Clinical Investigations involving ECG Electrodes

Objective
The main objective of this review is to provide an overview of the published literature on ECG signal quality, ECG electrodes as vehicles for cross infections, the offset-electrode concept and technical requirements of ECG electrodes. Clinical investigations and evaluations involving Ambu ECG electrodes are also described.

ECG electrodes as vehicles for cross-infection

The World Health Organization reported in 2002 that the problem of nosocomial-acquired infections affects 1.4 million people worldwide. In the United Kingdom, approximately 5000 patients die each year as result of healthcare-acquired infections and in a further 15.000 patients it is a substantial contributor [1]. For the British National Health Service, the cost of nosocomial infections is approximately EUR 1,5 billion per year. In 2000, 380.000 bed days per year 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 colonization of bacteria [3]. Re-usable ECG electrodes [4,5] and electrode pads [3,6] are among the causes of cross infection. The transmission of bacteria via re-usable electrocardiograph electrodes has been attributed to inadequately removed electrode gel [4].

In the 80's it became obvious that measures had to be taken to reduce the risk of cross contamination in the hospital environment. One of the measures was to change from re-usable to single use medical devices. However, within the last years some countries started to use re-usable ECG electrodes again, or even worse, 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 that of re-usable electrodes. However, a study done by Mannion et al. [7] concluded that there are clinical and economic consequences related to healthcare-acquired infections. The author calculated cost increments associated to the use of re-usable devices of approximately 2,8 times per patient, an increase in hospital stay of 2.5 times, and costs related to the time, effort and risks involved in cleaning (and eventually sterilizing) the re-usable medical products. Moreover, the author estimated an increased risk of death of 7.1 times for patients exposed to re-usable medical devices.

In 1973 Lockey et al. [3] reported a case involving 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 has been previously described [8], and the authors suggested that this was a likely source of the acquired infection.

Re-usable Welsh cup electrodes have also been shown to be a way of cross infection due to the inefficiency of conventional electrode cleaning procedures [5]. Cefai and Elliot [5] performed a blinded sampling of in-use Welsh cup electrodes in an ECG hospital service. They found that all the samples yielded between 5 and 100 bacteria colonies, predominantly coagulase-negative staphylococci, Bacillus spp. and micrococci. Furthermore, the authors found that electrode pads could transmit bacteria from one patient to another and that colonies of Staphylococcus saprophyticus (SS) were able to survive up to 36 hours in the conductive gel. The authors concluded that re-usable ECG electrodes might act as vehicles for cross infection, especially dangerous in hospitals where Staphylococcus aureus, which caused 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 electrodes.

Some studies have i nvestigated the efficiency of different procedures to clean re-usable electrodes. Trend et al. [4] compared the effectiveness of different methods used at the Queen Elizabeth Hospital, Edgbaston, United Kingdom. Initially, the most traditional method was tested, consisting of wiping clean the electrodes' bells after each electrocardiograph with a dry tissue removing most of the gel. At the end of the 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 starting the ECG sessions, mid-sessions, end of the day, and after the cleaning procedure explained above. The results showed that all samples were infected and at all times, including pre-use and after cleaning. The predominant organisms were coagulase-negative straphylococcim micrococci, Bacillus spp, and Klebsiella spp.

Other alternative cleaning methods were tested [4], including: 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 at 60 °C for 1 hour. The results showed that the only method that eradicated all bacteria was heating the electrodes at 60 °C for 1 hour.

Lately, single-use electrodes are being re-used between patients as a cost saving measure. Daley et al. [6] performed an in vitro study to determine if the single-use electrode could harbour skin bacteria or viruses, and whether 70% isopropyl alcohol by wiping for 2 seconds with a moistened swab 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).

Ambu A/S has performed 4 clinical investigations investigating the potential of vacuum system and Welsh cup electrodes to carry microorganisms compared to the Ambu Blue Sensor 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 were 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).

In the second investigation, the patients underwent conventional resting ECG measurements and were assigned to either the vacuum-system-group (150 patients) or the Ambu Blue Sensor 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 Blue Sensor SU electrodes were sampled 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 Blue Sensor SU electrodes showed no coloni forming units on the samples.
In the third (100 patients) and fourth (122 patients) study the aim was to compare the re-usable Welsh cups/plate electrodes and single patient disposable Blue Sensor SU electrodes. Patients who had to undergo a resting ECG exam were randomly assigned to 2 groups after order of admission: reusable electrodes (cups and plates) and disposable electrodes (Ambu Blue Sensor SU). Microbiology tests showed the presence of microorganisms and bacteria on the Welsh cup electrodes; the bacteria and microorganisms could not be removed by cleaning the product according to manufacturer's instructions. Several of the bacteria seen on the electrodes are described in literature related to hospital-acquired infections.

