Determination of di(2-ethylhexyl) phthalate in plastic medical devices

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Abstract

The presence of DEHP in dialysis and infusion sets for peritoneal dialysis and parenteral nutrition, which are made of PVC and other plastic polymeric materials, were investigated. Phthalate determination was carried out by gas chromatography–mass spectrometry method (GC–MS). The results showed that the peritoneal dialysis set (bag and tubing) made of PVC contains DEHP in significant amount, about 31–34%. Solution for peritoneal dialysis which was stored in the investigated PVC bag, contains low amount of DEHP, about 3.72 μg dm^{-3}. Infusion bottles which are made of LDPE, also contain DEHP but in lower amount than PVC bags. LDPE bottle for packaging physiological saline solution (0.9% NaCl) showed higher amount of DEHP than LDPE bottle for packaging Ringer's solution. In contrast, solution stored in bottle with lower DEHP level, *i.e.*, Ringer's solution, contained about three times higher concentration of DEHP than physiological saline solution stored in bottle with higher DEHP level. Concentrations of DEHP in Ringer's solution and physiological saline solution are 17.30 and 5.83 μg dm^{-3}, respectively. The obtained values are under estimated upper-bound dose of DEHP received by adult patients undergoing procedures of peritoneal dialysis and parenteral nutrition.

Keywords: phthalate, plastic material, medical devices, infusion set, peritoneal dialysis set.

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Phthalates, as diesteres of orto-phthalic acid, are organic lipophilic compounds, which are used as plasticizers. Phthalates are used as plasticizers to increase the softness and flexibility of plastics, notably PVC. But, they are not chemically bound in plastic materials and they can be leached into the environment [1–3]. About one million tonnes of phthalates are produced in Europe per year, and the most dominant phthalates are di-(2-ethylhexyl) phthalate (DEHP), diisodecyl phthalate (DiDP) and diisononyl phthalate (DiNP). In PVC materials, DEHP is the most used plasticizer [4,5].

Humans are exposed to phthalates in numerous ways, by dermal resorption, foodstuff or by inhaling air which contains phthalates. These compounds are present in a wide variety of products, which are often used by people, such as cosmetics, personal care products, food packaging, children toys, water bottles, rainwear, tablecloths, upholstery, etc. [6–10].

PVC medical devices contain on average 20–40% DEHP by weight. A lot of medical devices are made from PVC, such as intravenous bags and tubing, infusion tubing, blood bags, catheters, oxygen masks, peritoneal dialysis bags and tubing, enteral nutrition feeding bags, etc. [10,11]. Medical devices which contain phthalates may be important sources in susceptible subpopulations, including neonatal infants who are undergoing surgical interventions, but also to other hospital patients who receive nutritional supplements intravenously [13]. Phthalates are lipophilic compounds, and can be found in fats due to bioaccumulation process. The tolerable daily intake (*TDI*) values established by the European Food Safety Authority panel (2013) for benzyl butil phthalate (BBP), DEHP and dibutil phthalate (DBP) are 500, 50 and 10 μg/kg of bw per day, respectively [2]. Study of these types of chemical substances has increased in recent years because some of these compounds, such as DBP, BBP and DEHP, are suspected as endocrine disruptors and carcinogenic to humans. There is great concern about the toxicity of DEHP, especially for risk groups. Some of studied effects are mutagenic activity, carcinogenicity, peroxisome proliferation, infertility, etc [9].

DEHP is not chemically bound to the polymer and it can migrate when the medical device comes into contact with certain media such as blood, drugs, saline or water. Also, DEHP can be released when the device is heated. Due to these facts, the major factors determining the degree to which DEHP leaches from medical devices are temperature and storage time. Patients who are undergoing medical procedures, such as blood transfusions and haemodialysis potentially can be exposed to DEHP. When DEHP enters the human body, it is metabolized into various substances that are more readily excreted. The most important metabolite is mono-ethylhexyl phthalate (MEHP). Because conversion of DEHP to MEHP occurs primarily in the intestinal tract, exposures to DEHP by ingestion may be more

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hazardous than by intravenous exposure, because this path bypasses the intestinal tract. Some studies showed that DEHP can cause liver cancer in laboratory animals. It can be caused through the induction of peroxisome proliferation, which leads to oxidative stress and the generation of electrophilic free radicals, and then indirectly causing damage to DNA damage [14–16].

