GUIDELINES OF THE BWGCPE FOR GOOD CLINICAL PRACTICE CONCERNING SINGLE USE OR APPROPRIATE REPROCESSING OF ELECTROPHYSIOLOGY CATHETERS

10 september 2006

Introduction

These guidelines refer to the consensus documents of the European Society of Cardiology (Eur Heart J 19:1628-1631, 1998) and of the North American Society for Pacing and Electrophysiology (NASPE, now Heart Rhythm Association) (PACE 24:1297-1305, 2001).

In the line of these scientific organisations, the BWGCPE considers controlled and appropriate reprocessing of most (not all) electrophysiology catheters as Good Clinical Practice. Reprocessing is safe when the guidelines, as outlined below, are followed, constituting guidance for Good Manufacturing Practice (GMP). These guidelines of the BWGCPE are also inspired by its societal responsibility to provide cost-efficient health care: reprocessing both reduces costs and may be associated with more efficient procedures since more and more complex catheters can be used. This document is a non official paper written by the Belgian Working Group on Cardiac pacing and Electrophysiology, working group of the Belgian Society of Cardiology.

Catheters that are definitely not eligible for re-use:

- catheters containing a lumen that is exposed to the blood pool (e.g. open irrigated catheters; catheters for combined use of electrophysiological recording and dye injection; diagnostic angiographic catheters);

- catheters containing joints that cannot effectively be cleaned (e.g. catheters with different spokes like in a “basket” or “flower” configuration);

- catheters with coil-type electrodes;

- catheters used in patients with known infectious diseases (like hepatitis B or C, human spongiform encephalopathy, HIV, TBC, ...).

Guidelines concerning re-use of other catheters:

- Hospital procedures should be in place and documented to ensure safe reprocessing of all catheters. These consist of validated Standard Operational Procedures (SOPs) and Work Instructions (WI) dealing with all aspects of the reprocessing cycle (cleaning, resterilisation, evaluation of mechanical and electrical properties, tracking, responsibilities).

- All catheters should be labeled unambiguously and traced. Labelling allows to traceability for each catheter, i.e. where it is in the re-use process, in which patients is was used before and is used later, the number of reprocessing cycles, mechanical and electrical performance, reason for disposal, etc. The tracking database preferable should be in electronic form.

- Personel should be trained for the different tasks in the process. Records of this training schedule should be available.

- Resterilisation should be done according to accepted and validated procedures in accordance with the recommendations of the Belgian Superior Health Council (reference 1). The number of reprocessing cycles should be reasonable and dependent on the type of catheter. In-hospital data (from the tracking database) should be available to prove acceptabiliy for the number of reprocessing cycles for each given catheter. The database should be available for audit by peers from the BWGCPE. In the future, the BWGCPE will set up a uniform reporting system on catheter performance to centralise and synthetise the experience of all Belgian EP centers for different types of catheters.

- Observations concerning unanticipated mechanical or electrical failure should be reported (especially if these led to potential or effective patient danger) to 1) the Federal Government Department of Public Health, using a prespecified form as legally required (reference 2) and 2) with a copy of this form to the BWGCPE. These failures should be considered as "Adverse Events" or "Serious Adverse Events". This may provide the BWGCPE with data to exclude this type of catheter from further reprocessing, to limit the number of reprocessing cycles, or to provide specific instructions on reprocessing of the given catheter.

- Responsibility for the different parts of reprocessing should be explicitly specified within the hospital (as part of the documented procedures) and in accordance with legal requirements.

- A quality management system should be in place that continuously monitors the performance of the different steps of the reprocessing cycle. The parameters for quality control should preferably be part of the electronic tracking database. An internal global yearly evaluation, summarised in a short report and signed by the Head Physician of the hospital, is advisable.

References:

1) http://www.health.fgov.be/CSH_HGR/

2) https://portal.health.fgov.be/portal/page?_pageid=56,513103&_dad=portal&_schema=PORTAL