Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Short Report

Effectiveness of a SARS-CoV-2 infection prevention model in elective surgery patients — a prospective study: does universal screening make sense?

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SUMMARY

This observational study included patients who underwent pre-operative coronavirus disease 2019 (COVID-19) screening in order to preserve patient safety. Reverse transcriptase polymerase chain reaction (PCR) for severe acute respiratory syndrome coronavirus-2 was performed in 2292 of 8740 surgical procedures, and the incidence of a positive PCR result was 0.0022%. No healthcare-associated infections were detected. There was no difference in overall mortality or length of hospital stay compared with the same period from the previous year. A selective screening strategy to identify patients for PCR testing, based on isolation measures, presurgical clinical-epidemiological assessment and selected major surgeries susceptible to a poor COVID-19-related outcome, is effective and safe for patients and healthcare workers.

Introduction

In a surgical setting, patients with coronavirus disease 2019 may trigger in-hospital outbreaks and have worse post-operative outcomes [1]. A large international survey investigated global surgical practice during the COVID-19 pandemic, and highlighted the insufficient pre-operative screening for COVID-19 [2].

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It remains unclear whether or not polymerase chain reaction (PCR) testing should be performed for all or selected elective surgery patients, including those who are asymptomatic. Available data regarding a universal strategy or high-risk surgical procedure are limited [2,3]. To maintain a safe environment for all patients and healthcare workers (HCWs), an admission screening plan to test for severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) was implemented in the study setting, giving priority to surgical procedures with higher potential risk of adverse surgical outcomes for patients with undiagnosed COVID-19. This study aimed to evaluate the effectiveness and savings of this selective approach in elective surgery in order to preserve patient safety.

Methods

Alicante General University Hospital is a third level hospital academic health system located in Alicante, Spain. Results of all SARS-CoV-2 tests performed in a presurgical screening programme from 30th June 2020 to 23rd November 2020 were analysed. A presurgical action protocol with four components was developed by the COVID Group of the Centre's Infections Commission: (1) recommendation of isolation measures in the 14 days prior to elective surgery; (2) presurgical clinical evaluation with symptomatic assessment compatible with COVID-19 in the last 2 weeks [4] (see online supplementary material) and/or epidemiological contact with COVID-19 cases; (3) PCR indication criteria [(a) clinical features compatible with COVID-19 and/or epidemiological contact with COVID-19 cases in the previous 2 weeks and (b) major thoracic, cardiac or abdominal surgery or requiring subsequent stay in the resuscitation department, i.e. surgical procedures with higher potential risk of adverse surgical outcomes for patients with undiagnosed COVID-19] [5,6]; and (4) update surgical services regarding the detailed standard protective measures for surgical procedures. Protection for the eyes, nose and mouth using a mask and goggles, or a face shield alone, is necessary when it is likely that there will be a splash or spray of any respiratory secretions or other body fluids, as defined in standard precautions. Respiratory protection currently requires the use of a respirator with N95 or higher filtration to prevent inhalation of infectious particles when aerosol-generating procedures are performed. However, the final decision for a PCR request was made by the physicians responsible for the patient.

All screening tests were collected using nasopharyngeal swabs and analysed by reverse transcriptase PCR (RT-PCR; Cobas 6800 system; Roche, Basel, Switzerland). The average time for processing and obtaining results was 8 h, with the possibility of a response time $<$2 h if rapid PCR was required.

A false-positive PCR result for SARS-CoV-2 was defined as pre-operative screening with a positive result with a low viral load in an asymptomatic patient with: (1) chest x ray and blood test not suggestive of COVID-19; (2) two subsequent negative RT-PCR determinations and absence of seroconversion 14 days after the initial evaluation; (3) at least 6 days without symptoms from the date of the first PCR; and (4) no positive cases of COVID-19 in their immediate environment.

During the study period, Alicante General University Hospital maintained universal protective measures for surgical procedures [7] and comprehensive infection control policies outside them. In brief, these included isolation wards for patients with COVID-19, universal masking precautions for patients and staff, a comprehensive testing infrastructure for patients and staff, restricted visitation policies, COVID-19 transport guidelines, and multiple service-line-specific clinical protocols for patients with COVID-19 and patients under investigation.

SARS-CoV-2 infection was established in HCWs as a composite reference standard including RT-PCR results, immunoglobulin G serologic results, and development of symptoms consistent with COVID-19. The origin of transmission for new cases of SARS-COV-2 infection in HCWs was defined as socio-sanitary (unprotected contacts in work environment, in the inter-relationship between health professionals), social (out-of-hospital, in the usual living environment) or healthcare-associated (during patient care, in routine health care).

