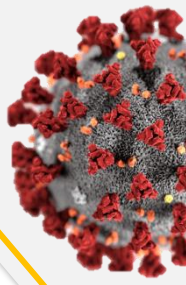
Hyper Light Disinfection Robot

Based on available evidence up to 3 July 2020



INTRODUCTION

A hospital-acquired infection (HAI), also known as a nosocomial infection, is an infection that is acquired in a hospital or other health care facility, such as nursing home, rehabilitation facility, outpatient clinic, diagnostic laboratory or other clinical settings. Infection is spread to the susceptible patient in the clinical setting by various means such as contaminated equipment, bed linens, or air droplets. The infection can originate from the outside environment, another infected patient, staff that may be infected, or in some cases, the source of the infection cannot be determined. [1]

Ultraviolet germicidal irradiation (UVGI) is a disinfection method that uses short wavelength ultraviolet (UV-C) light to kill or inactivate microorganisms by destroying nucleic acids and disrupting their DNA, leaving them unable to perform vital cellular functions. UVGI is used in a variety of applications, such as food, air, and water purification. In recent years UVGI has found renewed application in air purifiers.[2]

Currently, most UV disinfection devices primarily utilize ultraviolet-C (UV-C) radiation with wavelengths between 200 and 270 nm. At particular wavelengths such as 254 nm, UV-C light is able to destroy the molecular bonds and disrupt DNA or RNA via pyrimidine dimerization, causing death of a variety of environmental microorganisms.[3]

Hyper Light Disinfection Robot (Model P3) is a designed robot to prevent HAI using the UVGI disinfection method. It uses germicidal UVC at 254nm. The system consists of six amalgam UV lamps with rotational reflector technology. It is claimed to have the capability to eradicate >99.99% of microorganism including bacteria, viruses and pathogen within three meter radius in 15 minutes by destroying nucleic acids and disrupting DNA or RNA. The system also claimed to be eco-friendly with no ozone emitted and leaves no residuals due to the ability of amalgam lamp to

operate at high temperature (90°C), produce no ozone gas, generate low thermo-sensitivity and have a longer lifetime compared to conventional low-pressure mercury lamps.[4]

Figure 1: Pictures of Hyper Light Disinfection Robot

EVIDENCE ON EFFECTIVENESS AND SAFETY

Only one article was retrieved from the scientific databases such as Medline, EBM Reviews, EMBASE via OVID, Pubmed and from the general search engines [Google Scholar and US Food and Drug Administration (USFDA) on the Hyperlight disinfection robot itself. However, there were 134 titles retrieved on the UV-C disinfection technology. We also received one article (same as retrieved from database), one clinical trial report, two efficacy studies, nine laboratory test reports (but one in Chinese so that cannot be interpreted),CE mark and pre- and post- environmental culture analysis document from the company.

Finally, a total of seven articles were included in this review which comprised of five pre- and post-intervention studies [one study on Hyper Light Disinfection Robot (Model P3) and four studies on UV-C 254nm disinfection technology], one Health Technology Assessment (HTA) report and one secondary analysis study.

EFFECTIVENESS/EFFICACY

Hyper Light Disinfection Robot (Model P3)

Yang JH et al. (2017) conducted an in-vitro and pre- and post-intervention study at National Taiwan University hospital funded by Mediland Enterprise Corporation. The primary objective was to assess the effectiveness of the Hyper Light P3 in reduction of the most frequently encountered multidrug-resistant clinical isolates [*P.aeruginosa* (*MDRPA*), *Acinetobacter baumannii* (*MDRAB*), *multiple resistant staphylococcus aureus* (*MRSA*), *vancomycin-resistance Enterococcus* (*VRE*), *Mycobacterium abscessus* and *Aspergillus fumigatus*] on solid and liquid media. One petri dish placed on the table in the laboratory in each UV-C irradiation cycle. The height from petri dish to ground was 78 cm. The device was wheeled into different strategic positions that were 1 meter (m), 2 m and 3 m from the petri dishes with the same number of colonies, respectively. The above experiments were repeated with 5, 10 and 15 min of exposure time. Baseline petri dishes were left untreated outside of the room (i.e., positive controls). The protocol was repeated for each tested pathogens. For the in-vitro study, they reported that, efficacy of the Hyper Light P3 device was greater when the distance of petri dishes to UV-C device was shorter (1 m > 2 m > 3 m) and the exposure time was longer (15 min > 10 min > 5 min) (Table 1). However, the effect was less pronounced for *A. fumigatus* particularly at the distance of 2 to 3 meters.[3]

