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Short report

A survey to quantify wet loads after steam sterilization processes in healthcare facilities

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SUMMARY

Wet loads after steam sterilization of medical devices in healthcare facilities are unacceptable. However, little is known about their frequency in daily practice. An online survey was distributed via four national sterilization associations, in Australia (Sterilising Research Advisory Council of Australia (Vic), Inc. (VIC SRACA)), Belgium (Vereniging sterilisatie in het ziekenhuis (VSZ)), Italy (Associazione Italiana Operatori Sanitari addetti alla Sterilizzazione – Società Scientifica (AIOS)), and The Netherlands (Vereniging van Deskundigen Steriele Medische Hulpmiddelen (VDSMH)). Seventy-eight percent of 125 hospital sterilization facilities recognized wet loads, occurring at frequencies ranging from monthly to every load. Usually, wet loads were identified by the presence of water droplets; these loads were repacked and resterilized. Given the pervasiveness of wet loads, and their impact on reprocessing times and costs, strategies to reduce their frequency are needed.

Introduction

Steam sterilization is the most applied sterilization method to sterilize reusable medical devices in healthcare facilities [1]. According to standards for steam sterilization, loads should be dry after a sterilization process [2]. These standards define testing for 'dry' and 'wet', but they do not explicitly specify wet loads. More precisely, the clauses in

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standards contain phrases that refer to the process and a specific load configuration, e.g. 'The load dryness test, full load, textiles, is used to demonstrate that the operating cycle will not cause an unacceptable level of moisture to be absorbed by a standard test pack located in a full load of textiles' [3]. Furthermore, Annex G of EN 868-8 provides a methodology for a load dryness test of containers based on the weight increase due to condensate after steam sterilization processing [4]. This weight increase should not exceed 0.2% for metal loads and 1% for textile loads (with respect to the 'dry' weight). However, checking the weight of each pack before and after processing is impractical in everyday production and provides no information on the condensate distribution within the pack.

Generally, it is argued that wet loads are not acceptable because a wet wrapping, packing, or filter in a container would not act as a microbiological barrier, creating the possibility for recontamination. For instance, Perkins already stated that a wet textile pack is a significant hazard because of microbial migration [5]. It is currently assumed also that other microbiological barriers are not effective when they are wet [6,7]. However, in the literature this is explicitly stated only for surgical gowns and drapes made of carded cotton [8]. Data on synthetic materials typically used in steam sterilization processes are not available. Possibly, the issue of wet loads is just a dogma or 'myth', like various other steam sterilization myths [9,10].

Although specific examples of wet loads have been reported, information on the numbers and frequencies of wet loads is not available [11,12]. Consequently, it is difficult, if not impossible, to judge whether wet loads are an issue that should be addressed in a more fundamental way. Possibly, wet loads are incidental and only an issue for a specific combination of sterilizer, process, load, loading pattern and wrapping/packing. Therefore, it was decided to perform a short survey to obtain an indication of how often wet loads occur in the daily practice of steam sterilization of medical devices.

Methods

A short set of questions on wet loads was composed. Facilities in various countries were invited to complete the survey via their state or national sterilization associations: Australia (Sterilising Research Advisory Council of Australia (Vic) Inc. (VIC SRACA)), Belgium (Vereniging sterilisatie in het ziekenhuis (VSZ)), Italy (Associazione Italiana Operatori Sanitari addetti alla Sterilizzazione — Società Scientifica (AIOS)), and The Netherlands (Vereniging van Deskundigen Steriele Medische Hulpmiddelen (VDSMH)). The online survey could be completed anonymously. Information from the survey was non-attributable to a facility or individual person. The survey questions (together with the results) are presented in Table I.

Results

Overall, 125 facilities in four countries responded to the survey (Q1). In total 210 responses were received from 125 facilities. The total number of sterilizers involved was 458. In the facilities, on average 3.7 sterilizers are present (Q2).

The most frequently used definition for a wet load was 'any droplet on pack' (31%), followed by 'some droplets in pack' (18%); together these add up to 49% of responses. Overall, 78% of the participating facilities considered the presence of water droplets a qualifier for a 'wet load'. The remaining facilities defined wet loads as a 'puddle of water in or on pack' (Q3).

There was a wide range in the reported frequency of wet loads (Q4). The most common answer was once a month (47%); only 22% of the facilities reported that they did not encounter wet loads at all. In general, wet loads were randomly distributed across the sterilizers within a facility (Q5), and within a specific sterilizer (Q7). Wet loads often correlated with 'heavy trays' and 'trays with plastics' (Q6).

