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Surgical mask placement over N95 filtering facepiece respirators: Physiological effects on healthcare workers

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ABSTRACT

Background and objective: **Filtering facepiece respirators ('N95 Masks') may be in short supply during large-scale infectious outbreaks. Suggestions have been made to extend their useful life by using a surgical mask as an outer barrier, but the physiological impact of this added barrier upon the wearer has not been studied.**
Methods: **A surgical mask was worn over an N95 filtering facepiece respirator by 10 healthcare workers for 1 h at each of two work rates. Heart rate, respiratory rate, tidal volume, minute volume, oxygen saturation, transcutaneous carbon dioxide levels and respirator dead space gases were monitored and compared with controls (N95 filtering facepiece respirator without a surgical mask). Subjective perceptions of exertion and comfort were assessed by numerical rating scales.**
Results: **There were no significant differences in physiological variables between those who used surgical masks and controls. Surgical masks decreased dead space oxygen concentrations of the filtering facepiece respirators at the lesser work rate ($P = 0.03$) and for filtering facepiece respirators with an exhalation valve at the higher work rate ($P = 0.003$). Respirator dead space oxygen and carbon dioxide levels were not harmonious with Occupational Safety and Health Administration workplace ambient atmosphere standards. Exertion and comfort scores were not significantly impacted by the surgical mask.**
Conclusions: **Use of a surgical mask as an outer barrier over N95 filtering facepiece respirators does not significantly impact the physiological burden or perceptions of comfort and exertion by the wearer over that experienced without use of a surgical mask.**

Key words: environmental and occupational health and epidemiology, infection control, respiratory infection (non-tuberculous), ventilation, viral infection.

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SUMMARY AT A GLANCE

Ten healthcare workers wearing N95 filtering facepiece respirators with, and without, a surgical mask outer covering were physiologically monitored. No significant differences in heart rate, breathing rate, tidal volume, minute volume, transcutaneous carbon dioxide and oxygen saturation were observed with application of the surgical mask.

INTRODUCTION

The Severe Acute Respiratory Syndrome outbreaks and the recent H1N1 pandemic have raised concerns about the availability of filtering facepiece respirators (FFR), of which the most commonly used by healthcare workers (HCW) are the N95 class of FFR (N95 FFR), commonly (although incorrectly) referred to as 'N95 Masks'.[1] The Centers for Disease Control and Prevention estimates that upwards of 92 million FFR would be needed by US HCW for a 42-day pandemic influenza outbreak, and there are concerns that manufacturers might not be able to keep pace with demand.[2] Increased demand, as exemplified by the use of 18 000 FFR/day at Sunnybrook Hospital in Toronto during the 2003 Severe Acute Respiratory Syndrome outbreaks,[3] can rapidly outstrip local supplies. The Institute of Medicine has suggested that the concurrent use of surgical masks (SM), worn as an outer barrier, could potentially extend the FFR useful life.[2] SM have previously been recommended, used or tested, as a concurrent, complementary barrier in conjunction with various forms of respiratory protective equipment and oxygen delivery devices.[2,4–10] However, studies addressing the physiological impact of the concurrent wearing of SM with FFR are limited, although one study has shown minimal impact on breathing resistance by this combination respiratory protection.[11] Nonetheless, there are multiple other issues of concern associated with combined SM/FFR use for respiratory protection (e.g. communication,

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comfort, effect on FFR fit, impact on oxygenation and carbon dioxide retention and regulatory matters [e.g. National Institute for Occupational Safety and Health certification]).[1] The current study, part of a larger investigation into the effects of respiratory protective equipment on users,[12] examined the physiological impact on HCW of the concurrent use of SM as an outer barrier over N95 FFR and N95 FFR with an exhalation valve (N95 FFR/EV).

METHODS

Ten healthy HCW (three men, seven women), experienced with FFR, were recruited. Nine subjects had never smoked and one had not smoked in >1 year (20 pack year history for that individual) (Table 1). The study was approved by the NIOSH Human Subjects Review Board, and all subjects provided oral and written informed consent. Ethics approval was not required as subjects were not patients.

