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ORIGINAL ARTICLE

Behind the mask: extended use of surgical masks is not associated with increased risk of surgical site infection

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Abstract

Purpose COVID-19 has prompted significant policy change, with critical attention to the conservation of personal protective equipment (PPE). An extended surgical mask use policy was implemented at our institution, allowing use of one disposable mask per each individual, per day, for all the cases. We investigate the clinical impact of this policy change and its effect on the rate of 30-day surgical site infection (SSI).

Methods A single-institution retrospective review was performed for all the elective pediatric general surgery cases performed pre-COVID from August 2019 to October 2019 and under the extended mask use policy from August 2020 to October 2020. Procedure type, SSI within 30 days, and postoperative interventions were recorded.

Results Four hundred and eighty-eight cases were reviewed: 240 in the pre-COVID-19 cohort and 248 in the extended surgical mask use cohort. Three SSIs were identified in the 2019 cohort, and two in the 2020 cohort. All postoperative infections were superficial and resolved within 1 month of diagnosis with oral antibiotics. There were no deep space infections, readmissions, or infections requiring re-operation.

Conclusion Extended surgical mask use was not associated with increased SSI in this series of pediatric general surgery cases and may be considered an effective and safe strategy for resource conservation with minimal clinical impact.

Keywords Surgical mask · Surgical infection · COVID-19 · Pediatric surgery

Introduction

The emergence of COVID-19 has dramatically shifted institutional and national protocols for personal protective equipment (PPE) in the healthcare setting, emphasizing reuse and extended use of previously recommended single-use items. Traditional recommendations emphasizing strict removal of PPE, specifically surgical masks, before entry into patient care areas outside of the operating room have now been replaced with policies emphasizing extended use of the same disposable surgical mask for encounters with several patients [1]. There has been heightened concern for PPE shortage with recent increases in elective general surgery case volume throughout the COVID-19 pandemic, although case volume still remains below average. This concern is amplified with the potential for a surge of COVID-19 infections. Globally, the COVID-19 pandemic has required institutions to initiate strategies to both predict and manage PPE supply based on anticipated utilization rates, prompting changes to recommendations for PPE use [2, 3]. Operating room policy implemented during the peak of the COVID-19 pandemic within our institution limited each team member to one standard surgical mask for the duration of operative cases within a single day. N95 and powered air purifying respirator (PAPR) use protocols remain for patients who are COVID-19 positive and require emergent surgery [1, 2]. However, the clinical impact of this policy change is unknown, specifically the effect on surgical site infection (SSI) rate.

Although masks are universally used, the data supporting the ability of standard surgical masks to reduce surgical site infection are weak. Multiple studies, including few

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randomized controlled trials, have demonstrated no clear evidence that wearing disposable face masks by either the surgical team or ancillary staff in the OR during the operation decreases the likelihood of postoperative wound infections [3–6]. Furthermore, with increased emphasis on quality improvement, rigorous SSI prevention bundles have been implemented but notably lack specific guidelines for mask use or personal protective equipment in the operating room [7]. While multiple studies have demonstrated no statistically significant difference in SSI rates related to the single-use intraoperative masks, minimal data were investigating extended use of disposable surgical masks and impact on 30-day surgical site infection rates.

Recommendations for the conservation of PPE, especially in the operating room setting, raise concerns regarding increased risks to both patients and providers, and a lack of data leads to hesitation to support these recommendations. The results of this analysis will provide preliminary data to illustrate the clinical impact of single, extended use of disposable surgical masks within the operative setting before and during the COVID-19 pandemic, with specific attention to the impact on surgical site infection rate.

