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Restoration of elective spine surgery during the first wave of COVID-19

A UK-WIDE BRITISH ASSOCIATION OF SPINE SURGEONS (BASS) PROSPECTIVE, MULTICENTRE, OBSERVATIONAL STUDY



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study*

Aims

With resumption of elective spine surgery services in the UK following the first wave of the COVID-19 pandemic, we conducted a multicentre British Association of Spine Surgeons (BASS) collaborative study to examine the complications and deaths due to COVID-19 at the recovery phase of the pandemic. The aim was to analyze the safety of elective spinal surgery during the pandemic.

Methods

A prospective observational study was conducted from eight spinal centres for the first month of operating following restoration of elective spine surgery in each individual unit. Primary outcome measure was the 30-day postoperative COVID-19 infection rate. Secondary outcomes analyzed were the 30-day mortality rate, surgical adverse events, medical complications, and length of inpatient stay.

Results

In all, 257 patients (128 males) with a median age of 54 years (2 to 88) formed the study cohort. The mean number of procedures performed from each unit was 32 (16 to 101), with 118 procedures (46%) done as category three prioritization level. The majority of patients (87%) were low-medium “risk stratification” category and the mean length of hospital stay was 5.2 days. None of the patients were diagnosed with COVID-19 infection, nor was there any mortality related to COVID-19 during the 30-day follow-up period, with 25 patients (10%) having been tested for symptoms. Overall, 32 patients (12%) developed a total of 34 complications, with the majority (19/34) being grade 1 to 2 Clavien-Dindo classification of surgical complications. No patient required postoperative care in an intensive care setting for any unexpected complication.

Conclusion

This study shows that safe and effective planned spinal surgical services can be restored avoiding viral transmission, with diligent adherence to national guidelines and COVID-19-secure pathways tailored according to the resources of the individual spinal units.

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Keywords: Post operative COVID 19 infection, Elective spinal surgery, BASS collaborative, Multicentric study

Introduction

The novel coronavirus disease 2019 (COVID-19) was first identified in Wuhan, China.¹ Since its declaration as a pandemic by the World Health Organization on 11 March 2020, most governments have acted to ‘lock-down’ the country so that various resources including hospital beds, critical care facilities, and medical personnel are utilized

effectively in battling the pandemic. Channeling essential resources in the healthcare system to fight COVID-19 has led to a rise in waiting times of elective surgeries.²⁻⁴ A delay in surgery translates to a poor quality of life. A recent publication cited the number of patients on the waitlist for a hip or knee arthroplasty with an EuroQol five-dimension score of 0 has doubled over the last one year.

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Table I. Prioritization category, as per Federation of Surgical Speciality Associations.

Prioritization category	Description
1a: < 24 hours	Cauda equina syndrome (clinically and radiologically confirmed). Acute spinal cord compression+ neuro compromise (including MSCC). Spine trauma with instability ± neurological dysfunction, polytrauma patient. Infection with metalwork.
1b: within 72 hours	Spine trauma requiring stabilization without neurological compromise. Battery change for spinal stimulators. Paediatric osteomyelitis.
2: < 1 month	Degenerative surgery with progressive neurology/neurological deficit. Multidisciplinary team-directed spinal tumour surgery.
3: < 3 months	Decompressive surgery/injections for intractable radiculopathy. Childhood/adolescent spinal deformity.
4: > 3 months	Degenerative spinal surgery without neurological compromise/refractory pain. Slow growing spinal tumours (no neurological compromise). Adult spinal deformity with progression.

MSCC, metastatic spinal cord compression.

Table II. British Orthopaedic Association categorization of facilities.

Variable	Gold unit	Silver unit	Bronze unit
Buildings	Single point of access with COVID-19 checkpoint Separate site	Single point of access with COVID-19 checkpoint Building that can be physically separated into distinct areas with completely separate entrance and no contact with blue staff/patients	Single point of access with COVID-19 checkpoint Department that can be physically separated from other areas, but unable to achieve complete separation eg walk through common area en route to department
Diagnostics	Separate facilities	Separate entrances and rooms	Separate time slots/strict cleaning
Staff (in-work considerations, out of work also needed)	Robust screening/ testing Separate teams	Robust screening/testing separate teams for defined time periods	Robust screening/testing COVID-19 checkpoint and full change/shower
Co-dependancies (e.g. renal arthroplasty)	Co-dependancies available on same green site	Co-dependancies available on same site but with green/blue split	Co-dependancies available on different site but with green/blue split

Table III. Procedural distribution of patients in the study.

Indication	Patients, n
Degenerative spinal pathology surgery	167
Spinal tumour surgery	8
Deformity corrective surgery	41
Removal of metalwork from spine	4
Nerve root blocks plus caudal epidural injections	37

This score is considered as ‘worse than death’.⁵ Although data on waitlist on spine surgeries are not available, a similar impact on quality of life is expected.

