INTRODUCTION

Italy was stricken at the very beginning of the Covid-19 pandemic seriously and violently with the first case reported on February 20th, on a healthy young man admitted to ICU with atypical pneumonia of unknown origin, in Lombardy, a highly populated region in northern Italy. In the next 24 hours, the number of reported positive cases increased to 36, without links to patient 1 or previously identified positive cases already in the country. It was then clear that a cluster of unknown magnitude was present and additional spread was likely. On February 21st, an emergency task force was formed to lead the response to the outbreak. It was immediately apparent that the main problem would have been ICU surge capacity. On February 24th, the Regional Health Administration of Lombardy formally stopped all surgical procedures, except for urgent and emergent ones, intending to redeploy operation theatres, ventilators, anesthesiologists, and nursing staff to ICU activity. For time-dependent diseases and related networks, like trauma, stroke, cardiovascular surgery, and coronary disease, systems were redesigned to limit patients’ access to the hospitals overcrowded by SARS-CoV-2.
The pre-crisis total ICU regional capacity was approximately 720 beds. By March 22, the number of intubated patients for Covid-19 in Lombardy was 1280.

Children's Hospital "Vittore Buzzi" is a third-level pediatric hospital situated in Milano, Lombardy. It provides pediatric medical and surgical care (general pediatric, eye, ear, nose and throat, vascular, orthopedic and traumatological surgery) and maternal care. It handles around 3600 births/year and has a neonatal intensive care unit and a 7-bed pediatric intensive care unit. The surgical case number is around 3700/year.

On February 24th, Buzzi hospital too interrupted elective surgery according to Regional Health Authority recommendations. Specific Covid-19 procedures have been created for staff and patient protection and specific pathways for positive patients or patients whose Covid-19 status was still unknown. Due to the overload of cases, nasal swab results would take too much time, but regional epidemiological situations mandated to consider every patient potentially positive.

During the end of February and the beginning of March, Buzzi Hospital underwent transformations to treat Covid-19 patients. One OR was dedicated to infected or suspected cases, a second one was maintained “clean” for negative patients requiring urgent surgery but in which time had been sufficient to determine RT-PCR on nasal swab negativity. The other ORs were redeployed into ICU rooms for COVID-negative pediatric patients. The pediatric ICU—situated in another hospital block—opened to accept pediatric and adult COVID-19 patients.

On March 8, 2020, to contain the epidemic, Lombardy was put on lockdown and so was the whole of Italy the day after.

Surgical activity at the Children Hospital was maintained for emergency cases only from February 24th to May 15th.

Lockdown was then gradually released as the number of Covid admissions slowed, and ICU capacity was regained. On May 16th, Hospital Administration, following Regional Health Administration, declared a partial resumption of elective surgical activity. In the period between May 16 and September 30, elective surgical activity has gradually grown according to regional indications that have allowed to reach—in gradual steps—a maximum of 70% of pre-Covid surgical elective activity.

Aim of the present observational cohort study is to describe the testing pathway and case management offered to children admitted for elective and urgent surgery from May 16th to September 30th in order to provide patient and healthcare workers’ safety and the results of the Covid screening in a high Covid prevalence area.

2 | MATERIALS AND METHODS

This single-center, observational cohort study was approved as a service evaluation by our local research and development committee (Protocol number n. 2020/ST/061), conducted in line with information governance protocols and adheres to the standards of strengthening the reporting of observational studies in epidemiology (STROBE) statement.

Clinical charts of all patients undergoing surgery—elective, urgent, or emergent—were reviewed utilizing routinely collected institutional data (OR electronic database). Patient, surgical, and hospital demographic data alongside SARS-CoV-2 RT-PCR testing outcomes were evaluated utilizing case notes.

From May, 16th, on, patients were admitted to surgery if they were considered urgent elective surgery candidates (procedures non-deferrable beyond 30 days from diagnosis); cases were discussed in a weekly meeting together with the clinical director for anesthesia, the surgical team representatives, and the direction of the hospital.

The usual testing pathway is described hereafter; after testing, every child admitted to the ward in a single room with his caregiver, independently from swab status. Hospital wards have been divided into “Covid-zones” and “Covid-free zones”, on different blocks of the hospital or at least on different floors. No visitors are allowed.

2.1 | Urgent procedures

Children are admitted together with a caregiver. Both are swabbed on the day of admission; according to the clinical surgical plan, if deemed safe, surgery is postponed until swab results are present for both children and caregiver. If one of the two results is positive, the patient is treated as positive in the dedicated OR. If the clinical condition does not permit, the child is operated before the swab result and treated as a positive case.

