

**Evaluation of effectiveness of Sterigen as
an agent for fumigation and surface
disinfection**

Aims & Objectives

1. To evaluate the efficacy of Sterigen solution as an agent for fumigation in tertiary healthcare (HC) facility.
2. To evaluate the efficacy of Sterigen solution as an agent for surface disinfection in HC facility.
3. To evaluate the cost effectiveness of Sterigen as compared to the currently used disinfectants for surface disinfection and fumigation in HC facility.

Materials & Methods

Type of Study: Prospective study

Duration: 45 Days

Place: Main OT Complex of a tertiary HC facility

Study Protocol

The disinfectant, Sterigen Solution was generated through the Sterigen Disinfectant Generation system¹ installed in the main OT complex, by technicians posted on-site by the company.

Sterigen is prepared on site on the principle of electrochemical activation of commercial electrolyte solution (Sterigen C) and normal tap water by sterigen equipment. The resultant solution consists of a mixed oxidant of hydroxyl anions, peroxide anions, and oxonium ions along with hypochlorous acid, which can kill all bacteria, viruses, fungi & spores in a short contact time of 5 minutes. This solution can also remove biofilms.

Procedure of generation of Sterigen solution¹

The Sterigen equipment is a wall mounted unit. It consists of following parts:

- 1) Hydroprep unit – It is connected to tap water supply. It reduces the total dissolved solids (TDS) in the water. This is needed since a TDS value above 200 will not allow the disinfectant to get activated. A high TDS also leads to erosion of the internal wall of the equipment.
- 2) Hydroprep water storage tank – It is used to store the water after it has undergone treatment to reduce the TDS.
- 3) Sterigen C tank – It is used for storage of sterigen C electrolyte solution.
- 4) Sterigen System – This is the disinfectant generation system. In this unit the treated tap water mixes with Sterigen C and undergoes electrochemical activation by proprietary Sterigen technology to generate the active disinfectant.
- 5) Sterigen Solution storage tank – This acts as the storage tank for the active disinfectant. The solution is dispensed in 5 liters can from this tank through a tap.

Undiluted Sterigen solution was used for fogging of the OT. The solution diluted with tap water in 1:3 dilution was used for surface disinfection of the following:

- OT Table
- OT Lamp
- Anesthesia Trolley

- Instrument Trolley
- Floor
- Wall

A batch number was given to each lot generated. The batch number along with the date of manufacturing and expiry was mentioned on the label of the container. The label also gave details about the use of product in various dilutions for surface disinfection and fumigation (See Appendix for the format of the label).

A. Fumigation Protocol

- Fumigation studies were carried out in OT no.4 and OT no.5 using undiluted sterigen solution.
- Blood agar (BA) air settle plates were exposed for 30 minutes at the end of all surgeries, in the evening in both the OTs to record the aerial microbial load.
- The OT was then fumigated with Sterigen Solution with fogger machine.
- After fumigation, the OT was kept closed for 45 minutes.
- Aerial microbial load was checked again by BA air settle plates were exposed to the OT atmosphere for duration of 30 minutes.
- Each BA plate was then sealed and sent to the Microbiology Dept. for further processing.
- The effectiveness of fumigation was also assessed by using battery operated air sampler with nutrient agar strips.

Procedure of Air Sampling

The air sampler consists of a propeller that pulls a known volume of air in the unit and then propels the air outward to impact on a tangentially placed nutrient agar (NA) strip. The nutrient agar medium is set on a flexible plastic base. Nutrient agar strips were commercially obtained.

The OT air was sampled, both pre and post-fumigation with sterigen solution for a period of 4 minutes. The NA strip were then aseptically removed from the sampler and sent to the Microbiology lab for further processing.

B. Surface Disinfection protocol

- At the end of the OT schedule for the day, prior to disinfection with sterigen solution, 2 surface contact swabs (one for aerobic and one for anaerobic culture) were collected from each of the following sites:
 1. OT Table
 2. Overhead OT lamp
 3. Anesthesia trolley
 4. Instrument trolley
 5. Floor beneath the table
 6. Walls
- A dilution of 1:1 of Sterigen solution was prepared using tap water.
- Critical surfaces such as OT table, OT lamp, anesthesia and instrument trolley were disinfected by using 1:1 dilution.
- Other surfaces such as OT floors, walls and the OT corridor were disinfected with a 1:3 diluted sterigen solution.
- Post-disinfection, 2 swabs each were again collected immediately from the above mentioned surfaces. The swabs were sent to the Microbiology Department for further processing.

C. Laboratory Follow-up

1) Air-settle plates

The BA plates were examined after 16 – 18 hours of incubation at 37⁰C.