Table 1 Number of colony forming units of bacteria or fungi recovered after UV-C irradiation for specified time at different distance from the Hyper Light P3 device.

	Colony-forming units					
	MRSA	MDRAB	MDRPA	VRE	*M. abscessus*	*A. fumigatus*
5 min						
Control[a]	1.5×10^7	2.4×10^7	1.8×10^7	2.8×10^7	7.2×10^7	3.0×10^6
1 m	0	0	0	0	0	1000
2 m	600	0	200	1600	4600	300,000
3 m	4800	4200	3000	800,000	200,000	700,000
10 min						
Control[a]	7×10^8	3.5×10^7	8.2×10^8	3.4×10^8	9.2×10^8	3.0×10^6
1 m	0	0	0	0	0	600
2 m	400	0	0	0	800	240,000
3 m	2600	400	600	600	16,000	380,000
15 min						
Control[a]	1.02×10^9	1.08×10^8	2.6×10^7	1.6×10^7	5.0×10^7	3.0×10^6
1 m	0	0	0	0	0	200
2 m	0	0	0	0	0	2200
3 m	800	0	200	200	400	140,000

[a] Control means bacteria or fungus growth on baseline agar plates which were left outside of the room without UV-C irradiation. MRSA: methicillin-resistant *Staphylococcus aureus*; MDRAB: multidrug-resistant *Acinetobacter baumanni*; MDRPA: multidrug-resistant *Pseudomonas aeruginosa* (MDRPA); VRE: vancomycin-resistant *Enterococcus faecium*; *M. abscessus*: *Mycobacterium abscessus*; *A. fumigatus*: *Aspergillus fumigatus*.

The impact of using this device in disinfection of patient rooms in hospital setting was also evaluated in three uncleaned rooms previously admitted by patients harbouring *MRSA, VRE* and other nosocomial pathogens with at least a 7-day hospitalization. Swabs cultures were collected and incubated for 24 and 48 hours from seven high-touch surfaces (e.g., bedside table, telephone

and bedrail) in each room before and after use of the Hyper Light P3 device (placed at three different location). The device was run for 5 min at each site (total 15 min). They reported that, a total of 20 high-touch surfaces were sampled. Most reduction rates of total bacteria colony counts sampled from different surfaces in three patients' room after UV-C irradiation were 100%, except that of bedrail, bedside table and telephone (ranging from 0% to 98%). There was significant reduction reported in the median number of total bacteria colony counts after UV-C irradiation of 15 min after 24 hours incubation (35 CFUs versus 0 CFUs, p =0.0005) and 48 h incubation (165 CFUs versus 0 CFUs, p < 0.0001) of the samples respectively (Table 2).[3]

Table 2: Analytical data and comparison of bacteria colony counts on different surfaces in three patients' rooms before and after UV-C irradiation with incubation for 24 and 48 hours.

UV-C irradiation	Incubation time (hours)	No. of samples	Median CFU (IQR)	Min	Max	P value
Before UV-C	24	20	35 (2.5–135)	0	1700	0.0005
After UV-C	24	20	0 (0)	0	90	
Before UV-C	48	20	165 (72.5–302.5)	0	4370	<0.0001
After UV-C	48	20	0 (0–27.5)	0	550	

No.: number; CFU: colony-forming units; IQR: interquartile range; Min: minimum; Max: maximum.