Methods

After Institutional Review Board Approval (IRB #00001484), a single institution retrospective review was completed for all general pediatric surgery cases between August 2019–October 2019 and August 2020–October 2020. Included cases performed in 2019 were designated as pre-COVID-19 and those in 2020 as COVID-19 era cases. All patients were less than 18 years of age at the time of operation and underwent elective general surgery procedures. Appendectomy was excluded as this is not considered an elective procedure. Patients who underwent operative intervention during their hospitalization were considered to be at increased risk for nosocomial infections and were excluded, and those who were immunosuppressed and at higher risk for infection. Patients who tested COVID-19 positive were excluded because test positivity often precluded or delayed surgical intervention. Chart review was conducted for all the patients who met the inclusion criteria to identify indications for the procedure, as well as postoperative 30-day follow-up to identify the presence of SSIs. If a surgical site infection was identified, treatment course and outcomes were recorded. All the cases performed from August 2019 through October 2019 were performed under extant hospital policy which required replacement of surgical masks after every case for all operating room personnel, including the operating surgeons and trainees. In contrast, all the cases performed from August 2020 through October 2020 used the modified hospital and operating room policy restricting surgical mask use to one mask for each operative personnel, per day, unless soiled. Surgical masks were made available by a central operating room personnel who enforced this policy and controlled mask distribution. All available surgical masks within the operating room were American Society for Testing and Materials (ASTM) level 1. A basic cost analysis was performed for our institution to give an estimation of cost differential between the two time periods reflecting the different policies for mask use. The institutional cost for a box of 50 disposable surgical masks was obtained for all purchasing periods prior to and during the COVID period. We estimate for six core members of the operative team including the anesthesiologist, surgery attending, surgery fellow, surgery resident, scrub nurse, and circulating nurse. During the COVID period, only one mask allowance was calculated for all the cases during the day within the same operating room for each team member. Total masks used and total costs were calculated.

All the data were analyzed using standard statistical methods for the calculation of descriptive statistics.

Results

Within the 2 3-month periods, 488 cases met inclusion criteria: 240 in the 2019 cohort and 248 in the 2020 cohort. In each group, laparoscopic inguinal hernia repair was the most common procedure, followed by open umbilical hernia repair. Median case duration in the pre-COVID period was 24.9 min [IQR 16.9–38.0], and during the COVID period 25.2 min [17.2–38.1]. Three surgical site infections were identified within the 2019 cohort (Table 1) and two in the 2020 cohort (Table 1), with an SSI rate of 1.3% and 0.8%. All patients received appropriate preoperative antibiotic prophylaxis, if indicated, and underwent standard preoperative preparation with appropriate surgical scrub.

Within the 2019 cohort, 134 cases (56%) were performed laparoscopically, and 3 surgical site infections were identified within 30 days postoperatively. The distribution of cases with postoperative SSI within 30 days were laparoscopic inguinal hernia repair at the umbilical port site ($n=2$) and soft tissue mass excision ($n=1$). In the 2020 cohort, 113 cases (46%) were performed laparoscopically, and 2 surgical site infections were identified within 30 days postoperatively. Distribution of cases with postoperative SSI within 30 days were open umbilical hernia repair ($n=1$) and pectus bar removal ($n=1$). All postoperative infections were classified as superficial surgical site infections, were treated outpatient, and resolved with a maximum 10-day course of oral antibiotics.

The median institutional cost for a single box of 50 disposable surgical masks during the pre-COVID period

Table 1 Comparison of surgical site infection (SSI) rate during elective, pediatric general surgery procedures pre-COVID-19 (2019) and during COVID-19 (2020)

Cases	August 2019–October 2019 pre-COVID		August 2020–October 2020 COVID	
	Number of cases ($n=240$)	30-day SSI ($n=3$)	Number of cases ($n=248$)	30-day SSI ($n=2$)
Operative duration#	24.9 min [16.9–38.0]		25.2 min [17.2–38.1]	
Laparoscopic inguinal hernia repair	58	2	53	0
Open umbilical hernia repair	44	0	48	1
Laparoscopic cholecystectomy	25	0	13	0
Circumcision	24	0	38	0
Laparoscopic pyloromyotomy	19	0	19	0
Laparoscopic gastrostomy tube	16	0	9	0
Soft tissue mass excision	9	1	14	0
Open epigastric hernia repair	8	0	8	0
Soft tissue foreign body removal	8	0	6	0
VATS lung resection	7	0	8	0
Laparoscopic sleeve gastrectomy	4	0	0	0
Orchiopexy	4	0	4	0
Pectus excavatum repair	4	0	7	0
Thyroidectomy	4	0	3	0
Pectus bar removal	2	0	6	1
Breast lumpectomy	1	0	0	0
Laparoscopic fundoplication	0	0	2	0
Laparoscopic adrenalectomy	0	0	1	0
Costal cartilage excision	1	0	1	0
VATS sympathectomy	0	0	1	0
Open inguinal hernia repair	1	0	4	0
Thymectomy	1	0	2	0
SSI rate		1.3%		0.8%