Technical Requirements and Signal Quality

Diagnosis ECG recording and cardiac monitoring make use of increasingly sophisticated devices and electronic measuring techniques. In order for this equipment as a whole to function well high demands are placed on all the components in the measuring system. ECG electrodes are a weak link in the measuring chain. High requirements must be set on their electrical and mechanical properties if they are to fulfill their task as sensors of biopotentials [15].

Several studies are published regarding ECG artifacts caused by electrodes due to poor electrical contact, high skin impedance, and cable movement. These studies emphasize the importance of the electrode quality, the good electrical conductivity of the gel, and adhesive power of the electrode. Krasnow [10] summarized and classified 15 different types of artifacts observed from dynamic electrocardiography. The artifacts appear partly as pseudo-arrhythmias, mimicking supraventricular, ventricular junctional and dissociative rhythms, and non-arrhythmic artifacts, which can be misleading in the interpretation of Q waves, S-T segments, and T waves. Eight of the 15 artifacts have potentially serious consequences if misinterpreted, and in 2 instances an artifact almost led to the unnecessary implantation of an artificial pacemaker. In general these artifacts were not caused by the electrodes but by battery- or electric-motor failure from the ECG system, loose or broken connection, and electromechanical disturbance.

Kleinman et al. [11] published a case report showing ECG artifacts caused by extracorporeal tubing systems in patients under surgery. They provoked the artifact by testing different situations and found that an important condition to recoding the artifacts was poor skin-electrode contact. Knight et al. [12] described 12 cases where patients underwent unnecessary diagnostic or therapeutic interventions due to misdiagnosis of electrocardiographic recordings.

Ask et al. [15] investigated the long-term properties of 16 commercially available ECG-electrodes, some of them reusable and some disposable. The authors evaluated the polarization potential, electrical impedance, adhesion power, and skin reactions during a period of 7 days in 2 healthy volunteers. This publication is old and many of the electrodes mentioned are not longer available (including the 2 Medicotest electrodes mentioned in the article), moreover, the number of subjects is too low (2 participants). However, the article is considered in this review due to the methodology used to investigate electrode performance and some of the final observations. The authors found that the most stable polarization potentials were obtained for Ag/AgCl electrodes. The most stable electrode impedance was obtained for disposable electrodes with stable adhesion and equipped with an electrode cup or similar. These electrodes retain the gel and thereby prevent drying out. In the study, some of the electrodes with lowest impedance showed however, to be too aggressive to the skin and caused some skin reactions. Therefore, there is a compromise regarding how aggressive the conductive gel should be, so that the impedance is low but it does not cause skin reactions. The disposable electrodes with a large self-adhesive collar showed best and unchanged adhesion and mechanical properties during the test period.

Ambu A/S has investigated the performance of Blue Sensor SU electrode versus MSB (Maersk) Biotab electrode for resting ECG. The number of ECG registrations performed before an acceptable ECG trace could be obtained was lower for the Blue Sensor SU electrodes compared to the Biotab electrodes. This was most evident in the skin preparation group where 81% of the acceptable SU ECG traces were obtained during the first recording. In contrast, only 69 % of the usable Biotab ECG traces were obtained during the first recording. In the group without skin preparation, the percentages of usable first time recordings were 68% and 65% for SU and Biotab electrodes, respectively. Poor quality ECG traces were observed more frequently using Biotab electrodes compared to SU electrodes. The difference in the frequency of poor quality ECG traces between SU electrodes (21%) and Biotab electrodes (39%) was statistically significant in the group without skin preparation. In the patient group with skin preparation, the electrodes fell off in 1 out of 81 cases (1,2%) with Blue Sensor SU and in 12 out of 86 cases (14,0%) with the MSB Biotab electrodes. In the group without skin preparation, the electrodes fell off in 2 out of 67 cases (3.0%) with Blue Sensor SU and in 4 out of 65 cases (6,2%) with MSB Biotab. A total of 93% of the SU users found it very easy to remove the SU electrode from the patient's skin. In comparison, only 83% of the Biotab users evaluated it to be very easy to remove the Biotab electrodes from the patient's skin.
In conclusion, it was evaluated to be easier to obtain a good ECG signal quality using the Blue Sensor SU electrode compared to the Biotab ECG electrode. The SU electrode skin adhesive guaranteed a good skin attachment while still ensuring very easy electrode removal afterwards.