- The number of colonies was counted.
- A colony count of 30 or less was interpreted as “within permissible limits”.²
- A colony count in excess of 30 was interpreted as “not within permissible limits.”²

- Any colony of suspected *Staphylococcus spp* was subjected to identification for *Staphylococcus aureus* by standard microbiological methods.³
 - Even a single colony of *Staphylococcus aureus* was interpreted as “not within permissible limits.”¹
- 2) Nutrient Agar strips were examined after 16 – 18 hours of incubation at 37⁰C
- The number of colonies on NA strips **were** counted.
- The result was then expressed in terms of CFU/M3/MIN by applying the following formula:
- $$\text{CFU/M3/MIN} = \frac{\text{Total number of colonies on NA strip} \times 25}{\text{Time of exposure in minutes}}$$
- 3) **Surface Contact Swabs** – processing
- Each swab collected from the OT surfaces was immediately processed for:
 - Aerobic bacterial culture – on blood agar plates
 - Anaerobic bacterial culture – in Robertson’s Cooked Meat medium.
 - The swab was reported as “no organism isolated” if there was no growth in any of the 2 cultures processed as above.
 - Growth, if any, was identified up to the species level by standard microbiological methods.³

D. Cost Comparison

The cost of Sterigen Solution was compared with the currently used disinfectants for surface cleaning and fumigation. The rate of disinfectants as mentioned in the rate contract book of 2012 –13 financial year of the hospital was taken into account.

Results & Observations

Aerial Fumigation

Pre and post fumigation sampling was done by 2 methods.

- 1) Air Sampler: Nutrient agar strips were used for sampling.
- 2) Air settle plates: Blood agar plates were used.

Table 1: Results OT 4 - Blood agar plate

SR. NO.	COLONY COUNT – PRE FUMIGATION	COLONY COUNT – POST FUMIGATION WITH STERIGEN SOLN
1	16*	0
2	13*	0
3	39	4
4	42	2
5	30	4
6	34	3
7	28	3
8	17*	0
9	42	4
10	19*	4
11	4*	0
12	12*	0
13	23*	2

Table 2: Results of OT 5 – Blood agar plate

SR. NO.	COLONY COUNT – PRE FUMIGATION	COLONY COUNT – POST FUMIGATION WITH STERIGEN SOLN
1	29*	5
2	26*	0
3	13*	0
4	13	0
5	27*	5
6	21	1
7	16*	2
8	18	0
9	3	0
10	7*	3
11	3	0
12	19*	2
13	4	1
14	20*	2
15	15*	7
16	3	0
17	11*	0
18	5	0
19	26*	1
20	3	1
21	25*	2
22	15*	3
23	12	0
24	38	1
25	44	2
26	20*	9

(* suspected colonies of *Staphylococcus aureus* subjected to standard microbiological methods for identification

Post-fumigation colony count showed statistically significant reduction compared to pre-fumigation colony count.

Staphylococcus aureus was not detected in any of the post-fumigation air settle plates.

Table 3: OT 4 – Nutrient agar strip

SR. NO.	COLONY COUNT* – PRE FUMIGATION	COLONY COUNT* – POST FUMIGATION WITH STERIGEN SOLN
1	100	0
2	244	25
3	187	25
4	119	25
5	25	0
6	37	0
7	25	0

(* Results expressed in CFU/M3/MIN)

Table 4: OT 5 – Nutrient agar strip

SR. NO.	COLONY COUNT* – PRE FUMIGATION	COLONY COUNT* – POST FUMIGATION WITH STERIGEN SOLN
1	81	0
2	81	0
3	131	6
4	19	0
5	19	0
6	119	12
7	25	6
8	Fungal growth**	0
9	19	0
10	19	6
11	94	19
12	75	0
13	62	19
14	175	56

(* Results expressed in CFU/M3/MIN)

(** Single colony of fungal growth is interpreted as “not within permissible limits”)

Surface Disinfection:

A total of 5 swabs each were collected from the below mentioned sites.

- A) OT table
- B) Overhead lamp
- C) Anesthesia trolley
- D) Instrument trolley
- E) Floor beneath the OT table
- F) Wall

Each swab was subjected to aerobic and anaerobic culture.

Table 3: OT 5: Results of aerobic bacterial culture

SR. NO.	SITE OF SWAB	PRE DISINFECTION	POST DISINFECTION WITH STERIGEN SOLN
1	OT Table	NOI	NOI
	Overhead Lamp	Growth Detected	NOI
	Anesthesia Trolley	NOI	NOI
	Instrument Trolley	NOI	NOI
	Floor	Growth Detected	NOI
	Wall	NOI	NOI
2	OT Table	Growth Detected	NOI
	Overhead Lamp	Growth Detected	NOI
	Anesthesia Trolley	Growth Detected	NOI
	Instrument Trolley	Growth Detected	NOI
	Floor	Growth Detected	NOI
	Wall	NOI	NOI
3	OT Table	Growth Detected	NOI
	Overhead Lamp	NOI	NOI
	Anesthesia Trolley	Growth Detected	NOI
	Instrument Trolley	Growth Detected	NOI
	Floor	Growth Detected	NOI
	Wall	NOI	NOI
4	OT Table	Growth Detected	NOI
	Overhead Lamp	Growth Detected	NOI
	Anesthesia Trolley	NOI	NOI
	Instrument Trolley	NOI	NOI
	Floor	Growth Detected	NOI
	Wall	NOI	NOI