The authors concluded that the Hyper Light Disinfection Robot (model: Hyper Light P3) was effective in killing a number of multidrug-resistant bacteria, mycobacteria and fungi that are commonly encountered at hospital environment. A larger scale of clinical study is warranted to confirm its effectiveness as an adjunct to standard cleaning in reduction of nosocomial pathogens in healthcare settings.[3]

<u>UVC 254nm disinfection robot system</u>

There were several documents provided by the company which include the followings:

i. Nine laboratory test reports reported that UVC 254 disinfection robot system had antimicrobial activity up to >99.99% at 15 minutes of testing on *Aspergillus brasilensis*, *Escherichia Coli*, *Enterococcus feacalis*, *Klebsiella pneumonia*, *Pesudomonas aeruginosa*, *staphylococcus aureus*, *Clostridium difficile* and *Clostridium difficile (spores)*.[5]

ii. First efficacy study (a field exposure test) was conducted to evaluate the efficiency of UVC device (254 Disinfection Robot System) on *MRSA, VRE, E.Coli, P.Aeruginosa* and *C.difficile (spore)* at indicated time in 5ft and 9ft distance. The predicted exposure time to reach the germicidal efficiency was determined. They reported that, predicted exposure time (second) to reach the 4 $\log^{10}$, 5 $\log^{10}$ and 6 $\log^{10}$ reduction rate ranged from 22 to 409

seconds at 5ft and 29 to 472 seconds at 9ft. The *MRSA* had the shortest predicted exposure time while *P.aeruginosa* had the longest to reach the particular reduction.[6]

iii. Second efficacy study was conducted to produce data that provides basic information about UVC Light (254 UVC Disinfection Robot System) tested against *Influenza A (H1N1), Influenza B (Flu B)* and *Enterovirus 71 (EV 71)*. The study reported the viral titre reduction as presented in Table 3. However, the statistical significant difference among the result was not mentioned.[7]

Table 3: Mean reduction in viral titre

Virus	Treatment exposure (min)	Mean reduction in viral titre at distance	
		5 ft	9 ft
H1N1	5	1.699 $\log^{10}$	2.699 $\log^{10}$
Flu B	10	0.778 $\log^{10}$	1.778 $\log^{10}$
EV71	15	0 $\log^{10}$	0 $\log^{10}$

iv. Clinical trial done using (Hyperlight Model 1) at a hospital in Singapore reported that Log^{10} reduction at shorter distance were higher compared to the far one [After 15 minutes of treatment, at different distance (1.5 meter to 4.8 meter), log10 reduction for *MRSA* ranged from 4.2 to 1.8, *VRE* ranged from 3.8 to 1.1 and *Carbapenem-resistant Enterobacteriaceae* (*CRE*) ranged from 6.8 to 2.5 respectively]. Meanwhile, the log reduction for *MRSA*, *VRE* and *CRE* after 15 minutes of treatment at various place/ room in the hospital ranged from 0.3 $\log^{10}$ to 4.0 $\log^{10}$. The statistical significant difference of the results was not mentioned.[8]

v. The company also provided a pre-and post-intervention environment culture analysis for curtain in one ICU bed at Hospital Sungai Buloh. The report showed that, only *Paenibacillus pasadenensis* (10 CFU) detected before the intervention. There were no bacterial colonies isolated after 48 hours of incubation post-intervention. However, the information regarding study protocol and duration of exposure was not provided.[9]

