0%)	393 (21.3%)
7	708 (67.2%)	283 (65.3%)	224 (62.6%)	1215 (65.8%)
≥8	129 (12.2%)	43 (9.9%)	66 (18.4%)	238 (12.9%)
Missing	256	53	64	373
PSA (ng/ml ⁻¹)				
<10	664 (66.9%)	296 (72.4%)	212 (60.1%)	1172 (66.8%)
10–20	264 (26.6%)	97 (23.7%)	115 (32.6%)	476 (27.1%)
>20	65 (6.6%)	16 (3.9%)	26 (7.4%)	107 (6.1%)
Missing	317	78	69	464
Cancer risk profile				
Low/intermediate ^b	547 (50.8%)	220 (51.9%)	172 (45.7%)	939 (50.0%)
Locally advanced/advanced	530 (49.2%)	204 (48.1%)	204 (54.3%)	938 (50.0%)
Insufficient information ^c	233	63	46	342

Abbreviations: LRP = laparoscopic radical prostatectomy; ORP = open retropubic radical prostatectomy; RARP = robot-assisted radical prostatectomy.

^aOverall, there were 6 patients with T4.

^bOverall, there were 15 patients with a low risk cancer.

^cOverall, there were 4 patients with advanced cancer.

Table 3. Relationship between patient-reported outcomes post-procedure and type of radical prostatectomy (ORP, LRP and RARP): overall domain scores for EPIC-26 and EQ5D-5L and adjusted differences for RARP vs LRP and RARP vs ORP

	RARP	LRP	ORP	RARP vs LRP Adjusted difference (95% CI)	RARP vs ORP Adjusted difference (95% CI)
No. of patients	1310 (59.0%)	487 (21.9%)	422 (19.0%)		
EPIC-26					
Urinary (incont.) Mean (SD) Missing	70.5 (28.0) 70	68.5 (29.5) 28	70.1 (27.3) 31	1.2 (−1.7,4.2) <i>P</i> =0.4	−0.3 (−3.1, 3.1) <i>P</i> =0.9
Urinary (irrit./obst.) Mean (SD) Missing	91.4 (11.8) 183	91.2 (11.7) 70	91.0 (11.7) 78	−0.18 (−1.8, 1.5) <i>P</i> =0.8	1.02 (−0.70, −2.7) <i>P</i> =0.2
Sexual Mean (SD) Missing	24.4 (24.7) 33	20.1 (22.3) 7	18.6 (20.5) 14	3.5 (1.1, 5.9) <i>P</i> =0.004	4.0 (1.5,6.5) <i>P</i> =0.002
Bowel Mean (SD) Missing	94.2 (11.9) 90	93.8 (11.7) 38	94.2 (12.7) 42	0.30 (−1.1, 1.7) <i>P</i> =0.7	0.37 (−1.9, 1.1) <i>P</i> =0.6
Hormonal Mean (SD) Missing	86.8 (16.3) 72	8.6 (16.3) 29	86.4 (18.2) 42	−0.32 (−2.1, 1.5) <i>P</i> =0.7	0.75 (−1.2, 2.7) <i>P</i> =0.4
EQ-5D Mean (SD) Missing	0.90 (0.14) 16	0.89 (0.15) 7	0.89 (0.16) 12	0.00(−0.01, 0.02) <i>P</i> =0.66	−0.01(−0.01, 0.02) <i>P</i> =0.2

Abbreviations: LRP = laparoscopic radical prostatectomy; ORP = open retropubic radical prostatectomy; RARP = robot-assisted radical prostatectomy.

age, 60 years), compared two high-volume surgeons and used the EPIC-50 instrument rather than the EPIC-26, and these differences in study design are likely to explain the lower sexual function scores reported in our observational study. Previous smaller RCTs reported that patients having RARP had significantly better sexual function one year after surgery (Asimakopoulos *et al*, 2011) and had improved recovery of both urinary and sexual function (Porpiglia *et al*, 2013). This is in agreement with the results of previous systematic reviews comparing RARP with other RP types, including studies with a range of different designs (Ficarra *et al*, 2012a).

Other population-based or multi-centre studies demonstrated no or at best modest improvements in functional outcomes with RARP. However, these studies are limited by the use of non-standard instruments or single items to capture sexual or urinary function and inclusion of selected populations (Barry *et al*, 2012; Haglind *et al*, 2015; Gershman *et al*, 2016; O'Neil *et al*, 2016; Herlemann *et al*, 2017).

Three studies in the USA compared RARP and ORP. The first of these studies included patients from a claims-based database and found that patients reported a moderate or big problem with urinary continence following RARP but there was no difference in sexual function (Barry *et al*, 2012). The second study compared men having RARP in 2011 and 2012, with a historical comparison group who underwent ORP predominantly in 1994 and 1995, and found no significant difference in 12-month urinary function and a modest increase in sexual function with RARP (O'Neil *et al*, 2016). The third study included men who had a RP around 2011 and demonstrated higher, unadjusted 12-month urinary incontinence scores for RARP with no difference in functioning after this time (Herlemann *et al*, 2017).