A safe and efficient pathway for resuming elective spinal surgery was required to meet the demands after the lockdown in the first wave. This involved creating patient pathways in accordance with resource feasibility in individual units across UK. The UK Health Department, in conjunction with the national surgical and speciality bodies and the Royal Colleges of Surgeons, have set out guidelines on minimizing COVID-19 transmission in elective surgical patients. These included clinical prioritization of patients, risk stratification, preoperative COVID-19 swab real-time PCR (RT-PCR) test, self-isolation for 14 days, and dedicated site for elective surgeries.⁶⁻⁸

Prospective observational studies in various surgical subspecialties have been done during the COVID-19

pandemic. However, with major spine surgeries requiring overnight stay and occasionally prolonged inpatient stay it is imperative for national spine societies to perform studies to identify the effectiveness of elective spinal surgery pathways and review their outcomes to enable various organisations including health trusts across UK to have an overview and be prepared for forthcoming COVID-19 surges. With this background, we conducted a UK-wide, multicentre collaborative study, under the auspices of the BASS, to examine the safety of reconstitution of elective spinal surgical procedures during the pandemic. The objectives were to analyze postoperative COVID-19 infections, COVID-19-related adverse events, and surgical complications following elective spine surgery in the UK.

Methods

We conducted a prospective, multicentre observational study of rate of COVID-19 infection in patients undergoing elective spine surgery during the first wave of the pandemic. The inclusion criteria were all adult and paediatric patients who underwent an elective spinal surgery in the COVID-19 pandemic recovery period during the first wave. The exclusion criteria was any planned surgery which had to be done as an emergency (category 1a), and

Table IV. Number of patients in the study, as per the prioritization category.

Prioritization category	Description	Patients, n (%)
1a: < 24 hours	Cauda equina syndrome (clinically and radiologically confirmed) Acute spinal cord compression plus neurological compromise (inc MSCC). Spine trauma with instability ± neurological dysfunction, polytrauma patient. Infection with metalwork.	
1b: within 72 hours	Spine trauma requiring stabilization without neurological compromise. Battery change for spinal stimulators. Paediatric osteomyelitis.	5 (2)
2: < one month	Degenerative surgery with progressive neurology/neurological deficit. Multidisciplinary team-directed spinal tumour surgery.	89 (35)
3: < three months	Decompressive surgery/injections for intractable radiculopathy. Childhood/adolescent spinal deformity.	118 (46)
4: > three months	Degenerative spinal surgery without neurological compromise/refractory pain. Slow growing spinal tumours (no neurological compromise). Adult spinal deformity with progression.	45 (17)

Table V. Distribution of patients with complications following spinal surgeries.

Variable	Data, n
Medical conditions	14
Wound-related	6
Neurological	6
Dural tear	3
Dysphagia/voice change	3
Herniated disc remnant	1
Death	1

patients who tested COVID-19 positive preoperatively. A study proposal with well-defined aims and objectives, inclusion-exclusion criteria, and data collection tools were sent by personal communication to multiple spinal surgery units across the UK. Prioritization of surgical cases were based on the guidelines or directives issued by Federation of Surgical Speciality Associations (FSSA) (Table I). Categorization of level of COVID-19 precaution in surgical units was performed, as per the British Orthopaedic Association (BOA) guidelines⁶ (Table II).

Prospective data obtained from eight spinal centres for the first month of operating following restoration of elective spine surgery in each individual unit was available for analysis. Each spinal unit involved had varying periods of restoration of elective spinal surgical procedures, dependent on the individual hospital service provisions and the COVID-19 infection prevalence rates in the region. Hence the data collection period was different from each participating centre, but reflected the surgical activity when the COVID-19-free pathways were established in each hospital. All of these units are tertiary referral centres for spinal surgery services and are part of the major trauma network. Six of these spinal centres are based in England, and the remaining one each from Wales and Scotland.

Data collection included categorization of facilities, risk stratification, prioritization of cases, ASA grade,⁹ status of preoperative isolation of two weeks, COVID-19 status, procedure underwent, length of stay,

postoperative complications, symptoms of COVID-19 postoperatively, and requirement of COVID-19 RT-PCR test postoperatively.

The primary outcome targeted was the 30-day postoperative COVID-19 infection rate. COVID-19 infection was identified via a positive RT-PCR test postoperatively, and was performed solely based on patients' clinical symptoms giving rise to a suspicion of possible COVID-19 infection. The secondary outcomes which were analyzed were 30-day mortality rate, surgical adverse events, medical complications, and length of inpatient stay. The postoperative complications were stratified based on Clavien-Dindo classification of surgical complications.¹⁰ This widely accepted classification system focuses mainly on the therapeutic consequences of a complication and constitutes a simple, objective, and reproducible approach for comprehensive surgical outcome assessment. All patients were reviewed via a clinic consultation at the four- to six-week postoperative period.

