

The Secrets in the Steam

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Abstract: Introduction: There are several components in motion before steam reaches its destination. Each element plays a significant role in generating adequate steam for terminal sterilization of critical devices. The knowledge and awareness of factors that contribute to wet packs will assist in maximizing steam quality. Steam sterilization of critical devices such as surgical instruments in the acute care setting is fundamentally necessary to prevent infection. Sterile packaging that is wet after removal from the autoclave is considered contaminated. This wet pack presents a significant infection risk and indicates a defect in the sterilization process. The identification of wet packs prompted the exploration of the sterilization process. In reviewing the evolution of steam production, our investigation began in the boiler room. The assessments of the boiler operations, steam quality, and loading technique of the autoclaves were examined as possible contributing factors in the propagation of wet packs. Methods: The investigation was performed in a 592-bed non-teaching acute care facility in New Jersey. Methods to ensure the integrity of steam included; a cut point of < 3,500 ppm TDSs (total dissolved solids), (daily) calibration of the TDS analyzer to ensure accurate TDS measurement, increase in autoclave drying times, reduction of the weight density of surgical trays from 25 lbs. to 20 lbs., and revision of sterilization loading practices. Modifications were implemented from June 2015 to December 2015. Results: No wet packs were identified from January through May 2016. In June 2016, 2 wet packs were detected, and upon further analysis there was an increase in the water level of the boiler drum. After this special cause variation, no wet packs have been identified. Conclusion: The monitoring and documentation of boiler room parameters and CSP (central sterile processing) practice modifications may have impacted the reduction of wet pack.

Key words: Wet pack, wet steam, steam sterilization, boiler operations.

1. Introduction

Steam sterilization is widely used in healthcare facilities to render surgical devices or instruments free of microbial life. Steam quality is an important component to ensure proper sterilization. Steam sterilization is a method of decontaminating surgical instruments by exposing the objects to saturated steam in an autoclave machine eliminating all microorganisms [1]. Autoclaves generate high pressure and high temperature steam that circulates and penetrates perioperative containment devices to sterilize the instruments. “Saturated steam is at equilibrium with heated water at the same pressure, which means it contains the maximum amount of moisture without liquid condensate present” [2].

The observation of water remaining on or in a sterilized package from an autoclave or instrument pack is an infection risk. This is commonly referred to as a “wet pack.” During sterilization, the wetness in the steam clogs the pores of packed loads and prevents the steam from properly penetrating wrapped loads or sealed pouches [3]. Packaging is designed to maintain sterility and if critical instruments are wet, there is a potential for microorganisms to compromise the pack.

The type of steam that is required for steam sterilization is saturated steam. “Saturated steam has 3 to 5% of water and this moisture helps to destroy microorganisms at a lower temperature when compared to dry heat” [4]. “Wet steam”, also considered supersaturated steam, is a mixture of steam and liquid water and contains more than 5% water [5]. Supersaturated steam is inadequate in eliminating microbes due to the reduced heat transfer ability of the steam yielding a sterilization failure.

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2. Factors That Contribute to Wet Packs

TDSs (total dissolved solids) comprise inorganic salts (principally calcium, magnesium, potassium, sodium, bicarbonates, chlorides, and sulfates) and small amounts of organic matter that is dissolved in water is commonly found in boiler feed water [6]. Due to the amassing TDS in the boiler water, the steam bubbles formed are more stable, failing to pop when they reach the water surface.

Consequently, more bubbles are generated propagating foam giving rise to water carryover in the steam pipes (wet steam) leading to the autoclaves.

Excessive TDS impurities will contribute to the scale buildup in the boiler drum that has the potential to erode the steam pipework and hinder the ability of heat transfer. In addition, elevated TDS levels will impact control valves, heat exchangers, steam traps and turbines. Controlling the TDS levels is crucial in the production of high quality steam.

To prevent TDS levels from accumulating, the boiler operators measure the dissolved solids using gravimetric analysis. Precipitation gravimetry is a technique that uses a precipitation reaction to separate ions from a solution [7]. A normal TDS level range is between 2,000-3,500 ppm. If the TDS level is > 3,500 ppm, a continuous or intermittent blow down should be performed. Blow down is a control method where water is being removed from the boiler to purge excessive dissolved solids resulting in properly maintained water quality.

A high water level in the boiler drum leads to water carryover which could result in wet steam. The elevated water level decreases the water surface area not permitting steam to be released, resulting in carryover of water droplets through the steam header leading to wet steam. Ancillary pipelines such as steam traps facilitate the release of condensate promoting high quality steam. Steam traps are valves that open to discharge water buildup as well as air and other noncondensable gases from boiler feed water in the pipe system and close in the presence of steam.

“When condensate, air and noncondensable gases are removed as soon as they are formed, the steam has more surface on which to transfer heat energy” promoting more efficient steam for steam sterilization [8].

Malfunctioning steam traps allow condensate to pool in low areas in the piping system subsequently blocking steam passage squandering energy thereby reducing the integrity of the steam. The effectiveness of the steam traps is dependent on regular maintenance of the valves. A contaminated steam trap is the most common cause of a mechanical defect. Other causes of steam trap failures include pressure surges from defective pressure reducing valves and improper sizing and location of piping. In conjunction with competent steam traps, insulation of steam transport piping is another strategy in preventing heat loss securing quality steam to the autoclave.