A lightweight spandex vest incorporating physiological sensors and respiratory inductive plethysmography bands (LifeShirt System, VivoMetrics, Ventura, CA) monitored the heart rate (HR), breathing rate (f_B) and tidal volume (V_T). Minute ventilation ($\dot{V}_E$) was calculated as the product of $f_B \times V_T$. The LifeShirt was calibrated against a fixed volume at each use. Respirator dead space carbon dioxide ($V_{D\ resp}\ CO_2$) and oxygen ($V_{D\ resp}\ O_2$) were monitored at 18 samples/s (500 mL/min sampling volume) via analysers (AEI Technologies, Naperville, OH) coupled to a 2-mm internal diameter sampling line attached to a port extending through both the SM and FFR that was positioned equidistant from nares to mouth and corrected for standard temperature and pressure, dry. Sample gas was dried with a dessicant media (Perma Pure LLC, Toms River, NJ) and the gas analysers were calibrated daily using standards traceable to the National Institute of Standards and Technology. Continuous transcutaneous CO_2 ($tcPCO_2$) and O_2 saturation (SpO_2) measurements were obtained via a heated (42°C) earlobe sensor (Tosca 500 Monitor, Radiometer, Copenhagen, Denmark) that is a combination pulse oximeter and Severinghaus-type PCO_2 sensor.[13] The Tosca monitoring unit is calibrated over a 10-min period prior to each use.

The two cup-shaped models of N95 FFR studied (two manufacturers) were randomly selected from supplies in the National Strategic Stockpile, a federal government-maintained repository of medical supplies likely to be the first distributed to HCW in large-scale medical emergencies.[14] The two cup-shaped N95 FFR/EV models studied were selected because they are similar to the counterpart exhalation-valved models of the N95 FFR (same manufacturers). A single model of a Food and Drug Administration-cleared pleated, non-splash resistant, Type II SM (i.e. breathing resistance <3 mm H_2O pressure at 8 L/min flow[11]) was utilized. New N95 FFR, N95 FFR/EV and SM were used for each study session. Eight subjects passed quantitative respirator fit testing (attainment of fit factors ≥100, indicating leakage of ≤1% and compliance with Occupational Safety and Health Administration regulations[15]) with medium/large-size (e.g. standard) N95 FFR and N95 FFR/EV, and two subjects required small-size models to pass fit testing (SM were not in place over the FFR when fit testing was carried out).

Subjects were tested in tee shirts, shorts, socks, athletic shoes and the LifeShirt. Randomly assigned N95 FFR/SM or N95 FFR/EV/SM were donned in accordance with the manufacturers' instructions (e.g. FFR straps and SM ties were secured over the occiput and posterior upper cervical region) and positive and negative user seal checks were performed (with the air sampling line pinched off). The Tosca 500 sensor was attached to the left earlobe and subjects treadmill-walked for 1 h (cumulative FFR wear time by nurses per shift[16]) at each of two randomly assigned treadmill work rates representative of HCW activities: (i) 1.7 mph (2.74 km/h) treadmill speed (0% grade) that equates to stationary work (e.g. writing nursing notes, answering a phone, etc.); and (ii) 2.5 mph (4.03 km/h) treadmill speed (0% grade) that equates to bedside nursing patient care activities.[17] Subject perceptions of comfort and exertion were obtained every 5 min with numerical rating scales

Table 1 Subject demographics

Subject	Professional category	Age (years)	Weight (kg)	Height (cm)	BMI
1	Nurse	42	75.3	154.9	31.3
2	Nurse	22	47.6	165.1	17.4
3	Physical therapy technician	24	64.5	162.5	24.4
4	Physical therapy technician	23	126.4	162.5	47.7
5	Patient care assistant	20	105.4	182.8	31.5
6	Patient care assistant	34	55.4	157.4	22.3
7	Patient care assistant	20	68.8	187.9	19.4
9	Nursing student	21	56.8	165.1	20.8
9	Nursing student	22	69.5	170.1	23.9
10	Physical therapy student	23	85.8	182.8	25.5
Mean		25.1	76.0	169.1	26.4

