MEDICAL GLOVES RESIDUAL RISKS

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INTRODUTION

A wide range of hazardous processing chemicals is used during the manufacture of medical latex and synthetic gloves. The final product comprises organic and inorganic compounds. Residues of these chemicals posing a risk of irritant contact dermatitis, allergic contact dermatitis, and many other complications, especially for patients. Most of the complications have no allergic nature. Exposure to residues comes from dermal (cutaneous) or mucous membrane contact. Direct tissue or intra-vascular exposure also occurs via an open surgical wound through the use surgeon gloves.

The composition of the final product highly depends on the initial ingredients, which fluctuates, chemical reactions and leaching that occurs during processing. Cross-reactivity of various chemicals can occur. Quantification of each of the chemicals present in medical gloves and determination of it bioavailability are problematic. In this situation to indicate that the level of risk from residues is broadly acceptable manufacturer must do an assessment testing of finished gloves. Cytotoxicity evaluation of glove extracts in accordance with ISO 10993.5-96 is an adequate method for testing finished production directly at the factory. We tested a few tens of brands to understand real situation with chemical residues.

Table 1:

Extract dilution necessary for gloves to pass the test for cytotoxicity

№	Brand	Delution
1	Dermagrip	1:32
2	Perry X-AM	1:64
3	Medi-Grip PF	1:32
4	Medi-Grip Plus	1:64
5	Gammex	1:64
6	Protegrity with Neu-Thera	1:2
7	Protegrity SMT	1:2
8	SFM	1:64
9	IPM	1:128
10	Sempermed	1:4
11	Medigrip +	1:2
12	Dermagrip PF	1:2
13	Sikcare	1:4
14	Contour	1:64

Fig. 1. Cytotoxicity analyzer

METHODS AND MATERIALS

For cytotoxicity testing prime culture of bull spermatozoa was used. Frozen cells stored in liquid nitrogen are used that allows to ensure the unlimited storage and reduce time for work preparation. The motility of spermatozoa suspension is used as the endpoint. The spermatozoa suspension motility measurement is done strait in suspension. As soon as the extract is ready it takes 10 minutes to defrost granule of the bull's frozen sperm in glucose-citrate media, prepare reference and examined samples and start the experiment. Duration of the experiment is only 3 hours instand of more than 24 hours for constant cell lines. Short duration of expirement permits to test non-steril extracts. The method has no requirements for sterilyty of materials, instruments and euqipment used. The motility of spermatozoa suspension is measured by cytotoxicity analyzer (see Fig. 1). The operating principle is based on real time automatic computer microscopic videoimage analysis of spermatozoa suspension to measure its motility. Scoring for cytotoxicity is based on the value of the toxicity index I_t which is equal to the ratio of the weighted average time of spermatozoa suspension motility in the examined sample to that of spermatozoa suspension motility in the reference sample. I_t value is expressed in percents.

Latex, isoprene and nitrile gloves have been tested for cytotoxicity in accordance with ISO 10993.5-96 to assess the risk posed by residues. 54 brands were tested.

RESULTS

47 of 54 brands failed an evidence-based assessment testing of finished production. It means that their extracts comprise substances of clinical importance of high concentration. The range of cytotoxicity reaches delution of 1:128. For some brands required dilution rate to pass cytotoxicity test is given in Table 1. There is no evidence that exposure of patients and users is maintained bellow levels that can result in harm to health and manufacture can`t ensure a broadly acceptable risk. In conformity with Medical Devices Directives the presence of residue must be treated as a residual risk and the product packaging must have corresponding indication. Nevertheless none of the brands has warning concerning exposure to chemical residues. We must state that patients and users are not adequately informed about the nature of the residual risks.

Chemical residues are easy-extractable. The situation can be improved provided that gloves leaching at the finish stage of the manufacturing process is more thorough or special coatings to prevent extraction is used.

Prime culture of bull spermatozoa together with cytotoxicity analyser permits to do precise, very quick and cheap assay.

CONCLUSIONS

- Most of medical gloves placed on the market fail the test which ensures a broadly acceptable risk connected with exposure to chemical residues. The product does not conform Medical Devices Directives.
- The presence of residues must be considered as a residual risk. Gloves labeling needs to include a prominent indication on the packaging, that they contain chemical residues posing a risk of complications, especially for patients. For natural latex gloves this labeling must be additional to the warning about allergic responses.
- Prime culture of bull spermatozoa used together with cytotoxicity analyser is very comfortable for testing of finished production directly at the factory:

- results are obtained within 3 hours and less,

- the test method permits to test non-steril extracts,

- the cytotoxicity evaluation process is automated.