Ethical committee approvals were not required as no patient identifiable data were collected in the study. All the data assembled and analyzed for the study purposes was completely anonymised. The study was registered within each participating spinal surgery centre as a local service evaluation project.

Results

The study cohort comprised a total of 257 patients (128 males and 129 females) from the eight participating spinal centres across the UK. The median age was 54 years (2 to 88). Of these, 35 patients were aged less than 16 years, and most of them underwent scoliosis corrective surgery. The mean number of procedures from each unit was 32 (16 to 101).

In all, 195 patients (76%) self-isolated for 14 days prior to the elective procedure. Of the remaining, 28 patients isolated for one week and 11 for three days preoperatively. Data was not available for 12 patients, and 11 patients did not self-isolate preoperatively. Overall, 253 out of

Table VI. Distribution of complications as per the Clavien-Dindo classification of surgical complications.

Grade	Clavien-Dindo classification of surgical complications	Patients, n
1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions Allowed therapeutic regimens are: drugs as anti-emetics, antipyretics, analgesics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.	19
2	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.	7
3a	Requiring surgical, endoscopic or radiological intervention: Intervention not under general anaesthesia.	1
3b	Requiring surgical, endoscopic or radiological intervention: Intervention under general anaesthesia.	6
4	Life-threatening complication (including CNS complications)* requiring IC/ICU-management.	0
5	Death of a patient.	1

257 patients underwent a COVID-19 RT-PCR test preoperatively. The patients who did not have the RT-PCR test preoperatively underwent nerve root block injections. Most of the patients (167 patients; 65%) had elective surgery performed for degenerative spinal pathologies (Table III). The distribution of elective cases based on priority of urgency are depicted in Table IV, with the majority (118 patients; 46%) prioritized as category 3. As per the BOA guidance on risk categorization, 118 patients (46%) were classified as low risk; 106 patients (46%) were of medium risk; 27 patients (11%) were high risk; and six patients (2%) were of very high risk. According to BOA categorization of surgical facilities, the procedures were performed in 49 (19%), 82 (32%), and 126 (49%) as bronze, silver, and gold facilities, respectively.

There were 25 patients who had symptoms suggestive of COVID-19 postoperatively who underwent PCR tests, all of which turned out to be negative. One patient died 19 days after the index procedure, due to respiratory complications (negative COVID-19 test) and newly diagnosed disseminated renal cell cancer. In all, 32 patients (12%) had 34 complications (Table V), of which the most common were medical complications (23%). These complications were categorized according to Clavien-Dindo classification of surgical complications (Table VI). None of the patients needed postoperative care in an intensive care setting for any unexpected complications.

Discussion

COVID-19 has stalled elective orthopaedic lists across various nations, and has caused shortage of medical supplies, materials for surgery, manpower, and resources. Studies from the UK have reported substantial reduction in elective and emergency spinal operations during the peak of the pandemic.^{11,12} As healthcare services move in tandem with the pandemic, restoring safe elective spine surgery, this involves significant resource challenges. This initiative undertaken by BASS to ascertain the impact of restarting elective spinal services on healthcare resources challenged due to COVID-19 and to identify

COVID-19-related complications and death has not been reported before to our knowledge.

At the initial stages of the pandemic, literature had suggested to delay elective surgeries in view of COVID-19-related complications Bhangu et al^{3,4,6,7} investigated COVID-19 related pulmonary complications and mortality in a multicentre study across 24 nations. They reported that 51.2% of patients had COVID-19-related complications and 30-day mortality was 23.8% (268/1,128).¹³ However, 1,128 patients (74%) in the study had undergone emergency procedures rather than elective surgery. Similar studies from UK and the rest of the world in the initial days of the pandemic depicted an equivalent picture.¹⁴⁻¹⁶ But most of these multicentre collaborative studies highlighted the outcome of essential orthopaedic surgeries, rather than elective surgeries at the peak of the pandemic.