Table 3: OT 5: Results of aerobic bacterial culture contd.			
Sr.No.	Site of swab.	Pre Disinfection.	Post Disinfection
5	OT Table	Growth Detected	NOI
	Overhead Lamp	NOI	NOI
	Anesthesia Trolley	Growth Detected	NOI
	Instrument Trolley	NOI	NOI
	Floor	Growth Detected	NOI
	Wall	Growth Detected	NOI
6	OT Table	NOI	NOI
	Overhead Lamp	NOI	NOI
	Anesthesia Trolley	Growth Detected	NOI
	Instrument Trolley	Growth Detected	NOI
	Floor	Growth Detected	NOI
	Wall	NOI	NOI
7	OT Table	Growth Detected	NOI
	Overhead Lamp	NOI	NOI
	Anesthesia Trolley	Growth Detected	NOI
	Instrument Trolley	NOI	NOI
	Floor	Growth Detected	NOI
	Wall	Growth Detected	NOI
8	OT Table	Growth Detected	NOI
	Overhead Lamp	Growth Detected	NOI
	Anesthesia Trolley	Growth Detected	NOI
	Instrument Trolley	Growth Detected	NOI
	Floor	Growth Detected	NOI
	Wall	Growth Detected	NOI
9	OT Table	Growth Detected	NOI
	Overhead Lamp	Growth Detected	NOI
	Anesthesia Trolley	NOI	NOI
	Instrument Trolley	NOI	NOI
	Floor	Growth Detected	NOI
	Wall	Growth Detected	NOI
10	OT Table	Growth Detected	NOI
	Overhead Lamp	Growth Detected	NOI
	Anesthesia Trolley	NOI	NOI
	Instrument Trolley	Growth Detected	NOI
	Floor	NOI	NOI
	Wall	Growth Detected	NOI

(NOI – No Organism Isolated)

No anaerobes were isolated in pre and post disinfection swabs.

Cost Comparison:

The main OT complex, which consists of 5 OTs, uses the following agents:

1) Formaldehyde:

Formaldehyde (35 – 37 %) is used for fumigation of the OTs.

2) Potassium Permanganate (KMNO₄)

KMNO₄ is used for mixing with formaldehyde **for manual fumigation** i.e. when OT care machine is not used for fumigation.

3) Sodium hypochlorite (4 – 6 %)

Sodium hypochlorite, diluted to 1%, is used for surface disinfection for various OT surfaces such as OT table, anesthesia and instrument trolleys, overhead lamps etc. Undiluted hypochlorite (5 %) is used for managing spillages.

4) Saniquad P (Benzalkonium chloride – 20 %)

The agent is used for surface decontamination of floors, tiled walls and toilets. It is diluted to 4 % for this purpose.

Table 4: Monthly consumption & cost of currently used disinfectants

SR. NO.	PRODUCT	UNIT	APPROX MONTHLY QUANTITY	APPROX MONTHLY CONSUMPTION	COST PER UNIT IN RS	AMOUNT IN RS
1	Formalin	450 ml	24	10.8 lit	48.00	1152.00
2	KMNO ₄	400 gm	05	2 Kg	180.00	900.00
3	Sodium hypochlorite	5 lit	13	65 lit	625.00	8125.00
4	Saniquad P	500 ml	10	5 lit	97.00	970.00
	Total			82.8		11,147.00

The overall cost per litre for all the above disinfectants was observed to be Rs.134.62

During the study period 8 litres of Sterigen C solution was used for fumigation of the 5 OTs and surface disinfection of all the surfaces in the main OT complex. Since the closure time with sterigen is 45 minutes, it was used for fumigation on a daily basis in the main OT complex. Fumigation with formalin was routinely done only once a week. From 8 liters of Sterigen C Solution, 240 litres of undiluted sterigen solution was generated, which was then available for use, both in undiluted form (for fumigation) and in diluted form (for surface disinfection of non-critical areas in the ratio of 1:3 and for disinfection of critical surfaces in the ratio of 1:1).

Table 5: Monthly consumption & cost of sterigen solution

Sr. No.	Product	Unit	Quantity of Sterigen C used in 45 days	Sterigen solution generated in 45 days	Cost per unit of Sterigen C in Rs.	Amount in Rs.
1	Sterigen Solution	concentrate	8 lit	240 lit (generated from 8 lit Sterigen C)	1250.00	10,000.00
Total				240		10,000.00

(The Sterigen Solution generated was used in all OT's for Surface Disinfection during the trial period.)