Main outcomes

Development of secondary infection by HCWs due to the absence of universal screening

This was defined as confirmed secondary healthcare-associated COVID-19 due to patients with undetected SARS-CoV-2 infection undergoing elective surgery. A systematic evaluation of COVID-19-compatible symptomatology was performed in the health team who participated in the care process during admission.

Differed COVID-19 diagnosis in patients undergoing elective surgery

Patients were followed up on admission and for an observation period extending 30 days after discharge. PCR was performed if they started nosocomial fever or on the appearance of new symptoms compatible with COVID-19 after hospital discharge.

Clinical consequences for patients (undetected infection) due to the absence of universal screening

Length of hospital stay and in-hospital mortality were adjusted compared with the same period from the previous year.

For each week, the number of surgical procedures performed at the centre, procedures where SARS-CoV-2 PCR was performed, and positive PCRs were evaluated. In order to measure the distribution of SARS-CoV-2 PCR screening requests by surgical specialty, all surgical procedures performed by each specialty were collected and the frequency of PCR performance was quantified by department on 1 day per week (selected at random). All the information on the procedures was obtained from the Centre's Management Information System, and from PCR requests and results from the Microbiology Service Information System (Gestlab).

To calculate potential savings, the total number of elective surgeries performed during the study period (with or without SARS-CoV-2 PCR testing) and the average cost of a PCR procedure (material and staff costs) were taken into account. The COVID-19 infection rates in the health area were extracted from the Preventive Medicine electronic health record.

Categorical and continuous variables are given as frequency (percentage) and as median [interquartile range (IQR)], respectively. Differences between continuous variables were

evaluated using Student's *t*-test or the Mann–Whitney *U*-test, as appropriate. Correlation between continuous variables was evaluated using Pearson's *r*. The effectiveness of the SARS-CoV-2 infection prevention model was evaluated by the incidence of the main outcomes. SPSS v25 (IBM Corp., Armonk, NY, USA) was used for statistical analyses. $P<0.05$ was considered to indicate statistical significance. The study was approved by the institutional review board (EXP. 200145).

Results

Over the study period, a total of 8740 surgical procedures were performed at the study centre. Of these, SARS-CoV-2 PCR was performed in 2292 surgical procedures, and the incidence of a positive PCR result was 0.0022% (95% confidence interval 0.0009–0.0051) (5/2292). The positive results were distributed as follows: two in otorhinolaryngology; two in traumatology; and one in general paediatric surgery. There were 10 false-positive RT-PCR results for SARS-CoV-2 in pre-operative screening. The distribution of SARS-CoV-2 PCR screening requests by surgical specialty using a random sample is presented in Table I.

Detailed distribution of the findings by epidemiological week, and the cumulative incidence of positive SARS-CoV-2 PCR results in the health area over the preceding 14 days/100,000 inhabitants, are shown in Figure 1. During the study period, the cumulative incidence of positive results in the health area was >150/100,000 inhabitants for 42.8% (9/21 weeks) of the time.

The median proportion of PCRs requested for elective surgery procedure was 25.9% (IQR 18.4–32.4), and this was not affected by the accumulated incidence of SARS-CoV-2 infection in the health area (r=-0.35, P=0.113).

Table I
Distribution of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) polymerase chain reaction (PCR) screening requests by surgical specialty

	SARS-CoV-2 PCR screening request[a]		
	Yes (N=392)	No (N=1130)	%
Traumatology	104	21	83.2%
Dermatology	5	130	3.7%
Otorhinolaryngology	27	30	47.4%
Urology	67	134	33.3%
Gynaecology	1	110	0.9%
Ophthalmology	1	232	0.4%
General surgery	70	156	31.0%
Thoracic surgery	22	31	41.5%
Cardiac surgery	14	9	60.9%
Neurosurgery	4	70	5.4%
Children's tramatology	16	9	64.0%
Children's general surgery	7	93	7.0%
Children's otorhinolaryngology	41	4	91.1%
Vascular surgery	11	54	16.9%
Plastic surgery	2	47	4.1%

[a] In order to measure the distribution of PCR screening requests by surgical specialty, all surgical procedures performed by each specialty were collected and the frequency of PCR performance was quantified by service on 1 day per week (selected at random).

