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Complications Associated With Nasopharyngeal COVID-19 Testing: An Analysis of the MAUDE Database and Literature Review

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Abstract

Background: Nasopharyngeal swab testing, which has greatly increased in utilization due to the COVID-19 pandemic, is generally safe and well-tolerated, although it may be rarely associated with adverse events.

Methods: Publicly reported adverse events associated with nasopharyngeal COVID-19 testing within the Manufacturer and User Facility Device Experience (MAUDE) database and the published literature were queried.

Results: A total of 129 adverse events were reported, including 66 from the MAUDE database and 63 from literature review. The most common complications were swab fracture resulting in retained foreign body (47%), followed by epistaxis (17%), and headache (11%). Seven (12%) of the reported retained foreign body cases required removal under general anesthesia, while 1 (5%) of the epistaxis cases required surgical intervention. The most serious adverse event was meningitis following cerebrospinal fluid leak.

Conclusions: Patients and healthcare providers should be aware of the potential risks associated with testing, with attention to ensuring proper technique, and be prepared to recognize and manage adverse events.

Keywords

COVID-19, nasopharyngeal swab, MAUDE, adverse events, complications

Introduction

Diagnostic testing to identify individuals infected with SARS-CoV-2 is critical to COVID-19 containment and providing adequate and timely patient care. Over 363 million tests were performed in the United States as of March 7, 2021, with over 1 million new tests performed daily.[1] The nasopharyngeal swab is the recommended and most commonly deployed testing method.[2] We hypothesize that complications associated with nasopharyngeal testing are rare but do occur. Accordingly, their characterization is warranted to ensure that practitioners are aware of and equipped to manage such adverse events. We sought to identify publicly reported adverse events associated with nasopharyngeal COVID-19 testing. We queried the Manufacturer and User Facility Device Experience (MAUDE) database utilized by the Food and Drug Administration to report medical device-related complications.[3] Additionally, we performed a comprehensive literature review to identify complications reported in the published literature since the pandemic emerged.

Methods

This study did not require approval from the University of California Irvine's Institutional Review Board since data were collected from a publicly accessible database and previously published studies. The MAUDE database was queried for cases involving nasopharyngeal COVID-19 testing from December 1, 2019 to February 28, 2021 using the product class "Applicator, Absorbent Tipped, Sterile." Manufacturers reported in each event were recorded and individually searched in the database. Furthermore, we performed a literature search of published articles in PubMed, Ovid MEDLINE, and Cochrane databases using keywords

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["covid19" OR "covid-19"] AND "swab" AND ["complication" OR "complications" OR "cerebrospinal fluid leak" OR "CSF leak" OR "foreign body" OR "adverse events"]. The full abstract of each article was independently evaluated by 2 authors (AAH and KG). Additionally, the reference list of included studies and all articles that referenced these studies were screened. Inclusion criteria mandated the article was written in English and that the authors reported an adverse event relating to a COVID-19 nasopharyngeal swab test.

Results

The MAUDE search returned 416 results, of which 66 unique adverse events (from 8 swab manufacturers) were included. Fifteen of the 130 published studies generated from the literature search were included (Table 1), describing 63 adverse events. All reported adverse events are categorized in Table 2, demonstrating the most commonly reported complications following COVID-19 nasopharyngeal swab testing are swab fracture resulting in retained foreign body (47%), epistaxis (17%), and headache (11%). Of the 60 reported retained foreign bodies, 7 (12%) required removal under general anesthesia. The fragmented swab was not visualized on nasal endoscopy or imaging in 6 (10%) cases, increasing suspicion for possible foreign body ingestion. Only 1 patient (4.5%) experiencing epistaxis following testing required surgical intervention after failing clinical management with external pressure, ice packs, and cauterization. The most serious complication was cerebrospinal fluid (CSF) leak,[4–7] of which 1 case led to meningitis.[8]

Table 1. Summary of Studies Reporting Adverse Events Associated With COVID-19 Nasopharyngeal Swab Testing in the Literature.

