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GENERAL ORTHOPAEDICS

Safety evaluation of a strategy to restart elective orthopaedic surgery during the de-escalation phase of the COVID-19 pandemic

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Aims

To evaluate safety outcomes and patient satisfaction of the re-introduction of elective orthopaedic surgery on 'green' (non-COVID-19) sites during the COVID-19 pandemic.

Methods

A strategy consisting of phased relaxation of clinical comorbidity criteria was developed. Patients from the orthopaedic waiting list were selected according to these criteria and observed recommended preoperative isolation protocols. Surgery was performed at green sites (two local private hospitals) under the COVID-19 NHS contract. The first 100 consecutive patients that met the Phase 1 criteria and underwent surgery were included. In hospital and postoperative complications with specific enquiry as to development of COVID-19 symptoms or need and outcome for COVID-19 testing at 14 days and six weeks was recorded. Patient satisfaction was surveyed at 14 days postoperatively.

Results

There were 54 females and 46 males (mean age 44 years, mean body mass index (BMI) 25.6 kg/m^2). In all, 56 patients underwent major orthopaedic procedures. There were no exclusions. One patient had a postoperative positive SARS-CoV-2 RT-PCR test but had no typical symptoms of COVID-19 infection and no clinical sequelae. 99% of patients were satisfied with the process and 98% would recommend undergoing elective orthopaedic surgery in the study period.

Conclusion

In an environment with appropriate infrastructure, patient selection, isolation, screening, and testing, elective orthopaedic surgery is safe during the COVID-19 pandemic, and associated with high patient satisfaction. Further follow-up is required to establish that safety is maintained as the clinical restrictions are eased with the phased approach described.

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Introduction

The coronavirus disease 2019 (COVID-19) pandemic has disrupted public health worldwide and challenged healthcare systems. Most countries have taken unprecedented steps to meet demand and increase acute inpatient capacity. In an attempt to maximize inpatient bed availability and conserve resources, the National Health Service (NHS) England postponed all elective surgical procedures from 15 April 2020,[1] although many acute trusts postponed elective surgery well before this date in preparation for anticipated COVID-19 admissions.

Approximately 28 million elective cases have been cancelled or postponed worldwide during the 12 weeks of the COVID-19 pandemic.[2] The total number of cancelled operations in England is not currently published but it is expected that up to eight million people will be awaiting surgery by Autumn this year.[3] The normal volume of orthopaedic cases is estimated at 7,677,515, of which 6,295,041 cases were cancelled

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Table I. Phased clinical criteria for elective orthopaedic surgery.

Variable	Phase 1	Phase 2	Phase 3	Phase 4
Start date (isolation starts two weeks prior)	4 May 2020	15 June 2020	29 June 2020	3 August 2020
Age (years)	Under 70	Under 70	Clinical Frailty Score 1 to 3[18] (use of a stick for pain does not necessarily constitute vulnerable)	Routine risk assessment*
Body mass index (kg/m^2)	< 30	< 40	< 40	Routine risk assessment*
Diabetes permitted	No	No	No	HBA1C within standard parameters for elective surgery
Smoking	No	Permitted	Permitted	Permitted
ASA score[19]	I-II	I-II	I-II	Routine risk assessment*
Impaired renal function with eGFR < 60	No	No	No	Routine risk assessment*
Diagnosis of hypertension†	No	No	Permitted provided controlled†	Permitted provided controlled†
Arrhythmia	No	No	Permitted provided controlled†	Permitted provided controlled†
CVA or TIA	No	No	Yes, unless in last year	Routine risk assessment*
COPD	No	No	No	Routine risk assessment*
Asthma	No	Mild only‡	Mild only‡	Routine risk assessment*
Healthcare worker with patient contact within last 4 weeks	No	Permitted with isolation criteria	Permitted with isolation criteria	Permitted with isolation criteria
Vulnerable as defined by current NHS criteria[20]	No	No	Yes, if only classified as such on age and meeting other criteria	Yes with routine risk assessment*