Healthcare-associated COVID-19 in HCWs

One hundred and thirteen cases of COVID-19 were detected in 1736 HCWs during the study period; only two of these cases were healthcare-associated. Neither case was a member of the operating room or surgical ward staff.

Differed COVID-19 diagnosis in elective surgery patients

During the subsequent follow-up of the patients who underwent surgery none of them was diagnosed with COVID-19 within 30 days of admission, either during hospitalisation or on an outpatient basis

Length of hospital stay and in-hospital mortality

Overall mortality in the hospitalization area of the surgical departments did not change compared with the same period of the previous year [0.54% (IQR 0.47–0.66) vs 0.53% (IQR 0.37–0.54); P=0.561]. In addition, there was no difference in the median length of hospital stay compared with the same period in 2019 [5.32 days (IQR 5.08–5.54) vs 5.52 days (IQR 5.11–5.89); P=0.564].

Taking into account the average cost of performing a SARS-CoV-2 PCR test in the health department (37.7€) and the number of PCR tests avoided (n=6448), the potential cost saving over the study period from this care model was 243,686 €.

Discussion

Early results of this non-universal PCR testing programme for COVID-19 as part of a package of COVID-19 controls showed that, despite variations in the population incidence of COVID-19, there was a low incidence of COVID-19 in asymptomatic surgical patients; no cases of healthcare-associated infection were identified in HCWs or hospitalized patients in surgical areas; and there were no changes in overall mortality or length of hospital stay. There were more false-positive PCR results than true positive PCR results. These results do not support the common practice to test every case with RT-PCR before surgery [6,8–10], even in areas with a high incidence of SARS-CoV-2 infection.

There have been no consistent statements on surgical guidelines regarding perioperative screening of patients with COVID-19. Bellato *et al.* [2] reported global surgical practices including COVID-19 screening, preventive measures and in-hospital infection during the COVID-19 pandemic in early April 2020 in a cross-sectional online survey of 936 centres. In 71.9% of the centres, local guidelines recommended that pre-operative testing should be performed based on symptoms or suspicious radiological findings, while universal testing was recommended in 18.4% of centres. In-hospital COVID-19 infection was reported in 31.5% of centres; of these, 41.4% of centres failed to trace the source and 19.7% of centres reported that the infection originated from asymptomatic patients/staff. Recently, Cimen *et al.* [3] suggested that use of a symptom questionnaire and PCR testing are important tools for screening pre-operative patients, and the symptom questionnaire may be more directive in the future.