2.2 | Elective procedures

Patients are called and a telephonic questionnaire investigating possible Covid-19 symptoms and potential contacts with positive people is administered; if considered safe, child and caregiver are convocated to the hospital 2-3 days before the procedure for anesthetic evaluation and nasal swab for Sars-CoV-2. The caregiver answers a brief questionnaire investigating the presence of Covid-related symptoms or close contact to positive cases (Appendix 1); caregiver and child stay in hospital a couple of hours, with appropriate social distance measures with other patients, and are then officially quarantined in their home until the day of surgery. The maximal interval between evaluation with swab and surgery is 72 hours; after this time, if surgery is for any reason delayed, a nasal swab is to be repeated.
Nasopharyngeal samples are collected into viral transport media and processed with an ELITE InGenius® system and GeneFinder™ COVID-19 Plus RealAmp Kit assay (ELITechGroup, France) method; turnaround time for routine samples is usually 24 hours.

If patients or caregivers are identified at screening as COVID-19 positive, they are advised to self-isolate as indicated by Local Health Authorities, which are informed of the positivity; surgery is postponed, and they are then contacted again by the pre-operative assessment team after at least 14 days to assess their clinical status and plan a new date.

### 2.3 | OR procedures

ORs are divided for Covid-negative patients and Covid-positive or unknown status patients. Different pathways of access to ORs are utilized to bring the Covid-positive and Covid-negative patients to the ORs. Operators inside the ORs are equipped and protected with full PPE (sheltering face piece (FFP) 3 mask or equivalent; visor; long-sleeved gown; and gloves) for aerosol-generating procedures in both ORs. Covid-negative patients are transferred to the OR together with their caregiver and sometimes happen to have a short wait time just outside the OR area; after surgery, they are usually transferred extubated to the Post-Anesthesia Care area and spend some time there. Covid-positive and Covid unknown patients are transferred to the OR through a dedicated pathway (thoroughly sanitized after every passage) without their caregiver and enter directly the OR. They are then extubated in OR and spend their post-anesthesia time (usually 15 minutes if no complication arises) inside the OR. They are then transferred back to their room where the caregiver has been waiting. After every Covid-positive or unknown status procedure, the OR and passages are deeply sanitized, which requires a considerable amount of time.

### 2.4 | Statistical analysis

Data were compared to the same period data in 2019 and analyzed with Excel (Microsoft Windows 10) and R3.6.2. Fisher’s exact test was used to test if the distribution of urgent and elective surgeries is different between 2019 and 2020. Within urgent surgeries, a Chi-square test was performed to test for an overall imbalance of the types of surgeries between 2019 and 2020 and a post-hoc test on the Pearson’s residuals was performed to assess which specific type of surgery generated the observed difference. The P-values for this last analysis were adjusted using the Bonferroni’s method.

### 3 | RESULTS

During the period May 16th to September 30th, 2020, a total number of 820 pediatric surgeries have taken place in our institution, compared to a total number of 1075 in the same period of 2019. The patient’s mean age was 5.5 years (IQR 0-13.5 years) in 2020, and 6.5 years (IQR range 0-20 years) in 2019.

Of the surgeries in 2020, 474 (57.8%) were pediatric surgery procedures, 175 (21%) were ear, nose, and throat cases, 117 (14%) were orthopedic cases, 49 (6%) were vascular surgery procedures, and 5 (0.6%) were eye surgery cases. Odontoliatric surgery has been temporarily withheld. Elective cases have been 538 (65.6%) and urgent cases 282 (34.3%). In 2019, elective cases had been 864 (80.3%) during the same period and urgent cases 211 (19.6%). Rooms in the surgical ward usually accommodated 2 patients and their caregivers; after Covid every room has been used for one patient, with his caregiver, at a time, no matter their negativity at Covid tests in order to avoid any potential in-hospital virus transmission, thus reducing of 50% the ward capacity. This has been another limitation to resume activity.

Covid-19-positive cases have been 2 for pediatric surgery, elective cases (1%), and 2 for ear, nose, and throat elective cases (1.2%). These were asymptomatic patients in whom RT-PCR positivity for Sars-CoV-2 in pharyngeal swab has been an occasional finding and whose procedure has been postponed.

Among pediatric surgery urgent cases, two patients tested positive (2/257:0.7%): 1 was a 2-yr old girl admitted for burn lesions, asymptomatic under every other aspect, and the second one was a 3-yr-old girl admitted for peritonitis. Both underwent surgical procedures (debridement and laparoscopy, respectively).

