

ECG Electrodes: Single use and nothing else

Nazarena Mazzaro, PhD - Director Corporate Clinical Research and Biosafety - Ambu A/S

THE PROBLEM ...

The World Health Organization reported in 2002 that the problem of nosocomial-acquired infection affects 1.4 million people worldwide. Annually, in the United Kingdom approximately 5,000 patients die, and 15,000 more are substantially affected by healthcare-acquired infection [1]. For the British National Health Service, the cost of nosocomial infections is approximately £1 billion per year. In 2000, 380,000 bed days were lost due to delayed discharges and ward closures due to healthcare-acquired infections [2].

Bacteria cause the majority of healthcare-acquired infections. In general, any moist site in the hospital environment provides a potential site for the survival and multiplication of bacteria [3].

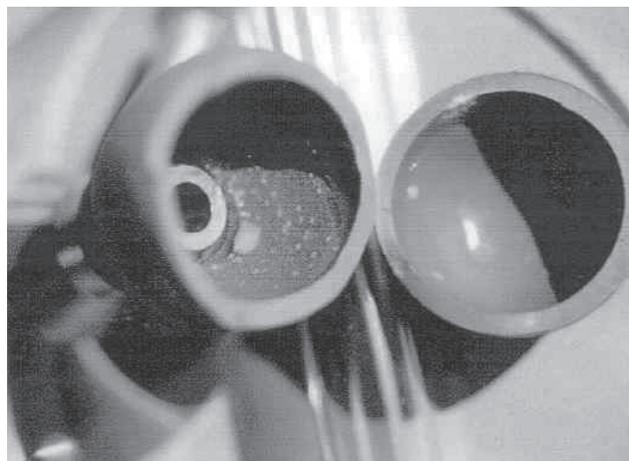
Re-usable ECG electrodes [4,5] and electrode pads [3,6] are among the detected causes of cross infection. Particularly, the transmission of bacteria on re-usable electrocardiograph electrodes has been attributed to the protective environment provided by remaining electrode gel when inadequately removed [4].

In the 80s, it became obvious that measures had to be taken to reduce the risk of cross-contamination in the hospital environment. One of the steps was replacing re-usable by single-use (disposable) medical devices. However, within the last years some countries started to use re-usable ECG electrodes again, or even worst, re-use single-use ECG electrodes [6]. The most common reason is the belief that the expenses associated to single-use ECG electrodes are higher than those associated with re-usable electrodes. However, a study done by Mannion et al. [7] concluded that there are clinical and economic consequences related to health-

care-acquired infection. The author showed cost increments of approximately 2,8 times (fold) per patient, and 2,5 fold increase in hospital stay, and costs related to the time, effort and risks involved in cleaning (eventually sterilizing) re-usable medical products. Moreover, the author estimated an increased risk of death of 7,1 fold for patients exposed to re-usable medical devices.

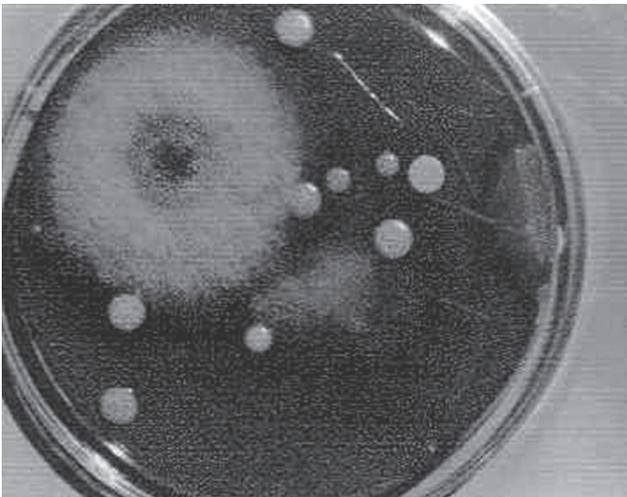
AIM

The aim of this manuscript is to provide a brief literature review within the field of ECG electrodes, focusing on the potential of re-usable ECG electrodes as the cause of cross-contamination in the hospital environment. Moreover, results are presented of two clinical investigations performed by AMBU A/S to compare the potential of vacuum system electrodes and the AMBU SU-disposable electrode of carrying microorganisms.