(i.e. the Borg Rating of Perceived Exertion [numerical range of 1–5, least to most exertion[18]]; modified Perceived Comfort Scale [numerical range of 1–5, least to most discomfort[19]]). Talking was permitted *ad lib* during testing to mimic HCW communicating with each other and patients while wearing FFR. Study sessions were generally limited to two per day, with a minimum 30-min break between individual sessions. Each subject participated in four exercise sessions (one for each N95 FFR/SM and FFR/EV/SM at each of two work rates). The N95 FFR and N95 FFR/EV were weighed before and after each test to assess any moisture retention. The study laboratory average temperature was 21.3°C (range 18.3–23.4°C) and relative humidity averaged 56.7% (range 46.1–72.8%). Previously published data[12] from the same study subjects wearing the identical N95 FFR and N95 FFR/EV models without a SM, were used for control purposes. All control studies were carried out within 3 weeks of study phases.

SPSS version 16.0 (SPSS Inc., Chicago, IL) was used for statistical analysis. All physiological data and $V_{D\ resp}$ CO_2 and O_2 data are reported as means (1 SD). The time of the sessions was 1 h and all variables are summarized as 1-min means at 1, 15, 30, 45 and 60 min (five stages). To assess the differences between N95 FFR and N95 FFR/EV with, and without, SM as an outer barrier at the two different intensity levels during 1 h of exercise, $4 \times 2 \times 5$ (N95 FFR type [N95 FFR, N95 FFR/SM, N95 FFR/EV, N95 FFR/EV/SM] × work rate [1.7, 2.5 mph] × time [1, 15, 30, 45, 60 min]) repeated-measures analyses of variance (ANOVAs) were performed for physiological variables (HR, f_B, V_T, $\dot{V}_E$, SaO_2 and $tcPCO_2$) using the values from the previous study report[12] as the control session for the comparisons. A $4 \times 2 \times 5$ (FFR type × work rate × time) repeated-measures ANOVA was performed to examine $V_{D\ resp}$ O_2 and $V_{D\ resp}$ CO_2 responses to the N95 FFR, N95 FFR/SM, N95 FFR/EV and N95 FFR/EV/SM at the two different exercise intensities. Significant interactions were further analysed utilizing one-way ANOVA and paired *t*-tests with Bonferroni corrections with the α-level set at $P = 0.05$. Exertion scores, comfort scores and FFR moisture retention were analysed by paired *t*-tests.

RESULTS

There were no significant differences, at both work rates over the period of 1 h, when comparing N95 FFR/SM with N95 FFR/EV/SM effects upon HR ($P = 0.75$), f_B ($P = 0.13$), V_T ($P = 0.42$), $\dot{V}_E$ ($P = 0.29$), SpO_2 ($P = 0.39$), $tcPCO_2$ ($P = 0.98$), $V_{D\ resp}$ O_2 levels ($P = 0.10$) and $V_{D\ resp}$ CO_2 levels ($P = 0.38$). Comparing controls with N95 FFR/SM and controls with N95 FFR/EV/SM, there were no significant differences for these same parameters, save for lower $V_{D\ resp}$ O_2 levels for N95 FFR/SM at 1.7 mph ($P = 0.03$) and for N95 FFR/EV/SM at 2.5 mph ($P = 0.003$), as well as a higher HR for controls at the 2.5 mph work rate ($P = 0.05$) (Table 2). The only significant difference in comfort scores was greater comfort for N95 FFR/EV/SM at 1.7 mph compared with 2.5 mph ($P = 0.01$).