A study comparing patients having RARP, LRP, and ORP performed by high-volume surgeons (> 25 procedures per year) in two centres in the USA found no evidence that sexual or urinary functional outcomes were linked to type of surgery (Gershman *et al*, 2016). It is important to note that European, population-based studies are lacking. One study in Sweden including 14 centres found slightly better 12-month sexual function in patients

having RARP compared with ORP but little difference in urinary function (Haglind *et al*, 2015).

A strength of our study is that it reports results from a contemporary national cohort study that collected data prospectively on all men newly diagnosed with PCa in the English NHS in 2014. Further strengths include a robust sample size, a high response rate to the survey (77.0%), the collection of patient reported functional outcomes at a fixed time period after diagnosis, and the use of the same validated instruments to determine disease-specific function and HRQoL from all patients.

Our study is subject to confounding by clinical indication. However, the observed patient and tumour characteristics were very similar across prostatectomy type, which reduces the potential impact of confounding. There were small differences that may have a favourable impact on patients who had RARP, given that these men were slightly younger with less comorbidities. Conversely, patients who underwent ORP more often had locally advanced disease (nodal positivity, a Gleason score ≥ 8 , or PSA level of ≥ 10), which may have a less favourable impact on these patients. We adjusted for age, comorbidity, ethnicity, socioeconomic background, and cancer risk profile in the analyses, but these characteristics had very little impact on the difference between the RP groups. Furthermore, the choice of type of surgery depended strongly on where a patient had his treatment rather than on his specific characteristics because most hospitals offer only one surgical technique at a given time (NPCA unpublished data). This further reduces the likelihood of patients being allocated to one treatment or another based on their individual risk characteristics at diagnosis. Data on lymph node dissection were unavailable in this study.

Similar to previous studies undertaken in England that presented patient-reported outcomes, non-responders were younger, more often non-white, and lived in less affluent areas (Hutchings *et al*, 2012). However, the response rate did not vary according to type of prostatectomy, suggesting that the impact of non-response on the observed difference is likely to be very small. As men were surveyed 18 months after diagnosis, the time from surgery to completion varied. However, the majority of men

completed the survey 12–18 months after surgery and there was no evidence that timing of surgery was related to RP type.

We were unable to administer the questionnaire at the time of diagnosis, making it impossible to adjust for potential baseline differences in patient function, bother and generic HRQoL. However, we included one question in our 18-month questionnaire asking men 'How would you rate your ability to have an erection at the time of diagnosis?'. The proportion of men who indicated that this was 'very poor/none' did not vary according to the type of prostatectomy (reported by 19.4% of men who underwent RARP, 20.3% who had LRP, and 20.7% who had ORP), which further supports the validity of our comparison.

Finally, this study was carried out at a time when RARP use was growing rapidly in the English NHS. In 2010, 12 of the 65 prostatectomy centres (19%) provided RARP, but by 2017, this had changed to 42 of the remaining 49 centres (86%) (Aggarwal *et al*, 2017). A 'learning curve' may therefore have had an impact on the results. The ongoing collection of patient-reported outcomes after radical treatment for PCa in the NHS will potentially demonstrate to what extent outcomes with RARP will further improve.

Robot-assisted radical prostatectomy has been rapidly adopted in many countries and has become the most common type of RP within the English NHS (The National Prostate Cancer Audit, 2016b; Aggarwal *et al*, 2017; Sujenthiran *et al*, 2017). Its use was partly informed by a large economic evaluation that found that RARP had a lower rate of positive surgical margins (18%) than LRP (24%), in addition to lower blood loss and shorter length of hospital stay although no differences in functional outcomes were reported (Ramsay *et al*, 2012). The first phase 3 RCT comparing RARP and ORP reported no difference in surgical margin status (Yaxley *et al*, 2016).

The results of our study, with its lack of clinically relevant differences in functional outcomes and in generic HRQoL among patients who had RARP, LRP, or ORP, do not support the dramatic shift to RARP, which has taken place in the English NHS and worldwide. These findings have wider implications for the English NHS when considering the adoption of new technology. Patient reported outcome measures provide important information enabling the comparison of treatments and providers, and support decision making by patients.

CONCLUSIONS

While RARP was associated with marginally better sexual function scores than LRP or ORP as reported by men 18 months after diagnosis, this difference is small and unlikely to be clinically significant. Our study includes a representative sample, as all men who had a RP in 2014 in each of the surgical centres in the English NHS were invited to participate. Our results demonstrate that the rapid adoption of RARP in the English NHS is unlikely to lead to substantial improvements in functional outcomes for patients. Continued monitoring of patient-reported outcomes is required to explore if the benefits of RARP will emerge in the future after urologists have gained further experience with this type of surgery. The expertise and skill of an individual surgeon, and comparative performance of a surgical centre should drive treatment decisions. Rather than surgical modality alone, robust provider-level functional outcome measures are needed to support decision making by patients.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

DISCLAIMER

The funders of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report.

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