REVIEW OF LITERATURE

In 1973 Lockey et al. [3] reported a case of a patient who underwent a by-pass cardiac surgery and was electrocardiographically monitored by using saline-soaked ECG electrode pads beneath metal contacts. On the second post-operative day the patient developed fever, was hypotensive and had increased pulse rate. A blood culture taken at that time yielded a Gram-negative bacillus after 3-weeks incubation. Similarly, on the fourth post-operative day a second blood culture revealed a Gram-negative bacillus after 24-hours incubation. A thorough series of blood testing and bacteriological investigations showed that the patient acquired a *Klebsiella aeruginosa* blood infection from the ECG electrode pads moistened with saline contaminated with the same serotype. Colonization of nurses' hands with *Klebsiella* species had been previously described [8] and the authors suggested that this was likely the source by which the patient acquired the infection.



Control Positivo (U.F.C.=12)

Re-usable Welsh cup electrodes have also been shown to be a via of cross-infection due to the inefficiency of conventional electrode cleaning procedures [5]. Cefai and Elliot [5] performed a blinded sampling of Welsh cup electrodes in use at the ECG service of a hospital. They found that all the samples yielded between 5 and 100 bacteria colonies, predominantly of coagulase-negative staphylococci and organisms such as *Bacillus* spp. and micrococci. Furthermore, the authors investigated the ability of electrode pads to transmit bacteria from one patient to another. An area of 1 cm² of skin from the forearm of 2 subjects was inoculated with a culture containing *Staphylococcus saprophyticus* (SS), and one ECG electrode was placed on those areas. Next, the electrode was removed and cleaned following the ECG services' practices, and re-positioned in other skin areas of the same subjects as well as on other subjects. Samples of those areas yielded the same colonies of bacteria, which were carried over several skin sites. Finally the authors found that colonies of SS were able to survive up to 36 hours in the conductive gel. The authors

concluded that re-usable ECG electrodes might act as vehicle for cross-infection. Especially dangerous in hospitals where *Staphylococcus aureus*, which caused the major pandemics and nosocomial problems in 1940 and 1950, is present [9]. The authors suggested that the best and most practical solution was adopting single-use disposable electrodes.

Some studies have also investigated the efficiency of different procedures to clean re-usable electrodes. Trend et al. [4] compared the effectiveness of different methods used at Queen Elizabeth Hospital, Edgbaston, United Kingdom. Firstly, the most traditional method, consisting on removing most of the conducting gel by wiping the electrodes' bells with a dry tissue after each electrocardiogram, was tested. In addition, at the end of each day, after approximately 8 patients, the bells and bulbs were washed in a 0,1% aqueous solution of chlorhexidine in warm water for approximately 2 minutes with a scrubbing brush. The electrodes were sampled 4 times during the day; before the beginning of the ECG sessions, mid-way into the sessions, at the end of the sessions, and after the cleaning procedure explained above. The staff at the hospital did not know the nature of the investigation; therefore, the cleaning procedure was the same as usual. The results showed that all samples were infected at each of the 4 described sampling times. The predominant organisms were coagulase-negative staphylococci micrococci, *Bacillus* spp, and *Klebsiella* spp. Other alternative cleaning methods, such as wiping the electrodes with dry tissues or tissues containing 70% v/v isopropyl alcohol, immersing the electrodes to 70% ethyl alcohol at room temperature for 10 minutes, immersing the bulbs in water at 50 °C for 2 min, and immersing the bulbs and bells in water 60 °C for 1 hour, were also tested [4]. The results showed that the only method that eradicated all bacteria was heating the electrodes at 60 °C for 1 hour. Lately, some hospitals are currently re-using single-use electrodes on several patients as a way of reducing costs. Daley et al. [6] performed an in vitro study to determine if the Red Dot (3M) electrode could harbour skin bacteria or viruses, and whether or not wiping it with a swab moistened with 70% isopropyl alcohol, for 2 seconds, would successfully kill adherent organisms. The study suggested that after the first use the electrodes could be transiently contaminated with skin flora and potential pathogens. Alcohol removed most, but not all, vegetative bacteria and reduced the number of viable herpes simplex virus (HSV).

CLINICAL INVESTIGATIONS PERFORMED BY AMBU A/S

In 1999 AMBU A/S performed two clinical investigations in collaboration with the University Hospital Kreiskrankenhaus - Lörrach, Germany (AMBU A/S internal documentation). The aim was to investigate the potential of vacuum system electrodes to carry microorganisms and to compare the risk associated with vacuum systems and disposable ECG electrode, taking for comparison the AMBU SU electrode.