The offset-electrode concept

Stretching the skin causes a reduction in the magnitude of skin potential, which is observed as motion artifact in the ECG recording [13]. Cables pulling ECG electrodes during the recording can cause this artifact. One solution is the use of offset electrodes, i.e. electrodes designed with the snap attachment separated from the gel column by means of silver-circuited strip like the Ambu Blue Sensor. Nieminski [14] published a study where 40 patients that underwent a coronary artery bypass graft were Holter-monitored after surgery by using offset or standard electrodes. The results showed that the offset electrode is associated with a highly significant decrease in computer-determined artifact. No difference was recorded regarding patients' tolerance to either of the electrode types. The author concluded that the offset design offers advantages in reducing computer-determined artifacts especially during ambulatory ECG recordings.

ECG Monitoring of Premature Neonatals

Infants receiving neonatal intensive care comprise a vulnerable patient population often demanding continuous monitoring of vital functions for long periods of time. The majority of the patients admitted to the NICU are premature neonates.
ECG monitoring of the neonatal patients is a standard routine procedure at most NICU departments. Due to incomplete skin development, the extremely premature neonatal patient has some special requirements to the ECG monitoring electrodes. To reduce water loss over the immature skin barrier, the extremely premature babies are often placed in incubators with a high relative humidity (60% – 80% rH) [16]. The high humidity environment makes it difficult for standard ECG electrodes to stay attached to the skin for longer periods of time. As a consequence, the electrodes often fall off, resulting in frequent disturbances of the neonatal patient during re-application of detached electrodes. In general, disturbances of the extremely premature neonatal patient shall be reduced to a minimum to ensure a "stress-free" environment. Another challenge, related to the ECG monitoring of extremely premature neonates, is the highly fragile skin, which easily tears and breaks leaving painful open sores and increased risk for infections. Consequently, the removal of adhesives from the immature skin is related to a risk of skin trauma, pain and infections [17-19]. Thus, the ideal ECG electrodes for the extremely premature neonates display extended adhesion to the skin even in a high humidity incubator environment while still being sufficiently easy to remove to reduce the risk of skin trauma to a minimum.

Ambu A/S has carried out a user evaluation regarding the performance of the Blue Sensor NEO X electrode intended for ECG-monitoring of preterm neonatal patients. Neonatal Intensive Care Units (NICUs) evaluated the use and performance of the NEO X electrode as part of the normal ECG monitoring routine. After approximately 2-3 weeks of use, the participating nurses were asked to fill-in an evaluation form each, regarding the use and performance of NEO X. The electrode, normally used in the department, was used as the reference electrode for comparison.
More than 70 neonatal patients, aged between 24 and 39 weeks of gestational age, were ECG monitored using the Blue Sensor NEO X electrodes. A total of 37 participating NICU nurses each filled-in and returned the NEO X evaluation forms. Compared to the reference electrodes, the NICU nurses evaluated the NEO X electrode positively. In

particular, the ability to stay attached to the skin of the neonate for an extended period of time and the adhesive properties in high humidity incubators were regarded as superior. Additionally, the flexible NEO X wire was appreciated for its softness compared to the wires of the reference electrodes. The "ease of removal" of the NEO X electrode was evaluated as reduced compared to the reference electrodes. However, the benefits derived from a reliable long-term adhesion outweighed the extra care needed during active electrode removal, since the majority of the nurses in Spain, Germany and Denmark recommended to buy the NEO X electrodes for use in NICUs.

Conclusion

The literature found illustrates the development within the area of ECG electrodes. Most of the articles found were published in the '70s, when single use electrodes were under development. Thus the literature argues the advantages of single use devices and risks associated with reusable electrodes in terms of cross infection.

Interestingly, there are 4 relatively recent publications [1,2,6,7] discussing again the risk of cross infection associated with reusable ECG electrodes, and surprisingly with the "re-use of single use electrodes" [6]. This topic is particularly relevant in countries where the health sector is facing economical challenges and the belief is that the cost associated to single use devices is higher than those related to reusable devices. However, some articles [1-6] argue against this belief, discussing the costs associated to cross infection in the hospital environments in the form of time and cost spent in disinfecting/cleaning devices, longer hospitalization periods due to infection, medicine to treat infections, and unsafe working environment for the clinicians.

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