There are multiple studies which were published which looked into the outcome of non-essential surgeries across UK following the first lockdown. Gammeri et al¹⁷ studied the incidence of COVID-19 and its complications in patients who underwent elective surgery in a separate facility. This included patients from various surgical specialities excluding paediatric surgery. No COVID-19-related complications or deaths were reported in their multicentre prospective study of 309 patients in the UK. All the patients isolated for 14 days prior to the proposed surgery and had undergone a COVID-19 PCR test swab preoperatively. A multicentre study reviewed similar outcomes in 500 non-emergency surgeries, of which 60% were cancer-related surgeries across various surgical subspecialities among 14 NHS trusts in a 'COVID-19-free' centre. The study, however, had ten patients (2%) who were diagnosed with COVID-19, out of whom only four (1%) had confirmed laboratory diagnosis. They did not report any COVID-19-related deaths.¹⁸ Chang et al¹⁹ looked into clinical outcome of patients who underwent orthopaedic surgery with a designated COVID-19-free pathway. They had 112 patients in total, of which one patient developed symptoms postoperatively, which

later resolved. No patients had a positive COVID-19 test in the postoperative period. They concluded that a COVID-19-free pathway would result in a low viral transmission and is the way out of the pandemic.

Our collaborative, multicentre study had similar results to other surgical subspecialties with regards to COVID-19-related complications and mortality. No study to date has looked into outcomes following purely elective surgeries in spine. A study from a UK tertiary spinal centre looked into the outcomes of 78 patients who underwent spinal procedures during lockdown, and reported five patients (6.4%) who tested positive for COVID-19 and two subjects who died due to COVID-19 in the first one month. However, the majority of these were emergency spinal cases, and these subjects underwent surgery prior to the issuance of guidance on resuming elective surgical service.²⁰

In our collaborative study, only one centre had all spinal surgeries done in 'gold category facility', which adheres to single point of entry and exit, robust testing, screening by separate teams, barriers to prevent cross contamination and COVID-19-appropriate measures. However, despite more than half of the surgeries occurring at silver and bronze facilities, there were no COVID-19-related infections or complications reported. Of the 25 patients who had symptoms suggestive of COVID-19 postoperatively who underwent PCR tests, all of which turned out to be negative. It is interesting to note that 16 of these patients had surgeries in a silver or bronze categorization of facilities.

In all, 37/257 patients (14%) had nerve root injections which were day care procedures. Though these are usually done as day cases, and do not involve general anaesthesia, they were included in the study as all these patients were admitted following the same "green" COVID-19-free pathways as the other patients in the unit. The mean length of stay was 5.2 days, with 78% of patients discharged under a week. In spite of a modest duration of exposure to a hospital environment, there was no incidence of COVID-19-related infections or complications, which is commendable. Similar outcomes have been reported in patients who underwent surgical procedures for cancer and who have been inpatient with an median length of stay of 10.8 days (SD 6.1; 5 to 37).²¹

Resuming elective spinal surgeries with COVID-19-appropriate measure with COVID-19-free pathway is a feasible option to reduce the waitlist amid the pandemic. Dynamic, flexible regional solutions with formation of local pathways/protocols are needed, along with diligent monitoring of outcomes. It is crucial that local authorities and trusts ensure that adequate space, required number of staff, equipment, resources, and a robust system are available to tide over the crisis of ever increasing elective surgical waitlist. Repeated audits may be conducted to ensure continuation of quality elective surgical services without jeopardizing the safety of patients and the health of staff. It may also be prudent to compare this collated

data with similar data collected following the second wave. This would also enable an audit of the spinal services to improve patient care and close the loopholes to prevent COVID-19-related morbidity in the future surges. A time-tested delivery of services can also act as a blueprint and guide the surgical fraternity in taking necessary steps in future pandemics.

Our study has limitations in that all planned spinal procedures, irrespective of their complexity, were grouped together. The study periods varied in different hospitals in keeping with the local service provisions and restoration of elective surgery practices. The data analyzed only one month of elective surgery activity and similar postoperative follow-up time frames. However, we feel that the study addresses the relevant topic of elective spine surgery that has not been published before. Our multicentre, UK-wide prospective study would boost the confidence of both the patient groups and the clinicians in continuing to provide safe elective spinal services in the midst of the pandemic.

In conclusion, our study shows that despite variations in infection prevalence rates and service provisions across spine centres in the UK, there is very low risk of hospital-acquired COVID-19 infection for elective spine surgery patients. Undertaking elective surgery is a balance between benefit and risk. This study provides information for shared decision-making between patients and clinical teams. It also adds confidence that planned spine procedures can be performed in a safe environment with appropriate infrastructure, COVID-19-secure patient pathways, and robust governance arrangements.



Take home message

- There is very low risk of nosocomial COVID-19 infections for patients admitted for planned spinal surgery in the UK.
- Elective spine surgery can be safely performed in the midst

of the pandemic with appropriate COVID-secure patient pathways and robust governance arrangements.

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- A. Durst: Designed the study, Investigation, Formal analysis, Writing – review & editing.
- N. J. Mathai: Manuscript writing, Investigation, Formal analysis, Writing – review & editing.
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