Phthalates can be detected using different methods, such as mass spectrometry (MS) [17,18], electron capture detection (ECD) [19], and flame ionization detection (FID) [20]. The analysis of phthalates is mostly performed by gas chromatography (GC) and this method presents better sensitivity than HPLC methods. Also, there are different preconcentration methods, such as solid-phase extraction (SPE), solid-phase microextraction (SPME), headspace solid-phase microextraction (HS-SPME), liquid-phase microextraction (LPME) and dispersive liquid-liquid microextraction (DLLME) [22–24]. The most conventional liquid-liquid extraction methods (LLE) performed with hexane, dichloromethane, ethyl acetate or acetone have recovery values in the range between 70 and 100% and is relatively short and easily performed. Because of that, LLE method for extraction and GC for the separation and analysis seem to be the best choices for extraction and detection of phthalates [25] .

Due to the fact that these compounds are present in the environment, the major problem in phthalate determination is the sample contamination during the analysis. This problem can be reduced or even avoided by reduction of number of sample preparation steps [26,27].

The aim of this work was DEHP determination in medical devices, such as dialysis set (bags and tubing) and infusion set (bottles and tubing) which is made of polyvinyl chloride (PVC) and low density polyethylene (LDPE). In this study, we compared PVC and LDPE plastic medical equipment in their capability of leaching DEHP into solutions. DEHP was determined in solutions Dianeal Low Calcium Peritoneal Dialysis Solution (contains 1.5% dextrose and 2.5 meq Ca L^{-1}), physiological saline solution (0.9% NaCl) and Ringer's solution which were stored in the investigated bags and bottles for three years and in the PVC and LDPE plastic medical equipmen by liquid extraction and GC–MS analysis. Based on the obtained results, the migration of phthalates from packaging to the stored infusion/dialysis solutions can be defined.

EXPERIMENTAL

Chemical reagents and instrumentation

High-purity DEHP was purchased from Sigma Aldrich (St. Louis, MO, USA). Dibutil adipate (DBA), which was used as internal standard, was purchased from Fluka (Buchs, Swizerland). HPLC grade *n*-hexane was purchased from Sigma Aldrich.

Preparation of stock and working solutions

Special care was taken to avoid the contamination of sample due to contact of reagents and solvents with plastic laboratory materials during sample preparation. All glassware was washed with hot water and soap, rinsed with ultrapure deionized water and subsequently thoroughly rinsed with dichlormethane. Glassware was then sealed with aluminum foil and stored in a clean environment to avoid adsorption of phthalates from the air. Usage of plastic consumables during the analysis is avoided whenever possible. No laboratory gloves were used during sample preparation and analysis.

All stock and working solutions were prepared in hexane. Individual stock solutions of DEHP and DBA were initially prepared at a concentration of 1 mg cm^{-3}. The stock standard was diluted stepwise with n-hexane to prepare at least 5 concentration levels of intermediate and working standards. Intermediate solutions were prepared by dilution of stock solution, and concentrations of intermediate solutions were 100 and 10 μg cm^{-3}. Working solutions were prepared by dilution of intermediate solutions and by adding DBA at concentration 1 μg cm^{-3}. All solutions were stored at 4 °C.

Sample preparation

Plastic medical devices, which are used for various techniques in medicine, were collected from the local hospital. Samples consisted of filled plastic dialysis bags and tubing from dialysis set (Baxter), infusion bottles (Hemofarm and Zdravlje) and tubing from infusion set (Mediset). Plastic materials were cut into pieces with area of about 1 cm^2. All samples were extracted for 3, 6, 15 and 30 days with 5 ml of *n*-hexane in glass vials.

Individual solutions which are usually present in formulations for peritoneal dialysis and parenteral nutrition were stored in PVC bags and LDPE bottles at room temperature. The analyzed samples were: solution for peritoneal dialysis (1.5% dextrose), physiological saline solution (0.9% NaCl) and Ringer's solution (NaCl, KCl and $CaCl_2$) for parenteral nutrition. Liquid samples were collected in glass flasks and stored at 4 °C until analysis. Since the usual shelf-life of infusion solutions is three years, migration rates of DEHP from plastic containers were measured after a period of 36 months in order to determine the maximum possible leached concentration of DEHP before expiration period of the medical product. The extraction procedure was carried out with 5 cm^3 of hexane for extraction of 500 cm^3 sample. To 500 cm^3 of each sample, 5 cm^3 of hexane was added and mixed 60 min and 24 h. The organic layers were transferred to glass vials, inter-

nal standard was added and aliquots were injected into GC–MS directly with no clean up stage.