The cost per litre for sterigen solution was observed to be Rs. 41.66. Saving behind 1 litre of disinfectant used was found to be Rs. 92.96

The average monthly consumption of 82.8 litres of all the currently used disinfectants.

The approx. monthly saving was found to be Rs. 7697.08.

Discussion

Fumigation

Fumigation with sterigen solution was carried out in the main OT complex by using a fogging machine. Air settle plates were exposed for 30 minutes before and after fumigation with sterigen solution in OT 4 and OT 5.

A marked reduction in colony count was observed post fumigation with sterigen solution in both the OTs. The post-fumigation results with sterigen solution were “within permissible limits”.

Similar results were also obtained with nutrient agar strips with post-fumigation sampling with air sampler showing a marked reduction in the colony count compared to pre-fumigation air sampling.

No growth of *Staphylococcus aureus* was detected after fumigation with sterigen solution. Comparatively, *Staphylococcus aureus* was detected in 7 instances in pre-fumigation air settle plates. Thus sterigen solution was observed to be effective in eliminating *Staphylococcus aureus* in addition to reducing the overall colony count as well.

The OT closure time with fumigation by sterigen solution is only 45 min compared to overnight closure with formalin. Thus fumigation can be done more frequently with sterigen solution, which can ensure a better OT environment for more number of cases as compared to fumigation by formalin.

Surface Disinfection

Sterigen solution was used for surface disinfection of critical (1:1) and non-critical surfaces (1:3) in the OT complex. Post surface disinfection, no bacterial growth was observed, in aerobic and anaerobic culture. Thus sterigen solution was observed to be equally effective as an agent of surface disinfection.

Sterigen solution was used for surface disinfection in the entire OT complex in dilutions of 1:1 and 1:3 during the study period. Sterigen solution, in undiluted form was used for fumigation. In contrast, currently used disinfectants in the OT include formalin (for fumigation along with potassium permanganate, when required), sodium hypochlorite (for disinfection of critical surfaces) and benzalkonium chloride (for disinfection of non-critical surfaces). The sterigen solution can thus be used as a multipurpose agent and reduce the amount of inventory of consumables to be maintained in the OT.

It should also be noted that chemicals like Formalin and sodium hypochlorite have acute and chronic toxicity associated with them and can cause respiratory tract, mucous membrane and skin damage to the healthcare worker. On the other hand Sterigen solution has no toxicity associated with it.

Cost Comparison

The average monthly expenses for the currently used disinfectants was Rs. 11, 147.00. Comparatively, the average monthly expense for sterigen solution was observed to be Rs. 10,000.00.

The overall cost per liter for all the currently used disinfectants was observed to be Rs.134.62. The cost per liter for sterigen solution was observed to be Rs. 41.66. Thus it was observed that there was saving of Rs. 92.96 behind each litre of sterigen solution used. This meant that there was a 69 % reduction in the average monthly expenses with use of sterigen solution.

The cost of the Sterigen equipment is approximately Rs. 9 lacs. Being a short duration study, the cost of maintenance could not be considered. Similarly the cost of man-power which would be involved in operating the equipment needs to be taken into account when applied on a larger scale.

In addition, the responsibility of production of sterigen solution by the hospital staff needs to be taken into account. The currently used disinfectants are available as “ready to use” preparations. This also brings in the issue of certification of quality of the disinfectant, which would then be the responsibility of the hospital staff. This is not the case with currently used disinfectants.

Summary & Conclusion

Sterigen solution is a mixture of oxidants of hydroxyl anions, peroxide anions, and oxonium ions along with hypochlorous acid, which can kill all bacteria, viruses, fungi & spores in a contact time of 5 minutes.

The present study was carried out in the main OT complex of Sir J J Group of Hospitals to assess the efficacy of sterigen solution for fumigation and surface disinfection. The cost of sterigen solution compared to the currently used agents of fumigation and surface disinfection was also evaluated.

Overall, fumigation with sterigen solution was found to be efficacious in reducing aerial bacterial counts of the OT room. It also inhibited growth of staphylococcus aureus. Sterigen solution was also found to be an effective agent for surface disinfection eliminating aerobic bacteria following application on surfaces.

Sterigen solution, when compared with currently used disinfectants, was found to be cost-effective with 69 % reduction in the cost of monthly consumption of disinfectants.

To conclude, sterigen solution was found to be effective as an agent of fumigation and disinfection.

However its cost-effectiveness will depend upon capital investment for machine and its maintenance. Also, another important issue of regulatory compliance and responsibility of disinfectant production etc. needs to be taken into consideration before any final decision is taken in this regard.

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