Authors, country	Study type, no. of Complication(s)	Type of complication(s)	Management	Outcome
Gaffuri et al,[16] Italy	Case Report, 1	Fractured nasopharyngeal swab during collection	Removal under general anesthesia	Full recovery
Stevens et al,[17] United States	Case Report, 1	Fractured nasopharyngeal swab during collection	None. Suspected ingestion	Full recovery
Fabbris et al,[9] Italy	Single-center Retrospective Review, 8	Fractured nasopharyngeal swab during collection (3); nasal septum abscess (1); epistaxis (4)	Removal under endoscopic view (2) or swallowed (1) for fractured swab, Incision and drainage for abscess, Nasal packing under local anesthesia for epistaxis	Full recoveries
Föh et al,[10] Germany	Single-center Retrospective Review, 2	Fractured nasopharyngeal swab during collection (2);	Nonsurgical removal (1); None, suspected ingestion (1)	Full recovery
De Luca and Maltoni,[12] Italy	Case Report, 1	Fractured nasopharyngeal swab during collection	Upper GI endoscopy/removal	Full recovery
Mughal et al,[19] United Kingdom	Case Report, 1	Fractured nasopharyngeal swab during collection	Nonsurgical removal	Unspecified
Azar et al,[19] United States	Case Report, 1	Fractured nasopharyngeal swab during collection	Nonsurgical removal	Unspecified
Wyman et al,[21] United States	Case Report, 1	Fractured nasopharyngeal swab during collection	Nonsurgical removal	Full recovery
Suresh[11], India	Case Report, 1	Fractured nasopharyngeal swab during collection	Removal under general anesthesia	Full recovery
Gupta et al,[18] United States	Single-center Retrospective Review, 41	Epistaxis (12); nasal discomfort (10); headache (7); ear discomfort (6); rhinorrhea (6)	Unspecified	Unspecified
Paquin et al,[4] United States	Case Report, 1	Cerebrospinal fluid leak	Endoscopic surgical repair	Full recovery
Sullivan et al,[5] United States	Case Report, 1	Cerebrospinal fluid leak	Endoscopic surgical repair	Unspecified
Mistry et al,[6] Australia	Case Report, 1	Cerebrospinal fluid leak previously treated for meningitis	Endoscopic surgical repair	Unspecified
Rajah and Lee,[7] Australia	Case Report, 1	Cerebrospinal fluid leak	Endoscopic surgical repair	Full recovery
Alberola-Amores et al,[8] Spain	Case Report, 1	Cerebrospinal fluid leak with meningitis	Empirical treatment with cefotaxime, vancomycin, dexamethasone ×14 days	Full recovery

Discussion

Nasopharyngeal testing for COVID-19 is generally safe and well-tolerated, with the risk of any adverse event ranging from 0.02% to 0.16% in previous single-center retrospective reviews.[9,10] Nevertheless, healthcare providers should be cognizant of and well-equipped to manage complications associated with testing. In general, most of these adverse events may likely be mitigated by proper sampling technique, where the swab is inserted parallel to the nasal floor as opposed to a more superiorly oriented axis.

Swab fracture resulting in a retained foreign body was the most common adverse event reported both in the MAUDE database and the literature. Swabs have an inherent breakpoint mechanism to aid in easy transfer to the transport vial. However, this breakpoint is vulnerable to accidental fragmentation during sample collection, especially in uncooperative patients or sedated patients upon whom undue force is applied.[11] Furthermore, when not inserted along the nasal floor axis, the swab may contact structures that can increase the risk of fracture, such as septal spurs and the inferior and middle turbinates. Retrieval was generally performed with or without local anesthesia under direct visualization with direct rhinoscopy or nasal endoscopy. However, if the fragmented swab is not visualized, patients must be carefully monitored for foreign body ingestion or aspiration. One report discussed the need for an upper GI endoscopy to avoid possible perforation given the ingested swab's body length and sharp pointed form.[12]

Although epistaxis was a rare and largely self-limited adverse event, its incidence warrants caution when testing individuals at increased bleeding risk. Mucosal trauma is the most likely etiology, which may be avoided by staying low in the nose. COVID-19 disproportionally affects the elderly, many of whom are treated with oral anticoagulants. Studies examining epistaxis rates following nasopharyngeal testing among such at-risk patients are needed, and a risk assessment should be considered prior to testing. Alternatively, less invasive testing methods including throat swabbing or saliva sampling can be considered.