GC–MS technique

Determination of phthalates was performed by Hewlett Packard 6890 gas chromatograph equipped with an Agilent 5973 mass selective detector and a DB-5 MS capillary column (30 m×250 mm×0.25 mm, Agilent, USA) for chromatographic separation. The oven is programmed from 60 (1 min) to 220 °C (1 min) at rate of 20 °C min^{-1} and after to 280 °C (4 min) at rate of 5 °C min^{-1}. The gas chromatograph was operated in splitless injection mode. The operating temperature of the MSD was 280 °C with the electronic impact at 70 eV. The MSD was used in the ion-monitoring (SIM) mode at *m*/*z* 149. The identification of target compounds was based on the relative retention time, the presence of target ions and their relative abundance. The quantification ion is *m*/*z* 149 for DEHP. The dwell time was 100 ms.

RESULTS AND DISCUSSION

The chromatogram in Figure 1 shows that the separation of DEHP and DBA, as internal standard, occurred within a running time of 20 min. Retention times for DBA and DEHP were 9.945 and 18.266 min, respectively.

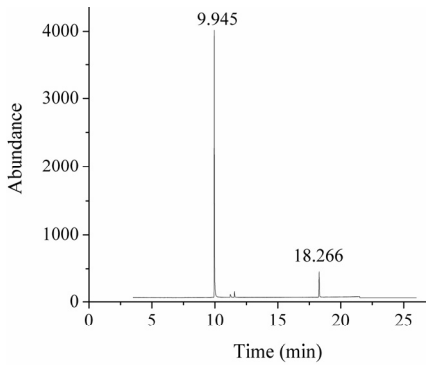

Figure 1. Chromatogram of a standard solution containing DEHP in concentration 0.25 µg cm^{-3} and DBA in concentration 1 µg cm^{-3}.

The analytical curve obtained for DEHP in concentration range 0.25–2.5 µg cm^{-3} is linear for the given range with coefficient of determination, R^2, of 0.9970 and linear equation y = -34868.945 + 170366.584x (Figure 2). Values of standard deviation for both coefficients, intercept and slope, were 1224.711 and 3329.021, respectively. *P*-value for obtained coefficient of determination was $P < 0.0001$.

The hexane extraction of solid samples has been applied for determination of DEHP due to high extraction efficiency for phthalates. The yield of extraction showed that more than 90% of the phthalates in solid samples are extracted in the first 15 days. Presented results are obtained after the extraction procedure which was carried out with the time period of 30 days.

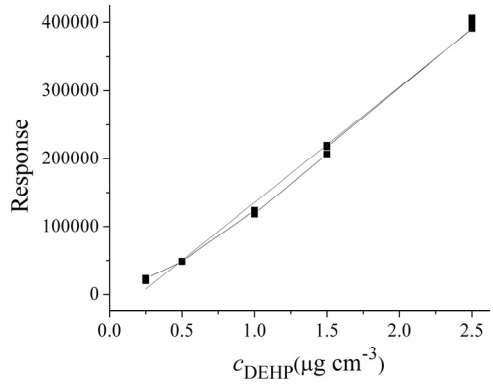

Figure 2. Analytical curve for DEHP for concentration range 0.25–2.5 µg cm^{-3}.

Table 1 presents the amount of plasticizers in the investigated set for peritoneal dialysis. DEHP was found in extracts from the bag and the tubing.

The determined DEHP concentration levels of 33––38% by weight of bag and tubing from peritoneal dialysis set are high but expected, bearing in mind the type of plastic material used for medical device production. The DEHP concentration levels in tubing were higher than DEHP concentration levels in dialysis bag, which is also expected due to more flexibile and soft performances of the tubing material.

Table 2 presents the amount of DEHP extracted from investigated LDPE solid materials. DEHP was found in the obtained extracts from the samples, although in low amounts.