None of the participating facilities used cotton as wrapping material and microbiological barrier [6,7]. Most wet loads are observed with non-woven wrapping systems (76%). The results for pouches and containers are comparable, 22% and 20%, respectively. If we only consider the 103 facilities experiencing wet loads, the responses show that 60% of the wet loads are associated with the use of MSM, SMS or MMS. The results for containers and pouches are again in the same range, 30% and 27%, respectively (Q8 and Q9).

Most of the facilities (87%) implemented strategies to prevent wet loads, ranging from placing tray-liners in the tray and splitting heavy trays (both about 48%) to, for example, using cotton tissue within or outside the pack (4%). Some facilities applied more than one strategy to prevent wet loads (Q10).

Wet loads were most frequently observed after 134°C processes (Q11). If a wet load was identified, the majority of the facilities (62%) reported that the load was repacked and resterilized (Q12).

Discussion

Although a common definition of a wet load does not exist, the presence of water droplets appears to be a key point in identifying wet loads. Possibly the subjective definition 'some droplets in or on a load' might be an acceptable definition for wet loads. However, it might be preferable to develop a more objective definition. In this respect one should note that none of the respondents to the survey reported using a quantitative method to identify a wet load.

The present survey, involving 125 facilities in four countries, found that 78% of facilities actually observed wet loads. However, in practice not every load can be checked for the presence of 'any' droplets in or on that load. Therefore, wet loads may occur more frequently than the rate reported. Most occurrences of wet loads seem to be related to heavy loads. In these situations, the issue can be reduced or even resolved, for example, by dividing heavy trays in more (lighter) trays. Preferably, specific attention should be given to heavy loads when loading protocols for steam sterilizers are developed or revised.

It appears that wrapping with MSM, SMS, and MMS often gives rise to wet loads. MSM, SMS, and MMS are artificial products that do not absorb moisture. The 'S' in the name of the material stands for 'spun-blown' and the 'M' for 'melt-blown'. These characters refer to the manufacturing method of a specific layer in the wrapping. For instance, MSM wrapping sheets consist of three layers, of which the first and third layer are melt-blown and the second layer is spun-blown.

Table I
Questions 1–12 of the 'wet load survey' and responses

Question 1: In which country is your facility?	$N = 125$
Australia	13 (10%)
Belgium	41 (33%)
Italy	42 (34%)
Netherlands	29 (23%)
Question 2: How many steam sterilizer(s) do you have in your sterilization department?	$N = 125$
1 sterilizer	6
2 sterilizers	27
3 sterilizers	36
4 sterilizers	23
5 sterilizers	19
6 sterilizers	5
7 sterilizers	3
8 sterilizers	4
9 sterilizers	0
10 sterilizers	2
Question 3: How do you define wet load?	$N = 210$
Any droplet on pack	31
Some droplets on pack	16
Puddle of water pack	10
Any droplet in pack	13
Some droplets in pack	18
Puddle of water in pack	8
Other	4
Question 4: How often do you have wet load in your sterilizer(s)? (One respondent did not answer this question.)	$N = 125$
We only have one steam sterilizer	5 (4%)
One specific sterilizer	9 (7%)
Two specific sterilizers	3 (2%)
Three specific sterilizers	2 (2%)
Random over our sterilizers	84 (67%)
Not applicable (all our loads and trays are dry)	22 (18%)
Question 5: If you have more than one steam sterilizer, the wet loads occur the most in: […].	$N = 125$
We only have one steam sterilizer	5 (4%)
One specific sterilizer	9 (7%)
Two specific sterilizers	3 (2%)
Three specific sterilizers	2 (2%)
Random over our sterilizers	84 (67%)
Not applicable (all our loads and trays are dry)	22 (18%)
Question 6. Are there specific loads that are wet?	$N = 182$
Wet type loads per facility:	
Heavy trays	71
Trays with plastic material	39
Trays with hollow instruments	10
Trays with plastic fixation material, such as mats	20
Not applicable (all our loads and trays are dry)	25
Other	17
Question 7: Is the 'wet' load located at the same place (location in the load)?	$N = 165$
Not applicable	15 (9%)
Random	55 (33%)
Always the same tray(s)	3 (2%)
Heavy trays	21 (13%)
Tray below heavy trays	7 (4%)
Tray at the lowest loading level	12 (11%)
Tray at the top loading level	9 (6%)
At the (un)loading level	10 (7%)
Not applicable (all our loads and trays are dry)	15 (12%)
Other	4 (3%)

