Multicenter Study on Clean Instruments (MRSA)

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1 Aim

How can the **degree of cleanliness** be **measured** on inner and outer surfaces of surgical instruments if the **bioburden** is **not visible**? Is there potentially infectious adherent **biological material after cleaning** which then has to be sterilized?

2 Material and Methods

To answer this questions an **exploratory multicentric clinical observational study** was conducted (**M**ulticenter-**R**estkontaminations-**S**tudie **A**ufbereitung - MRSA). Six typical **surgical instruments**, from **surgery** (Wertheim forceps), **traumatology** (rasparatorium), **laparoscopy** (forceps inlet, trocar valve, trocar sleeve), and **gynecology** (speculum) were examined in **five Central Sterile Supply Departments (CSSD)** of Germany to identify the **degree of cleanliness** after cleaning in washers/disinfectors including ultrasound.

Visibly clean surfaces were rinsed with ***Sodiumdodecylsulfate (SDS-elution)***. Different methods for protein analysis - semi-quantitative colorimetric ***Sangur-Test*** *(Boehringer, Ingelheim)* on hemoglobin, semi-quantitative colorimetric ***modified Biuret-Test*** *(Merck, Darmstadt)*, and quantitative photometric ***(ortho-Phthaldialdehyde) OPA-method*** - were compared concerning **clinical practicability**.

Selected instruments from the OT were analyzed (eluate) with different analytical methods.

3 Results

Proteins are found in small amounts in the eluate of **nearly every second instrument** and could not be related to a specific instrument design.

The quantitative **OPA-method** is **precise**, but not as easy to perform in daily routine - a photometer is necessary. **Sangur** and **Biuret** are easy to do in CSSD, but the results are **less precise**. Apparently, colours can be judged differently depending on person and light conditions. **Sangur** showed **too many negative** results while the other method showed positive results.

All methods depend on the **quality of elution**. The **recovery** from the instruments' surfaces is varying and will **never be 100%**. The recovery rate can be verified only in laboratory experiments. Under clinical conditions the **quantity of bioburden remains unkown**. Cleaning results themselves depend from different factors.

4 Conclusion

This exploratory study for the first time shows results of protein quantities, which can be eluted from surgical instruments, coming from the operating theatre (OT), after the cleaning step. It proves that the subsequent **sterilization** process after instrument cleaning has to **penetrate layers of remanent proteins** on the internal/external instrument surfaces. It concerns **all kinds of surgical instruments** and is not related exclusively to tube like minimally invasive instruments. Nevertheless, the influence of parameters like instrument design and surface accessability need a different *in vitro* study approach.

Optimization of instrument design and configuration of washers/disinfectors depend on a **precise measurement of cleaning efficacy**. A cleaning indicating system should be based on **protein detection** as the most relevant contamination.

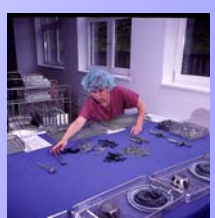
Quality management in surgery depends on **identification** of the **relevant parameters**. Cleaning **parameters** must be **examined *in vitro*** and **correlated** to the **clinical *in vivo* contamination** with the issue of a cleaning indicating system.

5 ml of SDS solution is applied to the selected instrument types.

Elution is performed equally for any instrument type.
Photo 3 shows the colorimetric Sangur-test *(Boehringer, Ingelheim)*.

Steps of the colorimetric Biuret-test *(Merck, Darmstadt)*.

Preparation of the sample for photometric measurement (OPA-method).



Dried instruments coming from the washer/disinfector are prepared for the final sterilization.