Infusion bottle of physiological saline solution shows the higher concentration of DEHP than infusion bottle of Ringer's solution. But in both cases, about 90% of amount was extracted after 6 days. Despite of

Table 1. Concentration of DEHP in the packaging material (mg g^{-1}) from plastic medical devices (PVC) used for peritoneal dialysis determined for different extraction times (3, 6, 15 and 30 days); SD – standard deviation (n = 3); a–c: values with the same letter within a row are not statistically significant different at the p < 0.05 level (Tukey's HSD test)

Sample	Extraction time, days			
	3	6	15	30
Dialysis bag	23.02±1.24[a]	25.82±1.05[a]	301.00±23.58[b]	324.98±14.17[c]
Tubing from dialysis set	162.63±11.38[a]	319.13±28.37[b]	325.33±8.10[b]	351.18±28.74[b]

Table 2. Concentration of DEHP in the packaging material (mg g^{-1}) from plastic medical devices (LDPE) used for parenteral nutrition determined for different extraction times (3, 6, 15 and 30 days) SD – standard deviation (n = 3); a–c: values with the same letter within a row are not statistically significant different at the p < 0.05 level (Tukey's HSD test)

Sample	Extraction time, days			
	3	6	15	30
Infusion bottle (physiological saline solution)	0.0608±0.0087[a]	0.0706±0.0238[b]	0.0729±0.0013[b]	0.0748±0.0019[b]
Infusion bottle (Ringer's solution)	0.0104±0.0016[a]	0.0277±0.0015[b]	0.0453±0.0033[c]	0.0481±0.0053[c]
Tubing from infusion set	106.05±3.89[a]	112.51±8.79[a]	321.25±3.15[b]	394.49±3.47[c]

that, extraction procedure was carried out for 30 days, due to maximum possible leaching amount determination. Tubing materials show much higher amount of DEHP by weight of sample.

Even though, the investigated plastic LDPE material commonly does not possess plasticizers, the DEHP was found in the infusion bottles and also in the physiological saline solution and Ringer's solution which were stored in the infusion bottles. The contamination of these solutions is higher which is not expected due to low level of phthalate in packaging. This can indicate that the contamination is probably not only from the bottles where they are stored but from the tubing material that are used in their industrial preparation.

The results obtained by liquid–liquid extraction of DEHP from peritoneal dialysis solution and solutions for parenteral nutrition are given in Table 3. Very low amounts were leached by Peritoneal Dialysis Solution from PVC dialysis bag, despite the fact that dialysis bag contains DEHP in high concentration level. Concentration of DEHP in Ringer's solutions is higher than concentration in peritoneal dialysis solution and physiological saline solution. While bottle of physiological saline solution shows higher percentage DEHP than bottle of Ringer's solution, liquid sample from the same bottle shows lower concentration of DEHP.

Table 3. DEHP concentrations (μg dm^{-3}) in peritoneal dialysis solution, physiological saline solution and Ringer's solution stored in PVC bags and LDPE infusion bottles for different extraction times (60 min and 24 h); SD – standard deviation (n = 3); a, b: values with the same letter within a row are not statistically significant different at the p < 0.05 level (Tukey's HSD test)

Sample	Extraction time	
	60 min	24 h
Dialysis solution	3.58±0.29[a]	3.72±0.21[a]
Physiological saline solution	5.83±0.55[a]	8.83±0.19[b]
Ringer's solution	17.30±0.25[a]	21.16±2.51[b]

Difference between values of DEHP concentrations obtained for different extraction times were compared to a critical value in order to see if the difference is significant. The post-hoc test, Tukey's test, was performed and the test compares the difference between each pair of mean values with appropriate adjustment for the multiple testing. The critical value of q was obtained from table values, and it is the point when a mean difference becomes honestly significantly different. Critical values for solid and liquid samples are 3.96 and 3.46, respectively [28]. Values of HSD (honest significant difference) for each pair were computed by Origin© program. Comparing was performed in case $p < 0.05$.

Results obtained after performing Tukey's post-hoc test shows that there is no significant difference between result obtained for 3 days extraction period and 6 day extraction period for dialysis bag, while for tubing from dialysis set, obtained results show that there are significant differences only between results obtained for 3 day extraction period and other extraction periods (6, 15 and 30 days). The same results as for tubing dialysis set were obtained in testing solid samples of infusion bottles with physiological saline solution, while in the case of infusion bottles with Ringer's solution, there is significant difference, except for the extraction period between 15 days and 30 days. Results obtained in testing solid samples of tubing from infusion set show that there is significant difference, except for extraction period between 6 days and 3 days.