#Median [IQR]

Table 2 Cost evaluation of mask use policies during elective, pediatric general surgery procedures pre-COVID-19 (2019) and during COVID-19 (2020)

	August 2019–October 2019 pre-COVID	August 2020–October 2020 COVID
Box cost (50 masks)#	$3.47 [$3.45–$3.51]	$4.70 [$3.62–$4.92]
Masks used	1440	612
Total cost#	$100.24	$56.15

#Median [IQR]

analyzed was approximately $3.47 [IQR $3.45–$3.51], and during the COVID period, the median cost per unit (50 masks) increased to $4.70 [$3.62–$4.92]. Total masks used during the pre-COVID period were 1440 for a total cost of approximately $100.24. Total masks used during the COVID period were 612 for a total cost of approximately $56.15 (Table 2).

Discussion

Extended surgical mask use was not associated with the increased risk for SSI within our cohort of pediatric general surgery patients. All the postoperative infections had a mild course not requiring admission, advanced imaging, or additional intervention. Our data provide evidence for the safety of extended surgical mask use in the setting of restricted resource utilization. After every case for both the patient and provider protection, the replacement of surgical masks is a practice based upon recommendations from governing bodies such as AORN that may not be the adequately evidence-based guidelines [8]. Rapid and significant operating room policy modification requiring the extended use of disposable surgical masks highlights the lack of evidence and paucity of literature on infection control requirements related to surgical mask use. There is no evidence to either support or refute policy change from one-time use to extended use. In this series, we demonstrated no effect on surgical site infection rate with extended use of disposable surgical masks compared to a single use.

Surprisingly, quality evidence for the benefits of intraoperative surgical mask use are lacking. There are no data to support the use of a surgical mask to prevent the development of surgical site infections. A 2020 meta-analysis identified 124 studies, including four randomized controlled trials, (1984–2002), which investigated the use of intraoperative surgical masks by both operating faculty and non-scrubbed ancillary OR staff [9–13]. In a pooled analysis, the overall effect of removing face masks demonstrated a risk ratio of 0.77 in favor of not wearing masks; however, none of the individual studies demonstrated statistically significant results. Multiple studies included randomization of ancillary staff within the OR to be masked or unmasked and did not demonstrate a difference in SSI rate. An important distinction is both the classification of the operative case as well as the subspecialty involved. There are no data to support surgical mask use stratified within each class of case (clean, clean-contaminated, contaminated, and dirty). A majority of studies and a Cochrane review (2016) address only clean cases, as advanced classes increase SSI risk by degree of contamination [5]. These studies, therefore, have limited external validity when applied to cases not classified as 'clean'. Subspecialties more likely to utilize implants such as orthopedic surgery, neurological surgery, ophthalmologic surgery, and cardiac surgery are often not included in these studies since the consequences of these infections are major morbidity and possible mortality. In these specialties, the benefit of single mask use may not outweigh the risk of severe morbidity and possible mortality with development of SSIs. In one case-controlled study, the odds ratio of developing infective endophthalmitis following cataract replacement was 3.34 when the operating staff was not required to wear a mask [14].

An additional consideration is the utility of surgical masks for the operating surgeon's safety and staff near the operative field. Although it is evident that surgical masks protect wearers from visible debris and contaminants, the lack of protection to micrometer particles—including bacteria and viruses—remains a valid concern. In a study of eight separate surgical masks, filter media was tested for the permeability of sub-micrometer contaminants and demonstrated filter penetration ranging from 20 to 100% [15]. An analysis of nine medical-grade surgical masks demonstrated poor filter performance and facial fit characteristics that did not adequately prevent inflow or outflow of sub-micrometer particles [16]. It may be assumed that protection is provided by wearing a mask in the operating room, mainly from macroscopic contamination; this may provoke a false sense of security and leads to under-reporting of critical exposures. However, it is important to acknowledge that our study was not designed to address the efficacy of surgical masks in preventing infection in the health care team. Furthermore, it remains unknown if a mask that is worn for extended use provides an increased risk for surgical site infection. In a study of 40 total joint arthroplasty cases, surgeons were stratified into groups for procedures lasting up to 6 h in 2-h intervals, and bacterial colonization on the internal and external surface of surgical masks was investigated to make recommendations for appropriate mask change intervals. Although the increases in bacterial colony-forming units were found after each 2-h interval, there was no increased risk for SSI among all groups at any time interval [17]. These results support our findings as there was also no change in surgical site infection rate with extended use of disposable surgical masks, similar to our cohort.

