THE MIGRATION OF PLASTICISERS FROM PVC HAEMODIALYSIS TUBES

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Potentially toxic plasticisers have been shown to exude from PVC tubing [1]. An in vitro investigation of the amount of the plasticiser bis-2-ethyl-hexyl-phtalate (DEHP) released from complete sets of tubing to a plasma pool was therefore performed. The DEHP release rates were examined for eleven different makes of tubing, polyurethane coated tubing, differently sterilised tubing and reused tubing.

Materials and Methods

Only complete sets of tubing including original fittings were used. From every make of tubing one piece was extracted in chloroform/methanol. Tubings were perfused for eight hours at 37°C using a peristaltic pump and a rate of perfusion of 200ml/min.

Two pools of plasma of 6L and 12L respectively were obtained from citrate stabilised donor blood, drawn handled and stored in glass bottles. Although a PVC tube was used for the drawing up, DEHP could not be demonstrated in the pools.

During perfusion experiments five to ten samples were drawn at equal intervals. The samples were kept at −18°C for a maximum of four weeks before analysis.

Analysis was performed by gas chromatography after extraction of the plasma with a 1:1 methanol/chloroform mixture by volume [2]. The mixture contained bis-2-ethylhexyladipate for internal standardisation. The non-aqueous phase was evaporated to dryness and redissolved in chloroform before chromatography.

Standards ranging from 10 to 100mg DEHP per ml were made up dissolving pure DEHP in plasma, and treated like the unknowns.

The gas chromatograph was a Perkin Elmer F30 with flame ionisation detector and 1/8" x 6' column with OVI1 filling. Oven temperature was 245°C.
Results

The DEHP content was at least 98% by weight of the extracted material for all tubes included in the investigation except for one which had an additional content of bis-2-ethylhexyladipate.

In all perfusion experiments the amount of DEHP released was linear with time. The coefficient of correlation between DEHP and time varied from 0.977 to 1.000 (mean 0.995).

*Perfusions with Plasma Pool I*

For ten sets of tubing of different make, the release of DEHP varied from 2.8 to 4.0mg/hr (mean 3.4mg/hr).

*Perfusions with Plasma Pool II*

For ten sets of tubing of the same make, the release of DEHP varied from 2.0 to 2.6mg/hr (mean 2.3mg/hr).

For two sets of tubing coated with polyurethane the DEHP release was 2.1 and 2.0mg/hr.

Eighteen sets of tubing of the same make were examined after being sterilised in different ways. Ten ethylene oxide-sterilised sets showed a mean DEHP release of 2.3mg/hr, five sets sterilised by 3.5 megarad a mean release of 2.3mg/hr and three sets sterilised by 2% formaldehyde for 24 hours showed a mean release of 2.4mg/hr.

For five sets of another make three non sterilised sets showed a mean DEHP release of 2.5mg/hr, two sets sterilised by 3.5 megarad showed a mean DEHP release of 2.6mg/hr.

To clarify the effect of reuse two sets of tubing were perfused four times. Between perfusions they were filled with 1% formaldehyde and stored for 48 hours. The hourly DEHP release values in mg were: 2.3, 2.2, 1.7, 1.5 and 2.7, 2.0, 1.3, 1.0.

Discussion

The relative variation between DEHP release is nearly identical for ten tubings of the same make and ten tubings of a different make and it is therefore concluded that there is no significant difference in DEHP release rate according to make.

The release rate from coated tubings was comparable with that of uncoated tubings. The DEHP release rate seems unaffected by any of the three methods of sterilisation commonly used and was decreased to approximately 50% of the original value by reuse of the tubings.

References

1. Neergaard, J, Nielsen, B, Faurby, V, Christensen, DH and Nielsen, OF (1975) *Nephron, 14*, 263

740