UVC 254nm technology for surface disinfection

A Health Technology Assessment (HTA) report was conducted by Health Quality Ontario (2018) to evaluate the effectiveness and budget impact of portable ultraviolet (UV) light surface-disinfecting devices for reducing hospital-acquired infections (HAIs). They systematically searched for studies published from inception of UV disinfection. They compared portable UV surface-disinfecting devices used together with standard hospital room cleaning and disinfecting versus standard hospital cleaning and disinfecting alone. The assessment excluded wall mounted devices, which are used in some hospitals. Finally, they included seven studies on pulsed xenon and three studies on mercury UV-C based technology (one cluster-randomised crossover trial, one interrupted time series and one pre-and post-intervention). All of them used mercury UV-C at 254nm (TruD, Optimum UV and IRiS 3200m). Length of follow up for baseline period ranged from five to 24 months. The report found that mercury UV-C was associated with statistically significant reduction in the combined HAI and colonisation relative rate (two studies -1 RCT, 1 observational). However, there was no reduction in HAI and colonisation relative rates for *MRSA* (two studies) or *VRE* (two studies) and no reduction in *C. difficile* infection relative rate (two studies).[10]

A secondary analysis of a multicentre cluster randomised controlled trial (2018) was conducted to compare four different strategies for terminal room disinfection in nine hospitals [standard disinfection (quaternary ammonium disinfectant); standard disinfection plus UV-C; 10% hypochlorite bleach; and 10% hypochlorite bleach plus UV-C]. However, 10% hypochlorite bleach was used instead of quaternary ammonium for *C.difficile*. They reported that, there was no significant difference in the hospital-wide risk of target organism acquisition between standard disinfection and the three enhanced terminal disinfection strategies for all target multidrug-resistant organisms [standard plus UV study period relative risk (RR) was 0.89 (95% CI: 0.79,1.00); p=0.052; 10 % hypochlorite bleach study period RR was 0.92 (95% CI: 0.79,1.08); p=0.32; and 10 % hypochlorite bleach plus UV study period RR was 0.99 (95% CI: 0.89, 1.11); p=0.89]. However, there was slight reduction in *C. difficile* with standard disinfection plus UV-C [RR 0.89 (95% CI: 0.80, 0.99); p=0.031].[11]

Four pre- and post- intervention studies [(study period ranged up to 12 to 24 months; one did not specify study period), duration of UV-C exposure ranged from ten to 45 minutes, UV-C dose ranged from 12000µWs/cm^2 to 22000 µWs/cm^2 (two studies did not mentioned about dosage)] also reported statistically significant reduction in microbiological burden following the addition of UV-C 254nm devices (Skytron IPT UVC, Optimum UV system, UVC Ultra V system and Tru-D) to standard manual cleaning, compared with standard manual cleaning alone in hospital setting.[12-15] Ranggi R et al. (2018) reported that HAIs incidence was 19.2% lower than the pre-intervention

period (4.87 vs 3.94 per 1,000 patient days; p = 0.006). Pavia M et al. (2018) found that there was 44% reduction in overall viral infection incidence among paediatric patients [incidence rate ratio was 0.56; (95% CI: 0.37, 0.84); p=0.003]. The HAIs with UV-C was lower compared to without UV-C [50.3/10,000 patient days (95% CI: 41.0, 59.6) versus 82.0/10,000 patient days (95% CI: 72.5, 91.5) respectively]. Anderson DJ et al. (2013) reported that there was significant reduction in total no of CFU for *VRE* [$\log_{10}$ 2.85 before versus $\log_{10}$ 1.18 after (1.68 $\log_{10}$ reduction; p< 0.001)], and *C. difficile* [$\log_{10}$ 2.86 before versus $\log_{10}$ 1.70 after (1.16 $\log_{10}$ reduction; p<0.001)] but not for *Acinetobacter* [$\log_{10}$ 1.71 before versus $\log_{10}$ 0 after (1.71 $\log_{10}$ reduction, p=0.25)]. Nerandzic MM et al (2010) reported that disinfection of hospital rooms with Tru-D reduced the frequency of positive *MRSA* and *VRE* cultures by 93% and of *C. difficile* cultures by 80%.

