

Title The clinical value of ultraviolet rays UV-C used for disinfection of endocavitary ultrasonography probes

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Reference Evaluations de technologies de santé
<http://alpha-recherche.aphp.fr/wp-content/blogs.dir/85/files/2015/03/AntigermixCEDIT.pdf>

Aim

The CEDIT assessed the value of ultraviolet rays UV-C used for disinfection of endocavitary ultrasonography probes (endorectal and endovaginal), potential carriers for microbiological contaminations between patients.

Conclusions and results

Technical aspects: The Antigermix disinfection unit manufactured by Germitec uses ultraviolet rays with a wavelength of 254 nm. Each probe is identified by an RFID chip attached to the cable enabling recording of device history for individual follow-up and traceability. The Antigermix unit is a class IIb medical device (CE marked since 2007).

Clinical aspects: Despite studies and efforts to create models, the infectious risk associated with the use of endocavitary probes is difficult to assess. The current French recommendations do not advise on the use of UV-C as a means of disinfection of probes between patients and are under review following a request from the Ministry of Health in July 2013.

The introduction of Antigermix highlights the question whether it is relevant or not to extend the systematic use of high level means of disinfection between patients, and in that case whether preference should be given to the UV-C technology or to the alternatives.

The three available clinical studies on the use of UV-C disinfection, all funded by the manufacturer, show that the Antigermix used in combination with other methods is a good means of disinfection. However, no study allows establishing the specific contribution by UV-C based disinfection and thus the role it can play in the disinfection process.

Further, two of the studies go outside the issue of endocavitary sonography. These studies are thus not relevant for clinical practice.

Economic aspects: No available arguments/data allow comparison of the efficacy and the costs associated with the different disinfection methods. The costs to take into account are linked to the equipment, its maintenance, downtime of sonography equipment and possible need for supplementary probes.

Organizational aspects: Disinfection practice may impact the organization in several ways:

- 1) Need for space to perform the disinfection procedures close to the place of use of the ultrasonography probes;
- 2) Non-availability of probes during disinfection;
- 3) Need for ventilation for certain disinfectants.

To minimise time-loss it is preferable to place the disinfection unit at the point of sonography exploration to avoid disconnecting and transporting the probes.

Recommendations

As the current level of evidence supporting the efficacy / effectiveness of Antigermix is very low (see medical aspects above), and in view of current French recommendations, the CEDIT considers that it is not necessary to systematically acquire Antigermix systems for endocavitary (endorectal and endovaginal) sonography purposes.

Methods

The CEDIT secretariat carried out a literature review and consulted an expert panel. The CEDIT assessment specifically addresses disinfection of ultrasonography probes using UV-C rays. No general review of methods for prevention of infectious risk or general recommendations for disinfection of such probes was performed.

Further research/reviews required

If the French guidelines (under review) for disinfection of endocavitary sonography probes evolve in the direction of high level disinfection methods, CEDIT considers that a prospective comparative study to establish the effectiveness and cost-effectiveness of this equipment and its appropriate use in the prevention of nosocomial diseases, has to be put in place.

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