ASA, American Society of Anesthesiologists Classification; eGFR, estimated glomerular filtration ratCVA, cerebrovascular accident; TIA, transient ischemic attack; COPD, chronic obstructive pulmonary disease.
*Routine risk assessment as would happen in routine circumstances when considering a patient for elective surgery in a private hospital with no HDU facilities.
†Uncontrolled hypertension diagnosed as > 140/90 mmHg in community, > 160/100 mmHg in clinic; Arrhythmia permitted provided controlled at preoperative assessment.
‡Moderate or severe asthma defined by daily use of steroid inhaler, or oral steroids or hospital admission within last 12 months.

during the peak 12 weeks of disruption due to COVID-19 (2,367,050 operations per week).[2] Orthopaedic surgery has the highest cancellation rate of 82% compared to other specialities.[2]

NHS England and the combined surgical colleges published a clinical guide to surgical prioritization which classified the majority of elective orthopaedic procedures as priority level 3 or 4 permitting a delay for up to or greater than months.[4] However, treatment delay is not desirable[5] and may affect longer-term clinical outcome.[6–8]

Initial experience indicates that patients with COVID-19 infection undergoing surgery demonstrate high rates of mortality, morbidity and intensive care unit (ICU) admission.[9,10] Consequently, the restart of elective surgery must be carefully considered if the disease remains prevalent in the community. The British Orthopaedic Association (BOA) published guidelines on restarting non-urgent trauma and orthopaedic care, comprising of three sections: capacity issues; infection prevention and control measures; and prioritization.[11] In parallel, other bodies have published similar recommendations.[12,13]

The Royal Berkshire NHS Foundation Trust was one of the first NHS trusts to have the opportunity to resume elective orthopaedic services in England. This opportunity arose because the trust transitioned to a de-escalation phase from 27 April 2020, and the three local private hospitals that were contracted to the NHS had not been required to accept inpatients from the trust, enabling them to work as cold sites for elective work. The orthopaedic department constructed a strategy for the restart of elective surgery based on the principles of phased relaxation of clinical criteria with continuous audit of safety outcomes and availability of resource. This study describes this strategy and reports safety outcomes and patient satisfaction of phase 1 of the strategy.

Methods

Eligibilty criteria for elective surgery. Elective surgery at our institution was stopped from 17 March 2020 to enable our theatres to be converted to an intensive care facility in readiness for COVID-19 admissions. Planning of a phased introduction of elective orthopaedic surgery was made over the subsequent weeks prior to de-escalation. The selection of clinical criteria was based on best available evidence,[6,12–17] considering the possible implications of a patient developing COVID-19 infection postoperatively, and recommendations from the BOA[11] and NHS England.[4] Patient and household isolation was initially seven days; however, this was increased to 14 days in response to Public Health England (PHE) instruction received on 15 May 2020.[17] The descriptions of each phase are shown Table I. For phases 1 to 4, any patient with a hospital admission over the past four weeks, or resident in a residential or nursing home, or who could not fulfil