(*continued on next page*)

Table I (*continued*)

Question 8: What sterile barrier (wrapping) method is used in your facility?	$N = 215$
Cotton	0
Crepe	11 (5%)
Non-woven wrapping, material such as SMS	95 (44%)
Pouches	47 (22%)
Containers	52 (24%)
Not applicable (all our loads and trays are dry)	7 (3%)
Other	3 (2%)
Question 9: Is a wet load related to a specific sterile barrier (wrapping)?	$N = 163$
No. of occurrences:	
Cotton	0
Crepe	5
MSM, SMS, MMS	62
Pouches	28
Containers	31
Not applicable	25
Other	12
Question 10: Do you take measures against wet loads?	$N = 173$
No 'extra' measures	16 (9%)
Tray-liners in the tray	60 (35%)
Cotton layers in the tray	4 (2%)
Textile clothing under the tray	6 (3%)
Dividing heavy trays in more (lighter) trays	61 (35%)
Textile clothing over the trays (petti-coating)	1 (1%)
Other	25 (14%)
Question 11: Are wet loads recognized in the same process?	$N = 130$
Not applicable	23 (18%)
Always 134°C process	78 (60%)
Always 121°C process	5 (4%)
Always 'short' (so-called 'flash') processes	1 (1%)
Not applicable (all our loads and trays are dry)	16 (12%)
Other	7 (5%)
Question 12: How do you handle wet loads?	$N = 125$
Not applicable	16 (13%)
Dry with sterile tissue	0
Repack and resterilize the load	78 (62%)
Repeat the full decontamination cycle (washing, disinfection, six sterilisations)	11 (9%)
Drying in an environment without controlled contamination, e.g. sterile storage	3 (2%)
Drying in warm open steam sterilizer	8 (6%)
No additional action	1 (1%)
Drying in an environment with 'known' possible contamination, e.g. the wrapping area or before the loading door	1 (1%)
Other	8 (6%)

From the survey one might deduce that the use of absorbing materials such as tray-liners reduces the frequency of occurrence of wet loads. Possibly, the condensate (water) is absorbed by these materials, preventing the appearance of visible droplets. However, it is not clear whether absorbing the condensate and retaining the moisture inside the absorbing material solves the issues related to wet loads. Entrapped water can also affect the storage conditions, exposing instruments inside the pack to humidity levels higher than the recommended levels [13,14]. A humid environment in the pack can have negative consequences from both a microbiological and corrosion point of view.

Most wet loads appear in 134°C processes. This might simply reflect the fact that most facilities operate 134°C processes, which increases the probability that a wet load is observed for such a process. An alternative explanation could be that at a higher temperature (134°C compared to 121°C) more condensate will be formed. More precisely, the amount of energy needed to warm up a medical device (md) in a steam sterilization process depends on the temperature difference (ΔT_{md}) between the start of a process and the sterilization temperature ($Q_{md} = m_{md}c_{md}T_{md}$), with Q_{md} the amount of energy (J) needed to warm up the medical device, m_{md} and c_{md} the mass (kg), and c the specific heat (J/(kg K)) of the medical device, respectively). In case of a larger ΔT, more energy is needed. In a steam sterilization process the energy is provided by steam. The energy is transferred to the medical device by condensation of steam on the surfaces of this device. Consequently, more condensate will be formed if ΔT is larger.

In a steam sterilization process, condensation and evaporation can be considered as reversible processes. The amount of energy transferred to the medical devices is sufficient to

evaporate the condensate on these devices during the drying phase. If, after the process, part of the condensate is no longer in thermal contact with the medical devices, some condensate will remain and the temperature of the devices will still be high. If this is the case, the wet loads are caused by an inadequate loading system or procedure. The loading procedure and method should be revised in such a way that the formed condensate will remain in thermal contact with the medical devices.

About 13% of the facilities reported not taking any precautions to prevent wet loads. These facilities may have used integrated strategies that are no longer recognized as specific precautions to prevent wet loads. Examples are well-developed loading procedures or the use of absorbent material for packing or reducing damage to the medical devices (tray-liners).

In conclusion, this survey demonstrates that in most (if not all) steam sterilizers, 'wet loads' occur. Considering the economic and organizational impact on handling times and costs, it may be worthwhile to investigate which modifications of the process, wrapping, or loading pattern, effectively reduce the frequency of occurrence of such loads.

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