Iatrogenic CSF leak is an unusual yet potentially fatal complication following testing. Whereas one case involved a patient with a pre-existing encephalocele[7], 4 patients did not have radiographic or visual evidence of a skull base defect before testing.[8–10,20] These reports illustrate the importance of proper nasopharyngeal swab technique which has been described through simulation models,[13] videos,[14] and graphics.[15] Furthermore, providers should exhibit increased caution in patients with history of sinus/skull base surgery and consider alternative testing methods including throat swabbing or saliva sampling. As many nasopharyngeal swabs are performed in a drive-through format, patients should be queried about prior endonasal endoscopic sinus or skull base operations prior to testing.

We recognize that the MAUDE database is limited, especially in describing patient characteristics and comorbidities which may help identify patients who are more susceptible to experiencing a nasopharyngeal swab-related adverse event. Reports of device-related complications are mandatory for industry and voluntary for providers and patients, thus data may be under-reported. Additionally, MAUDE reports may contain erroneous narrative information. There is also a possibility that some of the complications published in the literature may have also been submitted via the MAUDE database and therefore duplicated; however, the rate of complications found through the MAUDE database and the literature review do not suggest that this happened at a significant degree. While future peer-reviewed studies will continue to provide the strongest evidence on this topic, the MAUDE database helps fill the current gap in knowledge, making this study the most comprehensive overview of adverse events following nasopharyngeal COVID-19 testing.

Conclusion

Nasopharyngeal COVID-19 testing is rarely associated with complications, which nevertheless may result in morbidity and medical emergencies. Patients and providers should be aware of the potential risks associated with testing as well as the methods to manage complications. A risk assessment should be considered in patients who are at increased risk of bleeding, or those with a history of rhinologic or skull base disorders and/or surgery.

Author Contributions

Amir Hakimi, MD: Conception and design of the study, acquisition and analysis of data, drafting the manuscript, and accountable for all aspects of the work.

Khodayar Goshtasbi, MD: Conception and design of the study, acquisition and analysis of data, drafting the manuscript, and accountable for all aspects of the work.

Edward C. Kuan, MD, MBA: Conception and design of the study, analysis and interpretation of data, drafting the manuscript, and accountable for all aspects of the work.

Declaration of Conflicting Interests

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Ethical Approval

Not applicable, because this article does not contain any studies with human or animal subjects.

Table 2. Incidence of Adverse Events Related to COVID-19 Nasopharyngeal Swab Testing Reported in the MAUDE Database and Literature.

Complication	MAUDE database, No.	Literature review, No.	Total
Foreign body retention	48	12	60
Epistaxis	6	16	22
Headache	7	7	14
Nasal discomfort	1	10	11
Ear discomfort	1	6	7
Rhinorrhea	0	6	6
Cerebrospinal fluid leak	0	5	5
Eye discomfort	2	0	2
Nasal septal abscess	0	1	1
Anosmia	1	0	1
Total	66	63	129

MAUDE, *Manufacturer and User Facility Device Experience.*

Informed Consent

Not applicable, because this article does not contain any studies with human or animal subjects.

Trial Registration

Not applicable, because this article does not contain any clinical trials.