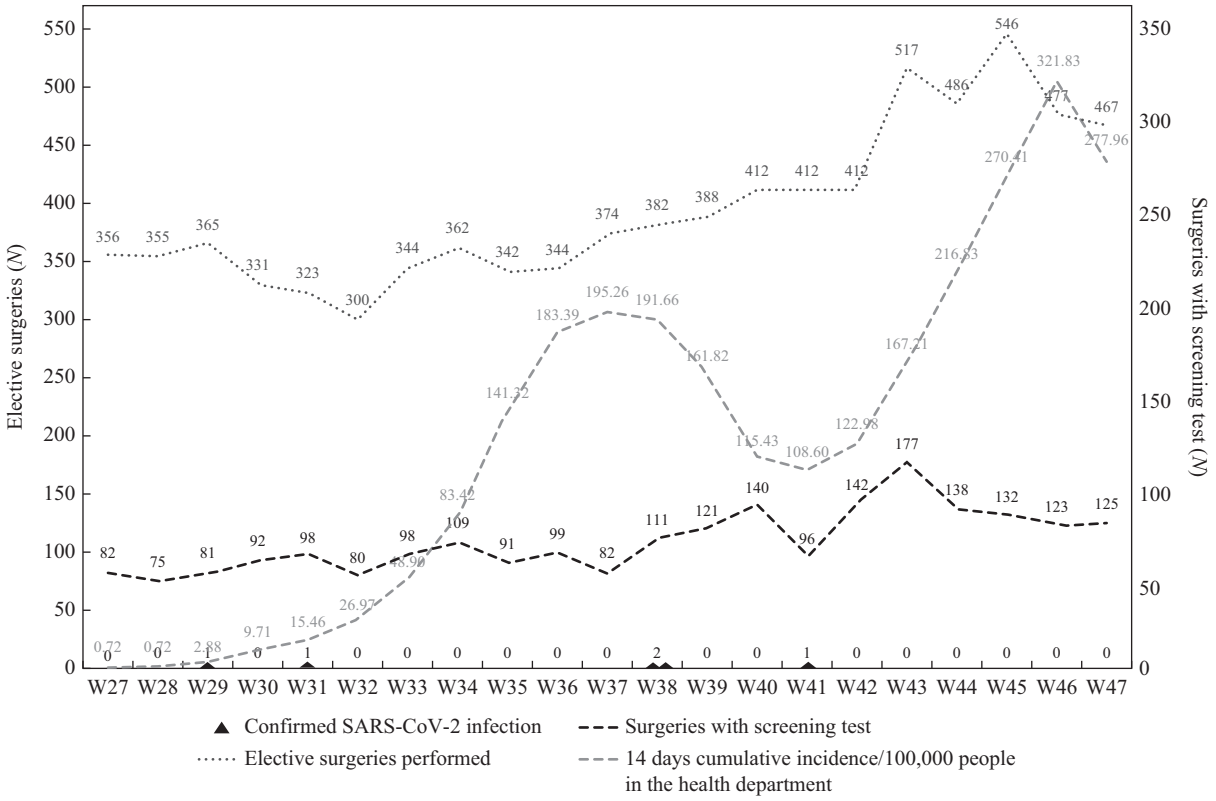

Figure 1. Distribution, by epidemiological week, of elective surgeries, procedures with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) polymerase chain reaction (PCR) performed, confirmed positive PCR results, and cumulative incidence of positive SARS-CoV-2 PCR in the health area.

The impact of false-positive PCR tests on patients by delaying surgery needs to be considered. Although SARS-CoV-2 PCR assays are widely reported to be nearly 100% specific, this only refers to analytical specificity and not clinical specificity (e.g. contamination, human error and detection of fragments of viral RNA from previous infection) [11]. The only published data on the full false-positive rate of SARS-CoV-2 tests in real-world settings appear to be from three studies that found rates of 1.1%, 0.3% and 3% in presurgical patients [10,12,13]. The multi-centre observational SCOUT study [10] in patients without COVID-19 symptoms before elective or emergency surgery under general anaesthesia reported differences between centres related to the prevalence of COVID-19 in the community. A negative PCR result does not exclude a patient from having COVID-19. Isolation of patients for 14 days before surgery, along with symptom and epidemiological contact assessment, may be more effective than universal PCR testing by minimizing the risk of undetected infections. Taking account of the likely lower real-world accuracy of PCR testing, the authors advocate targeted testing alongside other preventative measures, such as in their four-component presurgical action protocol.

This study had several limitations. The study was performed in an epidemiological context of medium-to-high incidence of SARS-CoV-2 infection. As only five COVID-positive patients were identified, the small sample size precluded definitive characterization of patient symptomatology. The extraordinarily low rate of PCR positivity in patients undergoing surgery is inherent to the selection of patients through a comprehensive strategy, which included: isolation prior to surgery in a population with high concern for their health, and possibly with a high rate of compliance with isolation measures; the evaluation of compatible symptoms and risk contacts; and the selection of surgical procedures that are susceptible to a poor outcome related to undiagnosed COVID-19. This means that the sample is no longer representative of the general population, with the prevalence of disease (probability of COVID-19) being very low in these selected patients. Thus, in this clinical setting, the positive predictive value of SARS-CoV-2-PCR is very low due to the low prevalence.

In summary, a strategy based on isolation measures prior to elective surgery, presurgical clinical evaluation for COVID-19 (symptoms, epidemiological contact), targeted testing, and robust universally applied infection prevention practices is effective and safe for patient and surgical outcomes. Universal pre-operative screening needs to be rethought, particularly as the incidence of COVID-19, and therefore the positive predictive value of testing, decreases. These data should serve as a 'wake-up call' for detailed compliance with the standardized protection measures in the surgical world. Continuous assessment of the effectiveness of prevention and control strategies, according to the institutional and local settings, should be the cornerstone for the maintenance or reformulation of comprehensive screening programmes by the health authorities.

Author contributions
Writing — original draft: JS-P, EM and OM-P. Writing — review and editing: J-EM, OM-P, JS-P, PC-S and PG-V. Conceptualization: JS-P and EM. Investigation: OM-P, PC-S and PG-V. Methodology: JS-P, EM and OM-P. Formal analysis: JS-P and OM-P. Project administration: JS-P. All authors have approved the final article.

Conflict of interest statement
None declared.

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Appendix A. Supplementary data

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