One of the ENT urgent cases was a 2-yr-old boy whose mother tested positive for Covid-19 and was treated as positive although his nasal swab was negative.

A two-tailed Fisher’s test was utilized to assess if the number of urgent surgeries was significantly higher than elective surgeries between 2019 and 2020. A significant increase of approximately 70% in pediatric surgeries (OR 1.68 [1.33-2.13], P < .001) and an even higher general increase in the number of surgeries was reported (OR 1.75 [1.43-2.15], P < .001). Considering only urgent procedures, a significant difference in the distribution of the type of surgery was observed (Chi-squared P-value < .001). In addition, a post-hoc analysis of the test residuals highlighted a significant increase in the number of appendicectomies (P = .004), burns (P < .001), and significant reduction in surgical sutures (P = .002).

No patients reported symptoms for Covid-19 after planned or urgent surgery, as investigated during the post-operative surgical check. If, during hospital admission, the patient or the caregiver would show any COVID-related symptom, they were tested again. This happened 3 times and none tested positive.

At the very beginning of the pandemic, in early March, 6/19 anesthesiologists and 2/12 pediatric surgeons presented symptoms and tested positive for Covid. Healthcare workers have been screened for Covid contact with antibody research in May, and the results were concordant with the previous symptomatic infections. In the subsequent period, including that in object of the study, no anesthesiologist, no pediatric surgeon, and no OR nurse tested positive.
At the end of February to beginning of March 2020, the Regional Health System has been rapidly reprogrammed with the aim to contain the wave of COVID-19 patients. Most of the hospitals in Milano and Lombardy have quickly transformed to accept and treat severely ill adult patients.\textsuperscript{3,4} The need for these transformations resides in the extremely high incidence of Covid-infected patients in Lombardy in the initial phase of the pandemic in Italy.

The decision to postpone non-urgent surgery has been considered necessary for multiple reasons at the beginning of the pandemic: leaving dedicated spaces and personnel to treat critically ill patients, reducing the number of blood products used in times of overutilization and shortage of donors,\textsuperscript{9} avoiding unnecessary patient traffic in the hospital, and thus reducing the risk of cross-infection among elective patients, hospital visitors, and COVID-19 patients, eventually preventing spread of infection from the hospital to the community.\textsuperscript{10}

The considerations for re-initiating and continuing elective surgery in pediatric practice are complex: a child is not a lonely planet but a complex galaxy strictly interconnected with his family, his education, and his caregivers’ work. Postponing a child’s surgery, for any reason, creates multiple problems to his family. At the same time, and for same reason, children surgery must be safe. Given what is now known about the prevalence of Covid-19 in the general pediatric population, hospital attendance for surgery may represent a child’s highest risk of Covid infection.\textsuperscript{11,12} Many children present for day case procedures with limited exposure to hospital environment and staff. Many others present with complex surgery exposing them to possible in-hospital infection. At the same time, every patient is a potential source of infection for healthcare workers.

At pre-operative screening, we performed swabs on essentially ‘asymptomatic’ patients (low pre-test probability of infection), when the test has been validated in symptomatic patients.\textsuperscript{13,14} Precise sensitivity of nasopharyngeal swab, moreover, has not been determined in children.\textsuperscript{15}

Given the incubation period and pathogenesis of SARS-CoV-2, a negative test 1 day does not guarantee the absence of infection the next. This, together with the high incidence of household transmission,\textsuperscript{16-18} prompted us to test both patient and caregiver to lower the possibility of false-negative results that could lead to intrahospital transmission of the virus. This approach is considered a higher level of attention posed to the risk of viral transmission and has not been proposed elsewhere\textsuperscript{19-21}; it proved effective at least in 1 case of the 7 positive (14% of total number of positive results). Strength of this study resides, in our opinion, in the strength of this approach to the child-caregiver unity.

Number of positive cases has been 7/820 (0.8%), a relatively small percentage. Although it has been postulated until now that children are somehow spared from the disease,\textsuperscript{22} it is also true that these data refer to a period coming just after a 2-months’ complete lockdown with schools closures and comprise the summer period with schools still closed and better possibility for open air activities. Type of surgery indicates a reduction in the elective cases percentage and an increase in urgent procedures, in absolute number. While the explanation for reduction in elective surgery is quite clear, as mandated by Regional Authorities, an absolute increase in urgent cases, on the other side, can be explained by the rise of domestic incidents witnessed during the months of school closure and home confining\textsuperscript{23} and possibly a lower acceptance of pediatric patients in non-dedicated pediatric hospitals during the pandemic period. Simple sutures have been treated in the ED instead of in the OR, as a choice to reduce movements of patients across the hospital. Difference in urgent cases’ number when compared to the previous year is important to notice because the pathway of testing has been different from elective cases as above mentioned.