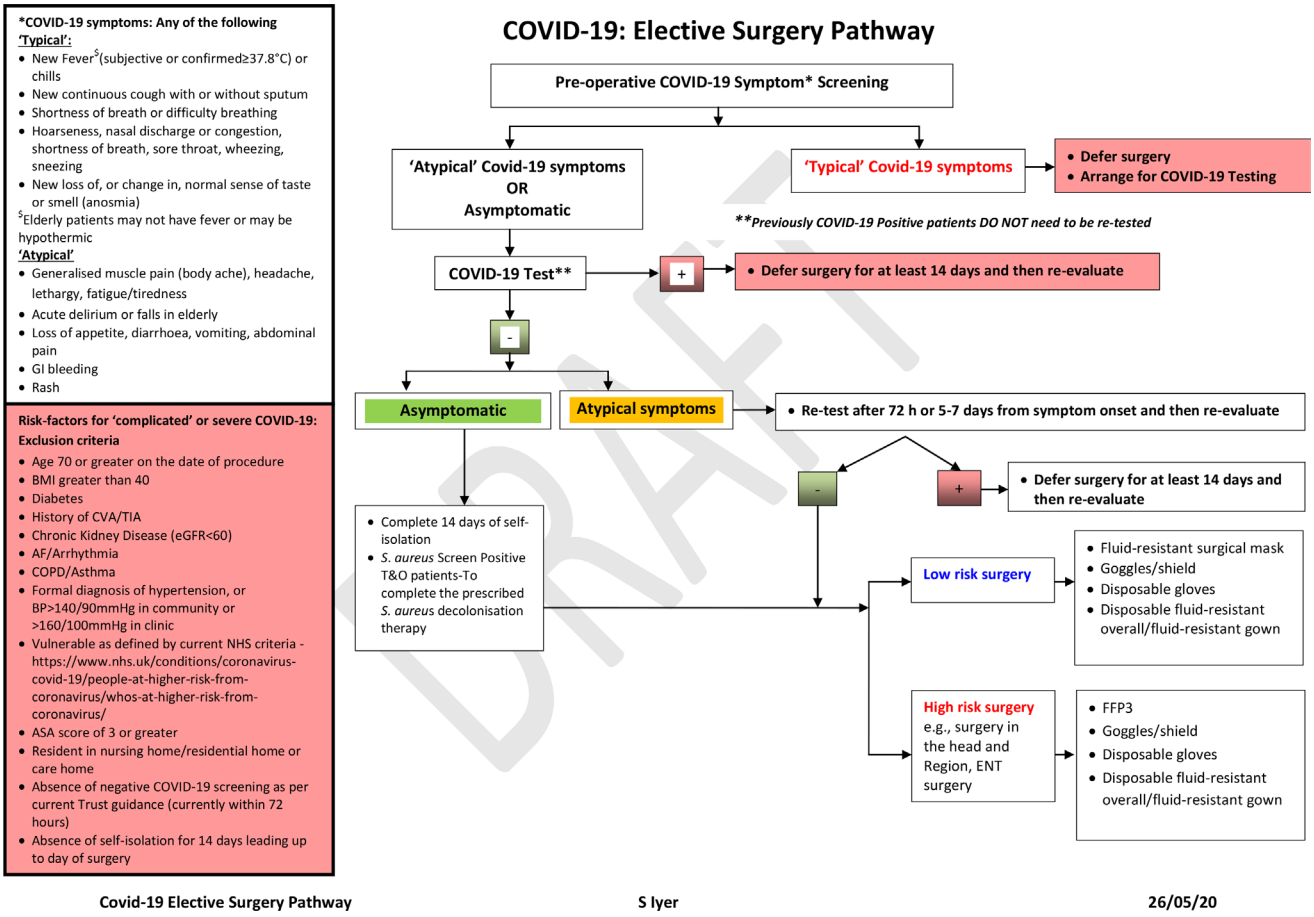

Fig. 1

COVID-19 elective surgery pathway.

the personal and household isolation criteria, was excluded. During the isolation period, any patient that developed symptoms of COVID-19 was excluded, as were patients with a positive result from a SARS-CoV-2 RT-PCR test performed at 48 to 72 hours preoperatively. Phase 4 patients will be eligible for surgery from 3 August 2020, constituting the end of the shielding period. Phase 5 represents a return to normal practice with elective orthopaedic surgery delivered on the trust site. It is not clear when Phase 5 will be possible.

The 4 's' principles (space, staff, stuff, systems)[13] were considered continuously at trust meetings to permit continuation of elective surgery during the study period. In fact, after initial restart on 4 May 2020, surgery was paused from 6 May until 18 May because of concerns regarding availability of personal protective equipment (PPE). The change from seven to 14 days of isolation also resulted in a subsequent reduction in activity for one week.

Preoperative assessment and isolation requirements. Patients identified as eligible at each phase entered the preoperative assessment pathway illustrated in Figure 1. Patients isolated with their household for 14 days (initially seven) prior to their surgical date, although household contacts were allowed to make essential journeys (including dog walking and shopping for example) provided they wore a mask and practiced social distancing. Five days prior to surgery they underwent preoperative assessment carried out by the preoperative assessment team with routine methicillin-sensitive *Staphylococcus aureus* (MSSA) swabbing for those undergoing prosthetic surgery, and screening questions related to COVID-19 symptoms (see Figure 1). All patients received an information leaflet explaining the different measures taken by hospital and staff to combat COVID-19.[21] At 48 to 72 hours preoperatively, all patients had a SARS-CoV-2 RT-PCR test (nasopharyngeal and throat swab) via a drive-through facility on the trust site.

