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Experience of Clinical Screening for Elective Orthopedic Surgery in The Midst of The COVID-19 Pandemic: An Alternative Proposal.

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Abstract

Background: The COVID-19 (Coronavirus disease 2019) pandemic is the largest global event of recent times, leaving millions infected and hundreds of thousands of dead worldwide. Colombia is no stranger to this situation, being subject to massive cancellations of medically necessary surgical procedures categorized as ¨non vital¨. The objective of this study is to show the results of a program of elective essential and non-essential low and medium complexity orthopedic surgeries performed during the mitigation phase of the COVID-19 pandemic with a pre-surgical clinical protocol, without serological or molecular testing, during April, 2020 in two institutions in Bogotá, Colombia.

Methodology : A multicenter, observational, retrospective, descriptive study of a cohort of patients who underwent elective orthopedic surgery at two institutions in the city of Bogota, Colombia, during April 2020. We performed a preoperative clinical protocol without including serological or molecular tests, an epidemiological survey, describing the type of surgery, their score in the MeNTs (medically necessary time sensitive) scale, and the presence of suggestive symptoms of COVID-19 postoperatively.

Results : A total of 179 patients underwent orthopedic surgery with an average age of 47 years (swilk= 0.021) (Shapiro-Wilk) ranging between 18 and 81 years, with a majority of females (61.5%). As for the surgeries, 86 (48%) were knee operations, 42 (23.5%) hand surgeries, 34 (19%) shoulder surgeries, and 17 (9.5%) foot and ankle surgeries. The average MeNTS of all patients was 44.6 points. During the two weeks after surgery, four patients were considered suspects for COVID-19 for presenting at least two symptoms associated with the disease representing an incidence of 2.3%. Two (1.1%) of these four patients consulted an emergency department where RT-PCR(reverse transcription polymerase chain reaction) type tests were performed, obtaining a negative result for SARSCov-2 (severe acute respiratory syndrome Coronavirus-2). No patients died or were hospitalized for symptoms associated with COVID-19.

Conclusion : Through the implementation of a pre-surgical clinical protocol (physical examination, clinical survey inquiring about signs, symptoms and epidemiological contacts), a pre-surgical isolation and without the performance of molecular or serological diagnostic tests, the present study showed good results in the performance of low and medium complexity elective orthopedic surgery at an early stage of the COVID-19 pandemic.

Level of evidence : IV.

Background

The emergence of the COVID-19 pandemic is the most critical global impact event in recent times, affecting almost 20 million people and leaving more than 700,000 dead across five continents at the time of writing (1). Health systems have had to adapt hospitalization and surgery services to meet the care requirements of the pandemic. Like the rest of the world, Colombia has had to redirect resources to increase its ICU (intensive care unit) bed capacity, a number of ventilators and health care personnel. This phenomenon, the risk of contagion for patients and health care personnel, has led to the cancellation of

non-vital surgical procedures (2). A study conducted in May of this year by the COVIDSurg Collaborative suggested that, on a global scale, orthopedics would be the specialty to cancel the most procedures due to this pandemic. Colombia would be one of the five countries with the highest number of surgical suspensions (3), leading to millions of dollars in losses in the health sector, an increase in patient complications, a deterioration in the quality of life and an increase in work absences (2)(4).

The literature that exists at this time to support or suspend elective surgical procedures is scarce and with limited scientific evidence (4)(5)(6)(7). Our preoperative protocol for the prevention of COVID-19 includes a preoperative isolation, a survey about signs, symptoms and epidemiological contacts, without preoperative serological or molecular testing(8), within the degree of uncertainty that exists regarding the pandemic, in a controlled environment such as operating rooms and taking into account the documented limitations of diagnostic tests(9), in a country with limited resources, it was considered pertinent to perform elective surgeries of low and medium orthopedic complexity.

Regarding the epidemiological moment in which the study was conducted, April 2020, it can be stated that Colombia was at the beginning of the mitigation phase, with an estimated 10% of the cases being of local circulation (10). The country was at a time of low prevalence of the pandemic with less than 50 cases per 100,000 habitants, although strict lockdown was already in place throughout the country (10)(11). By April 30, 6507 cases and 293 deaths had been reported, with Bogotá being the epicenter of the pandemic (12).

The objective of this study is to show the results of a program of elective low and medium complexity orthopedic surgeries with a pre-surgical clinical protocol performed during the mitigation phase of the COVID-19 pandemic regarding the presence of symptomatic cases, hospitalizations or ICU requirements, as well as the eventual mortality, during April 2020 in two institutions in Bogotá, Colombia.