In one of the studies, patients underwent conventional resting ECG procedures using vacuum ECG systems. Ninety-five electrodes were sampled and tested for presence of microorganisms. The vacuum electrodes were cleaned before the first patient/session of the day as recommended by the manufacturer of the electrodes. Microbiological samples were taken before the first patient, after the first patient, after the fifth patient, and after the last (tenth) patient of the day. The samples were incubated in blood agar plates and dermatophyte plates.

The microbiological results showed that before the first patient/session there was already an average of 30 *Staphylococcus Epidermidis* (SE) coloni forming units, evidencing the poor efficiency of the cleaning procedures. After the first and second patients there were more than 400 SE colonies and 40 micrococcus (MC) colonies in the samples. After the fifth and tenth patients the amounts of both, SE and MC colonies was higher than 400. Moreover, results of the coloni forming units on dermatophyte plates showed that while fewer fungi were found, some of the types were pathogenic (*Candida albicans* and *Trichophyton*).

Three hundred patients were incorporated to the second investigation. The patients underwent conventional resting ECG measurements and were assigned to either the vacuum-system-group (150 patients) or the AMBU SU-disposable-electrode-group (150 patients). Microbiological samples of both electrodes were taken before the first session/patient of the day for each group. The vacuum system electrodes were sampled as explained before (after patient 1, 5 and 10 every day). Moreover, the disposable SU electrodes were sample

after each patient. The microbiological results of the vacuum system showed that there was already an average of 2 coloni forming units of *Bacillus Subtilis* before the first patient/session, evidencing again the poor efficiency of the cleaning procedures. After the first patient there was an average of 14 coagulase negative staphylococci (CNS, staph. epidermis) colonies, an average of 12 CNS was found after the fifth patient, and finally, an average of 26 CNS was found after the last patient/session of the day (patient number 10). In this study, no colonies were found in the dermatophyte agar plates, indicating no fungi or pathogenic bacteria. The microbiological results of the SU electrodes showed no coloni forming units on the samples (0 coloni forming units).

CONCLUSIONS

This literature review presents evidence of the risks, disadvantages, and negative impact associated with re-using ECG electrodes. Single-use (disposables) electrodes are not only safer, and easier to use than reusable ones, but are also cheaper if considering the economic burden caused by efficiently cleaning re-usable electrodes, the time involved in this process, and the cost related to a nosocomial infection. A device designated for 'single-use' must neither be reprocessed nor be re-used, not even on the same patient. It should only be used on an individual patient, during a single procedure and then discarded. Clean and safe healthcare should be nothing but a right for every single patient. Effective prevention and control of healthcare-acquired infections have to be part of the every day practice in the healthcare sector and applied consistently by everyone.

REFERENCES

- [1] Getting ahead of the curve: a strategy for combating infectious diseases. Publication of the British Department of Health, January 2002.
- [2] The Management and Control of Hospital Acquired Infection in Acute NHS Trusts in England. Publication of the British National Audit Office, February 2000.
- [3] Lockey E, Parker J, Casewell MW. Contamination of ECG Electrode pads with *Klebsiella* and *Pseudomonas* Species. *British Medical Journal* (1973) 2:400-401.
- [4] Trend V, Hale AD and Elliot TS]. Are ECG Welsh cup electrodes effectively cleaned? *Journal of Hospital Infection* (1989) 14:325-331.
- [5] Cefai and Elliot TS]. Re-usable ECG electrodes – a vehicle for crossinfection? *Journal of Hospital Infection* (1988) 12:65-70.
- [6] Daley AJ, Hennessy D, Cullinan J, Thorpe S, Alexander R. Letter to the Editor: Potential microorganism transmission from the re-use of 3M Red Dot adhesive electrocardiograph electrodes. *Journal of Hospital Infections* (2005) 61:264-273.
- [7] Mannion PT. Hospital acquired infection - the current situation. *Hospital Pharmacist* 7(7): 178-182, July 2000.
- [8] Salzman TC, Clarck JC and Klemm L. (1967) In *Antimicrobial Agents and Chemotherapy*, p 97, Ann Arbor, Michigan, American Society for Microbiology.
- [9] Weinstein RA. Nosocomial Infection Update. *Emerging Infectious Diseases* (1998), 4(3): 416-420. This document has been prepared by Nazarena Mazzaro, Clinical Research Coordinator at Ambu A/S in May 2007.