Other considerations that can contribute to wet packs are the metal mass and loading configuration of the containment device into the autoclave. ANSI/AAMI (American National Standard/Association for Advancement of Medical Instrumentation) recommends that surgical instrument trays should not exceed 25 lbs due to the potential of compromising the sterilization process [9]. A containment device or instrument tray with a large amount of metal mass requires a longer time to dry due to the pooling of condensation around the solid devices resulting in wet packs [10].

The proper loading of the autoclave is a crucial practice to mitigate condensation during sterilization. For instance, placing a heavy orthopedic tray that has the potential to produce substantial amount of condensation will leak on the porous wrapped container on the lower level of the loading cart yielding a wet pack [11]. Placing heavier containment devices on the bottom of the autoclave loading cart is beneficial in reducing water condensation. Overcrowding of the autoclave will amplify the formation of condensation and interfere with the

re-evaporation of the excessive condensate [11]. Improper loading practices are obstacles for steam to effectively circulate in the sterilizer. Appropriate loading practices and controlling the weight and density of containment devices or surgical trays promote effective, safe sterilized devices to be utilized in the perioperative arena.

There are several components in motion before steam reaches its destination. Each element plays a significant role in generating adequate steam for terminal sterilization of critical devices. The knowledge and awareness of factors that contribute to wet packs will assist in maximizing steam quality.

3. Methods

After the identification of a wet pack, the OR (operating room) staff notified the Infection Prevention Department. The investigation was performed in a 592-bed non-teaching acute care facility in New Jersey from June 2015 to December 2015. The objective was to compare the incidence of wet packs before and after implementing process changes in the boiler room as well as in CSP (central sterile processing). The IPs (Infection Preventionists) and the CSP supervisor completed a retrospective analysis of the sterilization parameters. The assessment included the time of day, surgical tray type plus the weight, specific autoclave, position of tray on the loading cart and location of the identified wetness. The loading and weight distribution of the containment devices, instrument trays as well as other items placed on the loading cart relative to the autoclave chamber drain were reviewed.

In June of 2015, our initial measures in CSP comprised of increasing the drying time of the autoclaves from 35 minutes to 45 minutes. The new loading practice established an open “donut hole” configuration to support drainage of condensate and

prohibit overcrowding of the autoclave. The CSP staff was educated on the new alternative loading technique by the CSP supervisor.

As depicted in Table 1, the facility continued to encounter wet packs regardless of the interventions performed in CSP. This compelled the IPs to expand their scope of investigation to the beginning of the steam production process. The investigation of the boiler room included an evaluation of the TDS levels, temperature and level of water in the boiler drum as well as the assessment of the function and location of steam traps. Upon initial assessment, the TDS levels exceeded 5,000 ppm. After discussion with the Boiler Engineer and Plant Operations team, the goal for the TDS level was changed to < 3,500 ppm. The meticulous documentation of the TDS levels was noted three times a day in a log book completed by the boiler engineer. In collaboration with the IPs, the log book documentation was enhanced to include the appropriate action taken when the TDS levels exceeded 3,500 ppm. TDS levels could not be accurately validated, as the measuring device was not calibrated daily. The boiler room engineers integrated the daily calibration of the measuring device prior to measuring the TDS levels.

In 2015, additional wet packs were discovered which precipitated new filter installation in the autoclaves. Plant operation staff insulated 20 feet of steam pipe, repaired broken steam trap, added two supplementary steam traps to prevent water carry over. Collectively, the boiler room engineers and Plant Operations team instituted a continuous blowdown to reduce TDS in the boiler feed water. Furthermore, the sterilizer manufacturer removed the flex tubing in the autoclave feed and created a manifold to be congruent with their recommendations to reach optimal steam quality of 97%.

Table 1 Summary of wet packs in 2015-2016.

	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sept.	Oct.	Nov.	Dec.	Total
2015 # of wet packs	0	2	1	ND*	ND*	ND*	3	1	2	0	0	1	10
2016 # of wet packs	0	0	0	0	0	2	0	0	0	0	0	0	2

* Not documented.

The IPs engaged in active surveillance of the newly implemented process changes in the boiler room and CSP. The CSP supervisor collected data on process changes and reported during the Infection Control Committee meetings. All aforementioned departments were in daily communication during the quality improvements.

4. Results

At the end of 2015, 10 wet packs were identified. From January to May 2016, no wet packs were detected after implementation of numerous action plans. This reflects 80% reduction in the incidence of wet packs. In June 2016, 2 wet packs were discovered by the OR staff. The IPs reexamined all the sterilizer and boiler parameters to reveal an increase in the water level in the boiler drum. After this special cause variation, no further wet packs were identified in 2016.

5. Discussion

This investigation demonstrates that interventions focused on best practices in CSP and the boiler room can reduce the incidence of wet packs. Our data indicate a collaborative approach between CSP and plant operations, coordinated by IPs is an effective method in generating a safe perioperative environment. Each department involved utilized their expertise in managing and mitigating wet packs. Wet packs place a financial burden on the healthcare system as well potentially impacting the mortality of the perioperative patient.

The aggregated literature discussing sterilization process failures is comprised of multimodal strategies involving steam quality, operator proficiency, and loading practices of the autoclave. CSP staff should be competent in performing steam sterilization and comfortable in voicing a lapse in infection prevention practices. The analysis revealed everyone plays a crucial role in patient safety in the healthcare setting. The active interplay between departments supported by shared goals yielded a successful outcome.

6. Conclusion

Steam sterilization is imperative to the safety of the perioperative patient. Maintaining an effective sterilization process involves a multidisciplinary team appointed with the science of steam production to ensure a sterilized end product. Interventions designed to reduce wet packs together with proper boiler operations and maintenance contribute to an improved infection prevention outcome.

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