Italian anesthesiologists are also intensivists: the formal Specialization Title is “Anesthesia and Intensive Care.” Although every specialist is occupied mainly or totally in either OR ICU, the training received allows being interchangeable if necessary. This characteristic turned out to be useful for the Covid-19 Pandemic when OR staff (doctors and nurses) have been redeployed into ICU care as necessity requested. Intensivists in our institution are pediatric intensivists but have been, together with those who work as pediatric anesthesiologists, redeployed into adult ICU care as the biggest request has been for adult patients.\textsuperscript{26} Of the 19 colleagues constituting our Anesthesia/ICU Service, 4 only kept on working in the OR and 15 were employed in the ICU. This sudden move from children to adult care has been described in other countries too.\textsuperscript{25}

During the period May 16, 2020, to September 30, 2020, our hospital’s surgical activity has restarted with an increasing number of cases together with the relative authorizations of the Regional Health Authority that have been progressively wider.

At present, surgical activity is still not 100% of the pre-Covid era. Besides reducing spaces (ORs to be kept separated for Covid-19-positive patients), there is a structural problem in the wards. All rooms are two patients’ rooms ready to accommodate 2 pediatric patients and their caregivers. With the Covid pandemic, every room has been used only for 1 patient with his caregiver, irrespective of Covid status, to avoid potential in-hospital virus transmission. The relative shortage of beds has made a resume of surgical activity difficult under this aspect too.

Inside the ORs, healthcare workers were protected and equipped according to guidelines and airway management of patients has followed recent recommendations.\textsuperscript{26} Although there’s still controversy about the needed level of protection for aerosol generating procedures,\textsuperscript{27} a high level of protection has been deemed necessary after 6 colleagues of 19 in our service became sick with Covid-19 at the beginning of March, all of them working in the OR. It is also noteworthy that no OR nurse has tested positive for Covid.

We did not have the possibility to re-test patients after surgery, during the post-operative check. Results would have been confusing because patients are not quarantined after surgery. We screened them for symptoms (both in patient and caregivers) and, had they been present, they would have been tested.
The Covid-19 pandemic has modified our lives and our professions in multiple ways, facing us with a new reality that is going to last for a long time: it is in this perspective that we need to demonstrate the safety of procedures created to restart and continue pediatric surgery and pediatric anesthesia; with the limits of a relatively small sample of patients, but in a most hit area of the world, we aimed to show that careful care of patients and procedures and contemporary test of patient and caregiver allows a safe surgical and anesthesiologic activity.

AUTHOR CONTRIBUTIONS
Dr A. Camporesi designed the study, oversaw data collection and analysis, and participated in drafting and editing the manuscript; Dr Melloni conducted statistical analysis, and participated in drafting and editing the manuscript; Dr Diotto, La Pergola and Pelizzo participated in drafting and editing the manuscript; P. Bertani was involved in data acquisition and drafting and editing the manuscript; and all authors had final approval of the manuscript, approved the final manuscript as submitted, and agree to be accountable for all aspects of the work. The authors have no conflict of interest to declare. They authors did not receive any fund for this work.

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**APPENDIX 1**

Covid-19 questionnaire for patients and caregivers to be admitted to hospital

| Clinical symptoms                                                                 | Yes | No   |
|-----------------------------------------------------------------------------------|-----|------|
| Did you have household contacts affected by Covid-19 or with possible Covid-19 symptoms? |     |      |
| Did you have contacts—in the last 2 weeks—with people who then tested positive for Covid-19? |     |      |
| Did you receive hospital care in the last two weeks?                               |     | Specify date |
| Have you ever been tested with nasopharyngeal swab for Covid-19?                   |     | Specify date and result |
| Did you have fever (<37.5°C) in the last 3-5 days?                                 |     |      |
| Did you have cough or breathing difficulties in the last 3-5 days?                 |     |      |
| Did you have rhinitis in the last 3-5 days?                                       |     |      |
| Did you have diarrhea in the last 3-5 days?                                       |     |      |
| Did you have taste and smell problems in the last period?                         |     |      |