Table 2 Study variables at 60 min of FFR wear

Study variables	Respirator models: N95 FFR EV	N95 FFR EV/SM	N95 FFR	N95 FFR/SM	Respirator models: N95 FFR EV	N95 FFR EV/SM	N95 FFR	N95 FFR/SM
	1.7 mph (2.74 km/h) work rate				2.5 mph (4.03 km/h) work rate			
Heart rate (min)	95.1 (±9.7)	95.8 (±11.5)	98.1 (±8.5)	96.3 (±9.5)	106.4 (±9.3)	107.6 (±12.2)	106.4 (±9.2)	102.3 (±9.0)
Breathing rate (min)	25.2 (±6.1)	24.8 (±3.3)	25.2 (±4.0)	24.8 (±4.3)	25.5 (±5.7)	24.9 (±5.5)	26.6 (±6.8)	25.8 (±5.2)
Tidal volume (mL)	878 (±253)	949 (±168)	950 (±358)	923 (±223)	932 (±297)	1020 (±224)	945 (±241)	938 (±179)
Minute volume (L/min)	21.22 (±4.53)	23.35 (±3.62)	23.36 (±6.70)	22.30 (±3.74)	22.96 (±5.86)	24.77 (±5.23)	24.43 (±6.01)	23.73 (±3.37)
Oxygen saturation (%)	98.4 (±0.96)	98.1 (±0.72)	98.1 (±0.87)	98.4 (±0.72)	98.2 (±1.00)	98.3 (±0.71)	98.4 (±0.70)	98.1 (±0.68)
Transcutaneous carbon dioxide (mm Hg)	41.5 (±4.9)	41.4 (±6.4)	39.7 (±6.0)	43.1 (±6.0)	42.6 (±6.2)	43.0 (±7.4)	42.0 (±5.6)	43.0 (±5.8)
Respirator dead space oxygen (%)	16.46 (±0.60)	16.77 (±1.55)	16.63 (±0.58)	16.38 (±0.60)	17.19 (±1.14)	16.27 (±0.64)	16.61 (±0.62)	16.48 (±0.79)
Respirator dead space carbon dioxide (%)	2.89 (±0.36)	2.97 (±0.38)	2.89 (±0.23)	2.92 (±0.25)	2.95 (±0.49)	2.98 (±0.34)	2.85 (±0.36)	3.02 (±0.41)

N95 FFR, N95 filtering facepiece respirator; N95 FFR EV, N95 filtering facepiece respirator with an exhalation valve; N95 FFR EV/SM, N95 filtering facepiece respirator with an exhalation valve and surgical mask outer cover; N95 FFR/SM, N95 filtering facepiece respirator with a surgical mask outer cover.

Table 3 Comfort scores, exertion scores and moisture retention values

Conditions	Comfort scores (SD)	*P*-value	Exertion scores	*P*-value	Moisture gain (gm/h)	*P*-value
N95 FFR @ 1.7 mph versus	1.15 (±0.36)	0.21	0.77 (±1.08)	0.31	0.10 (±0.13)	0.29
N95 FFR/SM @ 1.7 mph	1.41 (±0.52)		1.15 (±0.36)		0.05 (±0.05)	
N95 FFR @ 2.5 mph versus	1.67 (±0.53)	0.78	1.21 (±1.63)	0.30	0.15 (±0.20)	0.61
N95 FFR/SM @ 2.5 mph	1.59 (±0.77)		1.67 (±0.53)		0.11 (±0.09)	
N95 FFR/EV @ 1.7 mph versus	1.53 (±0.66)	0.22	0 0.82 (±1.17)	0.91	0.11 (±0.09)	0.55
N95 FFR/EV/SM @ 1.7 mph	1.27 (±0.35)		0.88 (±1.26)		0.09 (±0.07)	
N95 FFR/EV @ 2.5 mph versus	1.43 (±0.45)	0.19	1.25 (±1.44)	0.56	0.17 (±0.11)	1.000
N95 FFR/EV/SM @ 2.5 mph	1.74 (±0.77)		0.92 (±0.91)		0.16 (±0.22)	
N95 FFR/SM @ 1.7 mph versus	1.41 ±(0.52)	0.19	0.77 (±1.08)	0.01	0.05 (±0.05)	0.05
N95 FFR/SM @ 2.5 mph	1.72 (±1.02)		1.21 (±1.30)		0.11 (±0.09)	
N95 FFR/EV/SM @ 1.7 mph versus	1.27 (±0.35)	0.01	0.82 (±1.17)	0.01	0.09 (±0.07)	0.46
N95 FFR/EV/SM @ 2.5 mph	1.74 (±0.77)		1.25 (±1.44)		0.16 (±0.22)	
N95 FFR/SM @ 1.7 mph versus	1.41 (±0.52)	0.16	0.77 (±1.08)	0.66	0.05 (±0.05)	0.22
N95 FFR/EV/SM @ 1.7 mph	1.27 (±0.35)		0.82 (±1.17)		0.09 (±0.07)	
N95 FFR/SM @ 2.5 mph versus	1.72 (±1.02)	0.57	1.21 (±1.30)	0.77	0.11 (±0.09)	0.57
N95 FFR/EV/SM @ 2.5 mph	1.74 (±0.77)		1.25 (±1.44)		0.16 (±0.22)	

N95 FFR, N95 filtering facepiece respirators; N95 FFR/EV, N95 filtering facepiece respirators with an exhalation valve; N95 FFR/EV/SM, N95 filtering facepiece respirators with an exhalation valve and surgical mask outer barrier; N95 FFR/SM, N95 filtering facepiece respirators with surgical mask outer barrier.