Surgical sites. Circle Reading Hospital and the Berkshire Independent Hospital (BIH-Ramsay Group) are private hospitals in Reading. They routinely perform elective orthopaedic surgery. Three laminar flow theatres at Circle Reading and one at the BIH were made available for use all day from Monday to Friday during the study period.

On arrival at the hospital, all patients and staff were screened by questionnaire regarding symptoms and temperature check. Patients were not allowed to bring

Table II. Surgical procedures performed.

Classification	Operation	n
Major (n = 56)	Total hip arthroplasty	11
	Total knee arthroplasty	3
	Hip arthroscopy	15
	ACL reconstruction	8
	Microdiscectomy	7
	Cervical foraminotomy	1
	Lumbar decompression and fusion	1
	Arthroscopic shoulder stabilization	7
	Arthroscopic rotator cuff repair	3
Intermediate (n = 27)	Knee arthroscopy	13
	Shoulder arthroscopy and decompression/capsular release	3
	Ankle arthroscopy	3
	Excision Morton's neuroma	2
	MTPJ arthroplasty	2
	Toe amputation	1
	Excision bony foot lesion	1
	MTPJ fusion	1
	Scarf osteotomy	1
Minor (n = 17)	Caudal epidural	6
	Lumbar nerve root block	4
	Cervical nerve root block	2
	Hip joint injection	2
	MUA knee	1
	Trigger finger release	1
	Carpal tunnel decompression	1

ACL, anterior cruciate ligament; MTPJ, metatarsophalangeal joint; MUA, manipulation under anaesthesia.

in papers or magazines. Visitors were not allowed. All patients were admitted to side-rooms and all current recommendations regarding PPE and patient contact were followed in all areas of the hospital. All patients were anaesthetised and extubated in theatre with just the anaesthetist and operating department practitioner (ODP) present. The surgical (surgeon, assistant, scrub nurse) and anaesthetic (anaesthetist, ODP) teams used a single FFP3 mask each per session with a fresh mask over the top for each case, plus eye protection. Circulating nurses and radiographers used FFP2 masks. Recovery staff used gowns, FFP3 masks and eye protection. A five-minute delay after the patient left theatre occurred before cleaning commenced to allow sufficient air changes. Upon discharge, patients were advised to isolate as per current PHE recommendations.

Staff testing has not yet been introduced in Reading. Surgeons and anaesthetists continued to work at the trust site. Staff illness, and if applicable COVID-19 test status, was recorded during the study period.

Study cohort and post-operative assessment. The first 100 patients to undergo surgery during phase 1 were surveyed using a proforma at 14 days and six-weeks postoperatively. The period of 14 days was selected because this reflected the postoperative period during which a patient that acquired COVID-19 through nosocomial transmission would be expected to develop symptoms. The six-week period was selected as representing a period of potential immunosuppression following surgery with potential higher risk of community-acquired COVID-19 infection. These patients underwent surgery over a five-week period between 4 May and 5 June 2020. The study was registered as a service evaluation.

Clinical assessment. Patients were surveyed as to the presence of symptoms that could be attributed to COVID-19, and whether they had a test and its outcome. Other complications or readmissions were recorded.

Satisfaction assessment. Using a Likert scale, patients were surveyed regarding a number of points with respect to undergoing elective orthopaedic during the COVID-19 pandemic: whether they felt adequately informed of the risks of undergoing surgery; their satisfaction with the process in place to undergo surgery given the COVID-19 restrictions; whether they were able to comply with the isolation requirements preoperatively; whether they would recommend having an elective orthopaedic operation under the COVID-19 restrictions to a friend or family member; whether preoperatively they were worried about contracting COVID-19 as a result of undergoing surgery; and whether they felt the arrangements for postoperative physiotherapy and wound care were satisfactory.

Results

From 17 March 2020, 2,423 patients were on the waiting list for elective orthopaedic surgery at our trust. Of these, 217 (9.0%) met the Phase 1 clinical criteria and were eligible for surgery. Following contact by our clinical administrative team, 93 of 217 (42.9%) eligible patients felt unable to comply with the isolation period, or did not want to undergo surgery at the time, and were therefore excluded. Three patients who were asymptomatic had positive SARS-CoV-2 RT-PCR test 48 to 72 hours preoperatively and were excluded. The study cohort consisted of the first 100 patients to undergo surgery and there were no exclusions. Overall, 95 of these patients were from the elective waiting list, and five patients who fell outside the phase 1 clinical criteria were permitted to proceed based on clinical urgency, with these cases being referred to a multidisciplinary team meeting (MDT) with the medical director of the trust. One was aged 71 years, and the other four had BMIs ranging from 30.2 to 32.0. Otherwise, the requisite criteria for Phase 1 were complied with in all cases.