We report the clinical impact of a policy change in a period requiring conservation of essential resources and equally demonstrate the minimal impact of surgical mask extended use concerning surgical site infection rate in this series of general surgery patients undergoing elective surgery. Our data provide evidence for the unique overuse of supplies that has become evident with the threat of supply rationing and PPE shortage. The counterbalance to limiting mask use and the possible financial impact of such policy change is the related cost of managing surgical site infections. However, our study did not demonstrate an increased risk of SSI in the limited mask use cohort. COVID-19 has forced the healthcare system globally to reconsider PPE use practices and promote more efficient utilization. In a study of 1270 patients undergoing closed reduction and percutaneous pinning of supracondylar humeral fractures, one fully sterile surgeon and one semi-sterile (no mask, sterile drape, or gown) were compared. They demonstrated no statistically significant difference in SSI rate within the group using only semi-sterile technique. The reduced use of PPE and OR time for these cases was extrapolated to provide an annual savings of approximately 3.7–4.4 million dollars [18]. These findings demonstrate that conservation of resources, notably PPE, may be implemented with minimal change to patient care and outcomes and may also provide a cost benefit. Although the cost differential of single mask use within our series seems trivial, it is important to note that application of a single mask use policy expanded across all the surgical specialties over time will demonstrate an even greater cost benefit. Extrapolation of the cost differential after implementation of a single mask use policy within our series is limited by the analysis of only a single specialty, in a limited time period. However, it is also important to note that there are associated institutional costs related to mask use that are often not acknowledged, such as the amount of waste created by single mask use and disposal after every case. In addition to increased cost and waste burden, the replacement of surgical masks by each team member after every case raises concern regarding the environmental impact of such practices, which is difficult to measure in this analysis. These concerns highlight an interesting avenue of further study to determine the environmental impact of our standard institutional protocols, specifically with single mask use, as this is a modifiable practice with potential for improvement. This discussion highlights the need and potential for developing more sustainable products such as biodegradable materials, which will further reduce our environmental impact.

Limitations to our study include the limited interval of cases reviewed and patient-related factors that may influence our analysis results. We elected to compare only 1 year of data in our analysis (2019), which we feel represents typical case volume during this quarter. Concerning capture of all the surgical site infections, we acknowledge that some patients may present to their primary care physician, pediatrician, or urgent care center if signs or symptoms of a surgical site infection are noticed. These may subsequently be treated without presentation to the original surgeon and, therefore, would not be included in our analysis. We provide detailed discharge instructions and the ability for 24-h contact with patients at all times, which we feel allows for reliable and expected communication between the patient and provider if issues arise. In addition, strict adherence and compliance with established policies including mask exchange when soiled, compliance with continuous use, and change of mask outside of the OR cannot be controlled for in our study. We cannot determine how many members of the surgical team changed their mask when visibly soiled with fluids from the operating field or damaged, and as such, we provide estimates for mask use to determine the number used and subsequent cost. Furthermore, we cannot comment on a relationship between soiled mask use and risk for SSI. We acknowledge that the duration of the policy implementation limits our sample size during the pandemic period. The period selected for review of COVID era cases represents a period of strict enforcement of the single mask use policy, and therefore, was felt to be the appropriate time frame for review; as a result, this limits our sample size for analysis.

Our study contributes to the body of literature evaluating current standard practice and policy change in the era of COVID-19. We demonstrated no change in patient outcomes or surgical site infection rate due to our institution's extended mask use policy in response to the need for PPE conservation. Future directions of this work may include additional studies to prove the safety of extended surgical mask use over a longer period, to provide data for future national infection prevention guidelines both within the OR and patient care areas.

Conclusion

Extended use of disposable surgical masks provided no additional risk of surgical site infection and no change in clinical outcomes in our series of elective pediatric general surgery procedures.

Author contributions All the authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by James A. Fraser, MD, Kayla B. Briggs, MD and Wendy Jo Svetanoff, MD MPH. The first draft of the manuscript was written by James A. Fraser, MD, and all the authors commented on previous versions of the manuscript. All the authors read and approved the final manuscript.

Declarations

Conflict of interest The authors have no relevant financial or non-financial interests to disclose.

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