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References

1. The COVID Tracking Project. Available at: https://covidtracking.com/data. (Accessed March 17, 2021).
2. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases; 2021 [updated February 26, 2021]. Available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html. (Accessed March 17, 2021).
3. U.S. Food and Drug Administration MAUDE-Manufacturer and User Facility Device Experience. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. (Accessed March 17, 2021).
4. Paquin R, Ryan L, Vale FL, et al. CSF Leak after COVID-19 nasopharyngeal swab: a case report. *Laryngoscope* 2021; 131(9):1927–1929. Doi:10.1002/lary.29462
5. Sullivan CB, Schwalje AT, Jensen M, et al. Cerebrospinal fluid leak after nasal swab testing for coronavirus disease 2019. *JAMA Otolaryngol Head Neck Surg*. 2020;146(12):1179–1181.
6. Mistry SG, Walker W, Earnshaw J, et al. The COVID swab and the skull base – how to stay safe. *Med J Aust*. 2020. Available at: https://www.mja.com/au/journal/2020/covid-swab-and-skull-base-how-stay-safe. [Preprint, 4 December 2020].
7. Rajah J, Lee J. CSF Rhinorrhoea post COVID-19 swab: a case report and review of literature. *J Clin Neurosci* 2021;86:6–9. Doi:10.1016/jocn.2021.01.003
8. Alberola-Amores FJ, Valdeolivas-Urbelz E, Torregrosa-Ortiz M, et al. Meningitis due to cerebrospinal fluid leak after nasal swab testing for COVID-19. *Eur J Neurol* 2021. Online ahead of print. Doi:10.1111/ene.14736.
9. Fabbris C, Cestaro W, Menegaldo A, et al. Is oro/nasopharyngeal swab for SARS-CoV-2 detection a safe procedure? Complications observed among a case series of 4876 consecutive swabs. *Am J Otolaryngol*. 2021;42(1):102758.
10. Föh B, Borsche M, Balck A, et al. Complications of nasal and pharyngeal swabs – a relevant challenge of the COVID-19 pandemic? *Eur Respir J* 2020. Online ahead of print. Doi:10.1183/13993003.04004-2020.
11. Suresh V. Anesthesia for extraction of a fractured COVID-19 nasopharyngeal swab. *Int J Pediatr Otorhinolaryngol* 2021;143:110611. Online ahead of print. Doi:10.1016/j.ijporl.2021.110611.
12. De Luca L, Maltoni S. Is naso-pharyngeal swab always safe for SARS-CoV-2 testing? An unusual, accidental foreign body swallowing. *Clin J Gastroenterol*. 2021;14(1):44–47.
13. Mark ME, LoSavio P, Husain I, et al. Effect of implementing simulation education on health care worker comfort with nasopharyngeal swabbing for COVID-19. *Otolaryngol Head Neck Surg*. 2020;163(2):271–274.
14. Itamura K, Wu A, Illing E, et al. Youtube videos demonstrating the nasopharyngeal swab technique for SARS-CoV-2 specimen collection: content analysis. *JMIR Public Health Surveill*. 2021;7(1):e24220.
15. Marty FM, Chen K, Verrill KA. How to obtain a nasopharyngeal swab specimen. *N Eng J Med*. 2020;382(22):e76.
16. Gaffuri M, Capaccio P, Torretta S, et al. An unusual retained choanal foreign body: a possible complication of COVID-19 testing with nasopharyngeal swab. *Ear Nose Throat J* 2021. Online ahead of print. Doi:10.1177/0145561321993933
17. Stevens MN, Lin GT, Tittman SM, et al. SARS-CoV-2 nasopharyngeal swab as a foreign body: a case report. *Ear Nose Throat J* 2021. Online ahead of print. Doi:10.1177/0145561321996836
18. Gupta K, Bellino PM, Charness ME. Adverse effects of nasopharyngeal swabs: three-dimensional printed versus commercial swabs. *Infect Control Hosp Epidemiol* 2020;42(5):641–642. Doi:10.1017/ice.2020.297
19. Mughal Z, Luff E, Okonkwo O, et al. Test, test – a complication of testing for coronavirus disease 2019 with nasal swabs. *J Laryngol Otol*. 2020;134(7):646–649.
20. Azar A, Wessell DE, Janus JR, et al. Fractured aluminum nasopharyngeal swab during drive-through testing for COVID-19: radiographic detection of a retained foreign body. *Skeletal Radiol*. 2020;49(11):1873–1877.
21. Wyman MT, Symms J, Viscusi C. Nasal foreign body, an unanticipated complication of COVID-19 care: a case report. *J Emerg Med* 2020;S0736–S4679(20):31425–31426.