There were 54 female and 46 male patients with a mean age of 44 years (18 to 71). In all, 92 patients underwent surgery at Circle Reading and eight at the Berkshire Independent Hospital. The mean BMI was 25.6 kg/m^2. Overall, 69 patients were treated in the first three weeks, and had isolated for seven days. After receiving guidelines

Table III. Responses to the satisfaction survey.

Statement	Strongly agree, n (%)	Agree, n (%)	Neither agree nor disagree, n (%)	Disagree, n (%)	Strongly disagree, n (%)
Satisfied with process	81 (81)	18 (18)	1 (1)	0 (0)	0 (0)
Would recommend having elective surgery to a friend or family	83 (83)	15 (15)	1 (1)	1 (1)	0 (0)
Preoperatively worried about contracting COVID-19 as a result of surgery	9 (9)	15 (15)	8 (8)	39 (39)	29 (29)
Adequately informed of risks	54 (54)	37 (37)	4 (4)	3 (3)	2 (2)
Able to comply with isolation requirements	69 (69)	28 (28)	3 (3)	0 (0)	0 (0)
Postoperatively felt at higher risk of contracting COVID-19 as a result of surgery	7 (7)	9 (9)	5 (5)	32 (32)	47 (47)
Able to undertake physiotherapy and wound-care instructions	60 (60)	29 (29)	3 (3)	5 (5)	3 (3)

on 15 May, the remaining 31 patients transitioned to 14 days isolation. Table II details the procedures performed.

Clinical assessment. There were no in-hospital complications. One patient (a 21-year-old female undergoing anterior cruciate ligament reconstruction on 19 May) had a positive postoperative COVID-19 test. This test, which occurred on 21 May, was organized as part of a national screening programme that her household were participating in. The patient did not exhibit typical symptoms (see figure 1) of COVID-19 infection, however did complain of fatigue, which could be an atypical symptom of COVID-19 or consequence of a general anaesthetic 48 hours previously. On interview, she stated that her partner, who did not live in the household, had also been isolating with her preoperatively also although they did not have a test. She made an uneventful recovery and did not require hospital admission. A further COVID-19 test a week later was negative.

There were no other patients that developed either COVID-19 symptoms or had tests in the two-week postoperative period, and no patients developed COVID-19 symptoms, nor had a COVID-19 test, between two and six weeks postoperatively.

One patient was reviewed for an oozy wound, and one patient attended the emergency department with persistent hiccups but was discharged without a COVID-19 test.

No clinical staff members developed possible COVID-19 symptoms, nor had a COVID-19 test, during the study period.

Satisfaction assessment. Table III details the responses to the satisfaction survey. The vast majority of patients (99%) felt satisfied with the process and would recommend having an elective orthopaedic procedure under the COVID-19 precautions. 91% of patients felt adequately informed of the risks of surgery and 97% felt able to comply with isolation. 79% disagreed or strongly disagreed that they felt at higher risk of contracting COVID-19 as a result of their surgery. The vast majority (89%) agreed that they were able to undertake postoperative instructions with regards to physiotherapy and wound care.

Discussion

The first reported death from COVID-19 in the UK was at the Royal Berkshire Hospital[22] on 5 March 2020. The hospital rolled out a phased plan from code red (escalation phase) to black (de-escalation) to deal with the pandemic. The de-escalation phase was announced by the chief executive on 27 April 2020, with assurance that the trust had passed the pandemic peak and met the baseline requirements of PPE and hospital capacity.[23–26] The NHS contract with the private providers provided an opportunity for a close collaboration for the outsourcing of elective surgical activity to these 'green' (non-COVID-19) sites, given that they had not been required to receive inpatient admissions. Plans to resume elective orthopaedic surgery were therefore formulated in line with recommendations.[11–13,23–27]