Methods

The present study is a multicenter, observational, descriptive, retrospective study of a cohort of patients undergoing elective orthopedic surgery in a high-complexity University

Clinic and a medium-complexity ambulatory elective surgery center ascribed to the former (Clínica Universitaria Colombia and Centro Médico Puente Aranda) of the Keralty organization, in Bogotá, Colombia between April 1 and 30, 2020. Clínica Universitaria Colombia is a general reference center where COVID-19 and non-COVID-19 patients are treated and operated. In Puente Aranda ambulatory surgery center, according to the protocol established for the pandemic, patients who are positive or suspected of having COVID-19 do not undergo surgical procedures.

All patients who were brought in for elective surgery underwent a pre-surgical clinical protocol conducted immediately prior to the procedure that included: a complete physical examination, a survey of COVID-19-associated symptoms (fever, dyspnea, cough, muscle pain, dysgeusia, dysosmia or diarrhea), and assessment of the presence of contacts with COVID-19-suspected or positive patients. The patients who

were to be operated were under mandatory quarantine since the city of Bogotá had been in strict confinement since March 20, 2020 (8)(13). If any positive findings were found in this protocol, the procedure was cancelled, and the patient was referred to the emergency department for appropriate management. No patient was tested (antibodies nor RT-PCR) for the presence of COVID-19 as part of our clinical protocol due to the limited availability of these tests in the country at that time of this study (8)(13).

The inclusion criteria were patients over 18 years of age who were candidates for elective orthopedic surgery in the two institutions described between April 1 and 30, 2020. Exclusion criteria included patients who were hospitalized at the time of surgery or who had any pre-surgical findings in the described pre-surgical protocol.

The primary variable was the incidence of confirmed or suspected patients for COVID-19, which was described as a discrete variable. Variables of secondary interest were type of surgery and Medically Necessary Time-Sensitive Scale (MeNTS), defined as nominal and continuous categorical variables, respectively (7). A data extraction was performed regarding the demographic characterization of the patients (age, sex, comorbidities, BMI)

(body mass index), presence of symptoms suggestive of COVID-19 in the two weeks following surgery, whether or not molecular or serological tests were performed for COVID-19 in the post-surgical period, the type of surgery performed, as well as its anatomical location, and the anesthetic classification of ASA (American Society of Anesthesiologist) were also included. The MeNTS scale (7) was applied retrospectively for each patient. The time frame of the 14 days is related to the clinical course of the disease, and our interest in establishing the risk of the eventual acquisition of COVID-19 in the perioperative environment.

Patient data were collected through patient records and routine post-release calls by Keralty staff, modified for the pandemic to look for signs, symptoms, and epidemiological contacts. An inquiry was also conducted as to whether any diagnostic tests for COVID-19 had been performed in the 14-day post-operative period and their results. In addition, all patients were confirmed through their medical insurance (Sanitas) database in search of patients who had undergone PCR-RT serological testing for COVID-19.

A descriptive statistical analysis was conducted. Continuous variables were analyzed with central tendency and dispersion measures according to data distribution. Kurtosis and Skewness values were used to evaluate data dispersion, considering a normal distribution for values of 0 and 3, respectively. The distribution of the data was corroborated with the Shapiro-Wilk statistic. Since some variables were normally distributed and others were not, means and averages are presented, as well as standard deviation and interquartile ranges for each continuous variable. Categorical variables were presented as frequencies and percentages. The MeNTS scale was calculated for each group of surgeries with mean and standard deviation. Data analysis was performed using the SPSS (IBM – International business machine corporation) version 25 statistical program.

Results

One hundred seventy-nine adult patients underwent elective orthopedic surgery at Clínica Universitaria Colombia (21%) and Puente Aranda ambulatory surgery center (79%) during April 2020 were included in the study. The mean age was 47 years, with standard deviation (sd) (standard deviation) of 14.83 ranging from 18 to 81 years, the majority being female (61.5%) (See Table 1). Regarding personal history, it was found that 60% of patients were overweight with a median of 26 for BMI (Swilk = 0.2), 19.5% had high blood pressure, 16% a history of smoking. Besides, 9% had hypothyroidism, 6% were diabetic, 4% had lung disease, 1.7% had coronary heart disease, 1.7% had collagen disease, 1.7% had a history of cancer.

In the post-operative period four patients were considered suspects for COVID-19 for presenting at least two symptoms associated with the disease representing an incidence of 2.3%. Two (1.1%) of these four patients consulted an emergency department where RT-PCR type tests were performed, obtaining a negative result for SARSCov-2. No patients died or were hospitalized for symptoms associated with COVID-19.