Significantly lower exertion scores were reported for controls compared with N95 FFR/SM and N95 FFR/EV/SM at 1.7 mph than at 2.5 ($P = 0.01$ for each comparison). There were no significant differences in average moisture retention (g/h) for N95 FFR/SM or N95 FFR/EV/SM compared with controls (Table 3).

DISCUSSION

Despite their extensive use over the past three decades, very little data exist regarding the physiological impact of FFR upon users.[20–22] The limited data available on the physiological impact of SM indicates that, at ≤60 min of continuous use (comparable to the present study), HR and SpO_2 are not significantly changed compared with baseline values.[23,24] The current study demonstrated that using SM as an outer barrier over N95 FFR or N95 FFR/EV by HCW, for 1 h at either of two work rates associated with the healthcare environment, did not result in a significant additional physiological impact over that of FFR alone. Given that much of the physiological burden associated with the use of FFR is attributable to the need for overcoming the filter media resistance to airflow; the additional layers of SM over an N95 FFR would be expected to have an additive effect upon breathing resistance.[25] However, breathing resistance of type II SM is quite low (<3 mm H_2O pressure[11]), and, when worn over different models of N95 FFR at low-to-moderate breathing volumes, has previously been shown to result in only an additional 4.6–10% increase in inhalation resistance and 5.7–12.3% increase in exhalation resistance.[11]

The $V_{D\ resp}$ of FFR serves as a repository for a portion of exhaled gases that are subsequently admixed with air drawn in with subsequent inhalations.[26] The greater the volume of $V_{D\ resp}$, the greater the potential for elevated $V_{D\ resp}$ CO_2 levels that, upon subsequent rebreathing, could lead to elevated arterial CO_2 levels and the stress of compensatory mechanisms (e.g. increased f_B, V_T and HR).[12] The wearing of SM over N95 FFR could theoretically impact $V_{D\ resp}$ by: (i) creating an additional amount of dead space between SM and N95 FFR; or (ii) decreasing the dead space of certain N95 FFR models (i.e. duckbill FFR) by compressive forces impinging upon the N95 FFR convex outline (depending on how tight the SM is secured). Semi-rigid N95 FFR (e.g. cup-shaped, moulded) may be less subject to SM compressive forces that other models (e.g. duckbill, pleated). Also, the $V_{D\ resp}$ created when SM are applied over N95 FFR/EV may be somewhat greater than over N95 FFR because the EV protrudes variably (according to model) from the surface of the N95 FFR, thereby creating an outpouching of SM. In the current study, there were no significant differences between N95 FFR/SM and N95 FFR/EV/SM with respect to $V_{D\ resp}$ O_2 and CO_2 ($P = 0.98$ and $P = 0.10$, respectively). However, significantly higher $V_{D\ resp}$ O_2 levels were noted for controls over N95 FFR/SM at 1.7 mph ($P = 0.03$) and trended towards significance at the 2.5 mph work rate ($P = 0.08$), suggesting a negative impact of the increased dead space provided by the SM. The significantly higher $V_{D\ resp}$ O_2 noted for controls compared with N95 FFR/EV/SM at the 2.5 mph work rate ($P = 0.003$) that was not observed at the 1.7 mph work rate ($P = 0.87$) suggests that the SM may theoretically negatively impact the function of the EV at higher work rates (given that EV normally function to decrease $V_{D\ resp}$).