The combined royal surgical colleges published a clinical guide to surgical prioritisation during the coronavirus pandemic.[4] Most elective orthopaedic procedures sit in categories 3 and 4. Having reviewed and contacted our waiting list, it was clear that only a minority of cases (9%) fulfilled the phase 1 comorbidity criteria, and of these, almost half were unable to comply with the personal and household isolation criteria, or were unwilling to have surgery during the pandemic. Our strategy was to approach the lower risk patients first, as advocated by Mouton et al,[25] before easing the clinical restrictions (Table I) in order to open up more of our waiting list, which we hoped would coincide with reducing COVID-19 prevalence in the community and inpatient burden at the trust. Our age threshold of 70 years in phase 1 and 2 was chosen to align with government shielding advice. We felt this could be replaced in phase 3 by the clinical frailty score, to enable a 'physiological' rather than purely chronological threshold, and enable the common orthopaedic cohort of patients over the age of 70 years with controlled hypertension or arrhythmias to have access to treatment. Phase 4 was timed to coincide with the government's termination of the shielding period, and thus effective for patients classified as vulnerable because of other comorbidities.

Currently, the data available on surgical outcome during the COVID-19 pandemic is limited largely to patients undergoing emergency procedures and indicates that patients that contract COVID-19 in the perioperative period have a poor prognosis.[9,10,28] Our study is the first review of elective orthopaedic operations performed on screened and tested patients in green sites in the UK after the COVID-19 pandemic peak. Over half of our patients underwent major surgery. 99% of the cohort remained COVID-19-free. It is not clear how the one patient in our study contracted COVID-19 postoperatively.

While our results overall are very reassuring, it is a concern that if this case had been a higher risk patient then the implications may have been more severe. Undoubtedly, staff testing will provide comfort as clinical criteria are relaxed. Staff testing was not available for phases 1 and 2 but we fully anticipate this will be in place as the phase 3 patients attend for treatment at the end of June. We anticipate phase 4 in a further month when shielding of vulnerable patients ends, although this will likely depend on the continued fall in population prevalence.[29] The phased strategy we have described has been applied to all surgical specialities at our trust. The relaxation of our criteria was considered appropriate for our local situation, and while this strategy may not be appropriate for all units at different stages of their de-escalation phase and with different available facilities, this framework may nevertheless be useful as a reference to work from.

Our experience of contacting patients on our waiting list was that some patients felt uneasy about undergoing surgery during the pandemic, and some were unable to comply with the isolation demands, resulting in roughly half of the eligible cohort proceeding with surgery. This experience mirrors the survey performed by Chang et al.[30] Deferring the burden of chronic musculoskeletal conditions will not make it go away, and the satisfaction and reassurance indicated in the survey, together with the clinical outcomes, provide data that our and other units may use to reassure and inform patients deciding whether to proceed with elective procedures. In the same way as our early phase criteria could be seen as being limiting, we have now reached the point where as lockdown is eased and government financial aid is withdrawn, families will by necessity need to return to work and therefore the 14-day isolation period may discriminate against certain groups. We therefore need to work to develop safe fast-track processes for such patients.

The main weakness of our study was that postoperative COVID-19 testing was not performed routinely, and it is therefore possible that some patients could have acquired asymptomatic infection, which could be spread to others. Higher risk patients than those included in this study could develop symptoms and require treatment. We hope that our strategy of relaxing the comorbidity criteria as the prevalence falls will mitigate this risk, but careful audit will be required as this happens. Although postoperative isolation was advised, this is impossible to police; however, we are not aware of any COVID-19 admissions to our hospital, whom were contacts of patients in this study. A further limitation of this study is that all the patients were treated in side-rooms, which although ideal from an infection control perspective, may not be feasible for other units contemplating return to elective activity on NHS sites.

In summary, in an environment with appropriate infrastructure, collaboration between primary care, NHS trusts and private hospitals, appropriate governance arrangements, preoperative screening, testing and patient selection, elective orthopaedic surgery can be safely resumed while COVID-19 is still present in the community. Ongoing audit will be necessary to confirm safety as comorbidity restrictions are relaxed in tandem with the introduction of staff testing.

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- R. J. Barnes: Designed the study, Prepared and reviewed the manuscript.
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