Of the procedures performed, 86 (48%) were of the knee subspecialty, 42 (23.5%) hand, 34 (19%) shoulder, and 17 (9.5%) foot and ankle (See Table 2). No patients were from hip or spine subspecialty, these procedures were suspended by institutional decision regarding the COVID-19 pandemic, since they were subjectively considered to be procedures of more significant duration, with higher bleeding, morbidity and probability of requiring ICU in the post-operative period. The average for all patients on the MeNTS scale was 44.6 (SD+/- 4.6) points. Only one patient surpassed the established safety limit of 55 points, scoring 59 points. The results by subspecialty and procedure are shown in Table 2. Concerning the type of anesthesia, 70 patients (40%) underwent general anesthesia, and the remaining patients underwent spinal anesthesia, blockades, or mixed anesthesia. According to the ASA anesthetic classification, 73 (40.8%) patients were ASA I, 101 patients (56.4%) were ASA II and five patients (2.8%) were ASA III, no patient was ASA IV or V. It is relevant to make special mention of the performance of 15 knee arthroplasties (surgical procedure of major theoretical complexity within the subspecialty of knee surgery), these patients had an average age of 68.9 (sd 3.6) years with a range between 56 and 79, an average BMI of 27.4 (SD+/- 3.6), for them the ASA score was I (20%), II (67%) and III (13%) and the average MeNTS score was 49.6 (sd 1.45).

Discussion

The present study shows the experience of performing elective orthopedic surgeries, essential and non-essential, of low and medium complexity with a pre-surgical isolation protocol, epidemiological survey, without pre-surgical serological or molecular testing at an early stage of the COVID-19 pandemic. The results obtained were satisfactory in that none of the patients presented serious symptoms, zero were hospitalized, and no postoperative mortalities occurred. This study aims to highlight that a clinical

protocol can be an alternative for performing elective surgery of low and medium complexity without performing laboratory tests, when these, for various circumstances, are not available.

Initial studies in China showed very unfortunate results in patients who underwent surgery during the incubation phase of the disease, with a mortality of 21%. On the other hand, a more recent study conducted in Spain about gastrointestinal surgery showed, in its elective surgery arm, only one positive patient out of 97 operated; this patient recovered successfully, being in accordance with our results(4), despite the fact that gastrointestinal surgery patients could have a higher risk compared to orthopedic patients and that this study was conducted at the peak of the pandemic in Spain.

A paper developed by Gruskay et al. suggests the need for widespread diagnostic testing of all patients brought in for essential surgery due to the high presence of asymptomatic patients, however, even this study did not perform laboratory testing of patients undergoing outpatient surgery. The patients included in the study were retrospectively evaluated with the MeNTS scale. This scale was calculated individually according to each pathology, its corresponding procedure and personal factors, yielding an average of 44.7 (sd 4.6) points showing a reasonable distance from the safety limit suggested by the authors of 55 points (7). We consider that our study suggests the importance of the use of this scale during the COVID-19 pandemic and shows strong trends towards its effectiveness in orthopedics.

The present study was conducted in the early stages of the pandemic in Colombia; however, it is expected that the behavior of the epidemic will present new outbreaks with complex epidemic dynamics, with oscillatory behavior in the trajectory of the epidemic wave (14). It is likely that the epidemiological moment of the study will occur again, both at the end of the epidemiological peak and with the possible resurgence, as well as in different geographical locations and even new pandemics.

We consider that the limitations of this study are related, in that it reflects only the early moment of the epidemic curve. Furthermore, its limited ability to detect asymptomatic positive COVID-19 patients or in the incubation phase of the disease. The results suggest safety in performing elective orthopedic surgery of up to medium complexity in early stages of the pandemic, but because of the nature of this study, its results are nor to be generalized nor extrapolated to other populations. They also suggest the effectiveness of the pre-surgical protocol in preventing patients with clinical suspicion of COVID-19 infection from undergoing surgical procedures, which could increase the risk of post-surgical complications (15).

We consider it necessary to carry out future studies at more advanced periods of the epidemiological curve and other levels of surgical complexity to establish more accurately the safety of elective orthopedic procedures.

Conclusion

The present study showed our experience in the performance of low and medium complexity elective orthopedic surgery at an early stage of the COVID-19 pandemic. The selection of patients by applying a

clinical protocol that includes a physical examination, symptom survey, and epidemiological contacts, as well as pre-surgical isolation, without the realization of serological or molecular testing, showed good results regarding the safe conduction of elective surgery in this group of patients under the described circumstances.

Abbreviations

COVID-19: Coronavirus disease 2019

MeNTs: medically necessary time sensitive

Swilk: Shapiro-Wilk

RT-PCR: reverse transcription polymerase chain reaction.

SARSCov-2: severe acute respiratory syndrome Coronavirus-2.

ICU: intensive care unit.