Results obtained in testing of liquid samples show that there is significant difference between obtained mean values for 60 min and 24 h extraction period for liquid samples of solutions for parenteral nutrition, while there is no significant difference between obtained mean values for 60 min and 24 h extraction period for liquid samples of dialysis solution.

On average, patient under peritoneal dialysis procedure receives about 8 dm^3 of peritoneal dialysis solution a day and it means that human body receives about 30 μg DEHP in total. This value is under estimated upper-bound dose of DEHP received by adult patients undergoing procedures of peritoneal dialysis 0.01 mg/kg per day (for adult with average body weight 70 kg). Furthermore, a considerable amount of the infused DEHP will be returned upon drainage of the perfusate from the peritoneum. Also, levels of DEHP which were detected in physiological saline solutions and Ringer's solutions are under estimated upper-bound dose of DEHP for these kinds of medical pro-

ducts, 0.005 mg/kg per day (for adult with average body weight 70 kg) [29].

CONCLUSION

A migration of DEHP from set for peritoneal dialysis that are made from PVC into dialysis solution and set for infusion parenteral nutrition that were made from LDPE into infusion solutions has been investigated. Concentrations of DEHP which are determined in peritoneal dialysis solution were about 3.72 µg dm^{-3}. Even though the determined concentrations in the dialysis set are higher than expected, the leached amount of DEHP in the dialysis solution is not significant. Although in low amounts, LDPE bags also showed DEHP in their composition. DEHP leached from PVC into solution is much higher than leached from LDPE bottles. The obtained values are under estimated upper-bound dose of DEHP received by adult patients undergoing procedures of peritoneal dialysis and parenteral nutrition.

The proposed sample preparation and sample extraction methods can be applied for the determination of these compounds in solid samples of different bottles used as medical devices and solutions stored in these bottles and bags. The presence of these compounds in the solid samples can be attributed to the different compositions of the plastic containers.

Control of material which is used for production of the plastic medical devices is essential to avoid human exposure to phthalates.

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IZVOD

ODREĐIVANJE DIETILHEKSIL FTALATA U PLASTIČNOJ MEDICINSKOJ OPREMI

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(Naučni rad)

Ispitivano je prisustvo dietilheksil-ftalata (DEHP) u medicinskoj opremi napravljenoj od polivinil-hlorida (PVC) i polietilena niske gustine (LDPE) koja se koristi u procesima peritonealne dijalize i parenteralne prehrane. Određivanje ftalata je izvršeno gasnom hromatografijom sa masenom detekcijom (GC–MS). Rezultati su pokazali da set koji se koristi u procesu peritonealne dijalize (kesa sa rastvorom i cevčica) napravljen od PVC sadrži DEHP u značajnoj količini, oko 31–34%. Rastvor za peritonealnu dijalizu, koji je čuvan u ispitivanoj PVC kesi, sadrži malu količinu DEHP, oko 3,72 μg dm^{-3}. Infuzione boce koje su napravljene od polietilena niske gustine (LDPE), takođe sadrže DEHP, ali u manjoj količini u odnosu na PVC kese. LDPE boca u kojoj se nalazio fiziološki rastvor (0,9% NaCl) sadrži veću količinu DEHP od LDPE boce u kojoj se nalazio Ringerov rastvor. Nasuprot tome, rastvori koji se se nalazili u bocama sa nižim sadržajem DEHP, tj. Ringerov rastvor sadrži oko tri puta veću koncentraciju DEHP od fiziološkog rastvora (0,9% NaCl) koji se nalazio u boci sa većim sadržajem DEHP. Određene koncentracije DEHP u Ringerovom rastvoru i fiziološkom rastvoru bile su 17,30 i 5,83 μg dm^{-3}, redom. Dobijeni rezultati su ispod utvrđenih dozvoljenih doza za DEHP kojima je odrastao čovek izložen tokom peritonealne dijalize i parenteralne prehrane.

Ključne reči: Ftalati • Plastični materijali • Medicinska oprema • Infuzioni set • Set za peritonealnu dijalizu