UVGI for air disinfection

Previously, there were four Technology Review reports (2006, 2008, 2010 and 2013) conducted by Health Technology Assessment Section (MaHTAS), Medical Development Division, Ministry of Health Malaysia which were related to UVGI. The latest report concluded that there were few scientific evidence to support the effectiveness and safety of Sanuvox UVGI indoor air purifier systems. As for other air disinfectant using UVGI, the technology may have potential benefit for airborne pathogen irradiation; however, more research is warranted. Moreover, UVGI is feasible in its application and the adverse events can be avoided with proper precaution and maintenance. [16-19] Latest information brief conducted in 2016 concluded that there was limited evidence on the efficacy/effectiveness of UVGI for reduction of bacterial and fungal in healthcare setting. However, the evidence provided is not supported by a proper scientific write-up.[20]

International agencies such as US FDA and NEA Singapore produced guideline and policy related to surface disinfectant including the use of UVGI. US FDA Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) stated that disinfection using UVA and UVC device was intended to augment disinfection of health care environmental surfaces after manual cleaning has been performed. Therefore, they only used as an adjunct to currently existing reprocessing practices and not a replacement or modification to such practices.[21]

Meanwhile, National Environment Agency (NEA) Singapore Advisory on Surface Cleaning and Disinfection for COVID-19 stated that, the effectiveness of the UVC device depends on the duration of exposure, intensity, distance of surface from source. High touch area also may be missed if not facing the UV light device.[22]

COST-EFFECTIVENESS

There was no evidence retrieved on the cost-effectiveness. The price for Hyper Light Disinfection Robot (Model P3) is approximately RM 350k per unit. The amalgam bulb price is RM 4000 per unit and need to be changed every 12000 hours. (Information provided by company during product demonstration on 13 February 2020)

The Health Quality Ontario estimated the 5-year budget impact [in 2017 Canadian Dollars (CAD)] for a hospital with purchase of two portable mercury UV-C devices to be $634,255, equivalent to 2.102 million (based on Bank Negara Malaysia average exchange rate of 2017 CAD$1 to RM3.315). First-year cost (CAD$304,708 / RM1.01 million) was the highest due to purchasing cost of devices (cost of each device: CAD$124,517 / RM412,773) and staff/operating cost (CAD$55,675 / RM184,563). Cost in subsequent years was generated by maintenance and operation of devices (between CAD$55,675 / RM184,563 and CAD$82,387 / RM273,113 annually). Budget impact results were sensitive to the number of devices purchased by the hospital, frequency of daytime use, and staff time required per use.[10]

SAFETY

There was no evidence retrieve on the safety of Hyper Light Disinfection Robot (Model P3). However, it received CE mark (IEC 601010-1:2010/ IEC 61326-1:2012) and approval from Taiwan FDA.[14] UV disinfecting devices include UV radiation chamber disinfection devices, which are regulated as Class II devices.[21]They must only be executed by trained professionals, as exposure to UV can cause harm such as injury to the skin and eye.[22]

CONCLUSION

There was very limited evidence retrieved to suggest that Hyper Light Disinfection Robot was effective in reducing bacteria, viral and spore. However, the effect depends on the distance and duration of the exposure.

There was limited evidence on the effectiveness of UV-C 254nm for surface disinfection in reducing overall viral infection incidence among paediatric patients and reducing combined HAI and colonisation relative rate. However, it's effectiveness in reducing bacteria and spore such as methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistance Enterococcus (VRE) and Clostridium difficile, when used as an adjunct to standard manual cleaning and disinfection in

hospital setting was inconclusive. The safety profile could not be determined. Based on the budget impact analysis by Health Quality Ontario, the adoption of this technology may impose high cost implication.

Hence, more research is warranted for Hyper Light Disinfection Robot. The unit price of the device and maintenance cost should be taken into consideration.

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Based on available evidence up to 3rd July 2020.

Disclosure: The authors of this report has no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia.

Disclaimer: This rapid assessment was prepared to provide urgent evidence-based input during COVID-19 pandemic. The report is prepared based on information available at the time of research and a limited literature. It is not a definitive statement on the safety, effectiveness or cost effectiveness of the health technology covered. Additionally, other relevant scientific findings may have been reported since completion of this report.

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