BMI: body mass index

ASA: American Society of Anesthesiologist

SD: standard deviation

IQR: interquartile range

Declarations

The study follows all the ethical principles of medical research. The project and the participants were approved by the Ethics Committee of the Fundación Universitaria Sanitas in Bogotá, Colombia, presented on June 11, 2020. The requirement of informed consent was waived by the Ethics Committee due to the type of study.

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request: edsp33@yahoo.com

The authors declare that they have no competing interests.

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Tables

Table 1. Demographic variables.

Variable	Number of Patients	Data presentation
Age (years ± SD) [d]	179	47.5 ± 14.83 b [a]
(years, IQR)		49 (36-57)
Gender [c]		
Female	110	61.4%
BMI [e]	179	26.5 ± 3.79 [a] b
		26 (IQR 24-29)
ASA Score [c]		
I	72	40.78%
II	101	56.42%
III	5	2.79%
IV y V	0	0%
Comorbidities		
Arterial Hypertension [c]	35	19.55%
Coronary disease [c]	3	1.68%
Diabetes [c]	11	6.15%
Hypothyroidism [c]	16	8.94%
Cancer [c]	2	1.12%
Pulmonary disease [c]	5	2.80%
CKD[c]	0	0%
Rheumatoid arthritis [c]	3	1.69%
Others [c]	2	1.12%
HIV **c**	0	0.%
Smoking [c]	29	16.20%
Surgery Site [c]		

Puente Aranda	142	79.33%	
Clínica Colombia	37	20.67%	
Surgical time[f]	179	69.4 ± 39.2 [a] 60 (IQR 50-80)	b
Post-operative hospitalization [c]			
No	175	97.77%	
Si	4	2.23%	

Anesthesia type [c]

General	71	39.66%
Spinal	72	40.22%
Blockade	5	2.79%
Local	4	2.23%
Combined	27	15.08%
Contact with COVID-19 [c]	5	2.79%
Presence of symptoms [c]	4	2.23%
Medical attention [c]	2	1.12%
COVID-19 Positive [c]	0	0%
Tests for COVID-19 [c]	2	1.12%

BMI= Body mass index, COVID-19 = Coronavirus Disease 2019

a Values presented as average and standard deviation b Values presented in median and interquartile range c Values presented in frequency and percentages.

d Skewness -0.05, Kurtosis 2.40 and Shapiro-Wilk (Swilk) 0.02 =considered non- normal distribution e Skewness 0.28, Kurtosis 3.14 and Shapiro-Wilk (Swilk) 0.20 = considered normal distribution f Skewness -1.96, Kurtosis 5.14 and Shapiro-Wilk (Swilk) 0.00 = considered non-normal distribution

Note: Since there are variables with normal distirbution and others not, it was considered to present means and averages as samples of central tendency and standard deviations and interquartile ranges as measures of dispersion.

Table 2. MeNTS scale regarding type of surgery and anatomical location.

Type and location of surgery	Frecuency (Percentage)	Average MeNTS scale
SHOULDER		
Rotator cuff	29 (16.2)	47.1
Instabilty	2 (1.1)	44.7
Arthroplasty	1 (0.6)	59.0
Others	2 (1.1)	46.0
Subtotal	**34 (19.0)**	**47.2** ± **2.7** [a]
HAND		
Carpal tunnel	10 (5.6)	42.3
Trigger finger	1 (0.6)	41.0
Arthrodesis	2 (1.1)	44.5
Tenosynovectomy	1 (0.6)	48.0
Ganglion cyst	7 (3.9)	41.1
Fractures	10 (6.1)	35.4
Removal of osteosynthesis material	4 (2.2)	44.0
Others	7 (3.9)	43.0
Subtotal	**42 (23.5)**	**40.3** ± **4.9** [a]
KNEE		
Arthroplasty	15 (8.4)	49.0
Anteriro Cruciate ligament	22 (12.3)	44.4
Meniscoplasty	25 (14.0)	46.4
Patellar malalingment	17 (9.5)	46.7
Removal of osteosynthesis material	1 (0.6)	44.0
Others	6 (3.4)	45.3
Subtotal	**86 (48.0)**	**46.4** ± **2.4** [a]

FOOT/ANKLE			
Forefoot	5 (2.8)	48.4	
Midfoot	1 (0.6)	45.0	
Hindfoot	2 (1.1)	44.0	
Foot Fractures	4 (2.2)	32.5	
Onicectomy	2 (1.1)	32.5	
Removal of osteosynthesis material	3 (1.7)	40.3	
Subtotal	**17 (9.5)**	**41.8**	**± 6.5 [a]**
TOTAL	**179 (100)**	**44.7**	**± 4.6 [a]**

MeNTS = Medically Necessary Time-Sensitive [a] Values presented in average and standard deviation.