Although the values for $V_{D\ resp}$ O_2 and CO_2 were not harmonious with Occupational Safety and Health Administration workplace standards (i.e. <0.5% CO_2 [as an 8-h time-weighted average]; atmospheres

<19.5% O_2 are considered deficient), these standards apply to the ambient workplace atmosphere, not $V_{D\ resp}$.[12] From a clinical standpoint, the N95 FFR microenvironment seemingly had limited impact in that it did not result in any significant differences over controls in mean SpO_2 or $tcPCO_2$ over the course of 1 h. (Table 2) Although there were no significant differences in mean $tcPCO_2$ levels associated with the use of N95 FFR/SM and N95 FFR/EV/SM compared with controls, it should be noted that two test subjects (female ex-smoker, male non-smoker) attained elevated mean 60 min $tcPCO_2$ levels (i.e. female ex-smoker, 53.6/60.8/54.0/56.0 mm Hg; male non-smoker, 48.1/48.0/47.0/48.4 mm Hg) during the four trials, thereby emphasizing the great variability on the impact of N95 FFR between individuals.

Comfort is an important issue with respect to N95 FFR tolerance.[27] In the current study, the only significant difference in comfort scores was related to the work rate (i.e. improved comfort at 1.7 mph vs 2.5 mph for N95 FFR/EV/SM [Table 3]), suggesting that placement of SM over N95 FFR or N95 FFR/EV, in and of itself, does not cause any decrease in comfort compared with controls, over 1 h. However, comfort might be impacted by wear time inasmuch as a recent study of HCW reported greater mean tolerance time for N95 FFR (5.8 h) than N95 FFR/SM (4.1 h) and for N95 FFR/EV (7.7 h) compared with N95 FFR/EV/SM (4.3 h), indicating that placement of SM over N95 FFR resulted in the least tolerated form of respiratory protective equipment.[27] The only significant differences in exertion scores in the present study were also work rate related; less exertion was noted at 1.7 mph versus 2.5 mph for N95 FFR/SM ($P = 0.01$) and N95 FFR/EV/SM ($P = 0.01$) compared with controls. (Table 3) Otherwise, it does not appear that the placement of a SM over cup-shaped models of N95 FFR or N95 FFR/EV has a significant effect upon exertion at the work rates studied.

It has been anecdotally suggested that, with extended wear, exhaled moisture entrapped in the filters of FFR or SM can theoretically result in increased breathing resistance.[2,9,28,29] In the current study, no significant differences in the weight of N95 FFR or N95 FFR/EV were observed before and after 1 h of use with SM. (Table 3) This is probably related to the relatively low workloads and the hydrophobic nature of the study N95 FFR.[30]

Study limitations include the small sample size (10 HCW) and the fact that only two models each of N95 FFR and N95 FFR/EV and one model of SM were tested. The ventilation data from respiratory inductive plethysmography are not as accurate as other laboratory-based equipment (e.g. pneumotachygraph, spirometer), but recent exercise studies have reported high correlation coefficients.[31,32] Similarly, $tcPCO_2$ data are not as accurate as arterial measurements, but studies demonstrate improved accuracy[33,34] and transcutaneous measurements avoid the pain and potential complications of arterial punctures or indwelling arterial sampling lines (e.g. thrombosis, infection, hematoma formation, etc.). Treadmill exercising, while useful in delivering quantifiable amounts of exertion, is a continuous action rather than the intermittent bouts of activity of varying levels of exertion throughout the day in the healthcare environment. However, if anything, this represents a worst case scenario in that there was no respite during the hour-long exercise activity as opposed to real-life situations of generally shorter duration in healthcare. The current study was undertaken in a laboratory setting rather than an actual healthcare environment; however, laboratory studies may actually represent the upper boundary of study parameter measurements.[20]

In conclusion, the use of SM as an outer barrier to increase the useful life of N95 FFR and N95 FFR/EV, did not result in a significantly increased physiological burden for HCW, compared with no use of SM, when tested over 1 h at healthcare environment work rates. Comfort scores, exertion scores and N95 FFR moisture retention were not markedly impacted by this combination of respiratory protection. The use of SM as an outer barrier is a potentially cost-efficient method for extending N95 FFR useful life when demand exceeds supply. Further HCW studies will be needed to address the physiological burden of wearing FFR, with and without SM, for more prolonged periods (as would occur in a pandemic influenza) and the impact of various styles of N95 FFR (e.g. flat-fold, duckbill, cup-shaped, etc.) upon the physiological impact. Most importantly, studies are needed to determine whether a SM outer barrier maintains N95 FFR hygiene without compromising its function.

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