

Information to nurse care services was delivered by a pharmacy intern and a public health nurse after each insertion and during changes in dressings. Medical criteria (indications, complications, catheter operating times and removal reasons) and handling criteria (evaluation sheet by installers) were listed.

Results Mean age was 74 ± 15 years (G1) and 70 ± 17 years (G2). There were seven successful insertions and three failures due to venous access difficulties in G1; there were eight insertions in G2. Midlines were placed by anaesthetist (94% of cases) for antibiotic therapy or nutrition.

Median catheter use duration was 7 (2–24) days for G1 and 15.5 (1–65) days for G2. The reasons for withdrawal were: end of treatment (28.6% G1, 37.5% G2), accidental withdrawal by the patient (28.6% G1, 12.5% G2), thrombosis (14.3% G1), clogged catheter (12.5% G2), death (12.5% G2) and worsening of health (14.3% G1).

Positive opinions were expressed regarding the length of the catheter (100% G1 vs 33% G2) and ease of installation (86% G1 vs 67% G2). Comments were made for G1 (“rigid guide”) and for G2 (“complexity of handling a peel-away sheath”); 80% of installers who tested both devices preferred the Smartmidline.

Conclusion and relevance The various clinical situations and small number of patients made the medical criteria not relevant to make a choice. The handling criteria and practicality of the Smartmidline, as evaluated by caregivers, led to its recommendation. To secure its use, a hygiene protocol has been implemented in the hospital. To facilitate the interface between hospital and community carers, instructions for patients, doctors and pharmacists have to be reinforced.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Section 3: Production and Compounding

3PC-001 COMPATIBILITY AND STABILITY ASSESSMENT OF A SODIUM GLYCEROPHOSPHATE FORMULATION MIXED IN BAGS FOR NEONATAL TOTAL PARENTERAL NUTRITION

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10.1136/ejhpharm-2020-eahpconf.48

Background and importance At the end of 2018 there was a shortage and withdrawal from the market of D-fructose-1,6-diphosphate (Esafosfina), a phosphate source for the extemporaneous preparation of bags for neonatal total parenteral nutrition (TPN). Therefore, a solution of sodium glycerophosphate (Natriumglycerophosphat-Ampulle Fresenius) was imported from abroad. This solution is different because it contains L-malic acid as an excipient. No stability data on Natriumglycerophosphat-Ampulle Fresenius in TPN bags were found in the literature.

Aim and objectives To test the compatibility and stability of Natriumglycerophosphat-Ampulle Fresenius in TPN bags we prepared.

Material and methods Neonatal TPN formulations are customised: therefore, we identified three test formulations, with

varying concentrations of phosphate, calcium and magnesium (critical components), with and without lipids. Turbidity and pH controls were planned at appropriate time intervals (0, 24, 48, 72 and 96 hours after preparation) and under different storage conditions (room temperature, refrigerated and at 37°C). These controls were performed either with lipid free or with all in one formulations (all components, including lipids, are mixed in the same bag).

Results In lipid free formulations there was no formation of a precipitate at room temperature or under refrigerated conditions. The absorbance of the solutions at 600 nm (turbidity reading) remained below 0.010, which means no evidence of precipitation. There was precipitate formation under storage condition at 37°C (after 72 hours in test bags No1 and No2 and after 96 hours in bag No 3). The determining factors of the formation of this precipitate are alteration and degradation of the amino acids and the resulting pH reduction. In all in one formulations, we assessed stability with a microscope. Coalescence started in a bag 48 hours after preparation. Solution pH ranged from 5.5 to 6.5.

Conclusion and relevance Sodium glycerophosphate (Natriumglycerophosphat-Ampulle Fresenius) can be mixed with the usual components for neonatal TPN. In the test formulations there was no physical or chemical incompatibility. Lipid free formulations were stable for at least 96 hours. All in one formulations should be infused within 24 hours, especially if the amount of lipids is high.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-002 MICROBIOLOGICAL STABILITY TEST OF 15% TOPICAL RESORCINOL FOR QUALITY CONTROL

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10.1136/ejhpharm-2020-eahpconf.49

Background and importance Hidradenitis suppurativa (HS) is an inflammatory skin disease that causes painful boils and abscess formation, especially localised in intertriginous areas. Resorcinol is a phenol derivate, and in topical self-treatment decreases the size and pain of HS lesions.

Topical 15% resorcinol is prepared as a pharmaceutical compound and there are no data in the current literature on the microbiological stability of formulations of topical resorcinol 15%. The European Pharmacopoeia (EP) established acceptance criteria (chapter 5.1.4) for microbiological quality control of the compound. Previous to the microbiological quality assay, the EP also established the necessity of a suitability test of the method.

Aim and objectives The objective of the study was to develop a microbiological growth assay to perform a microbiological stability test for quality control of this resorcinol formulation.

Material and methods The composition of the formulation of topical resorcinol 15% tested was: resorcinol 15 g, purified water 15 g, sodium metabisulfite 0.1 g and lanette base cream qs 100 g.

To determine the ability of microorganisms to grow in the formulation, several reference strains, according to the EP (chapters 2.6.12 and 2.6.13) were selected: *Pseudomonas*

aeruginosa (ATCCVR 9027TM), *Candida albicans* (ATCCVR 10231TM), *Aspergillus brasiliensis* (ATCCVR 16404TM) and *Staphylococcus aureus* (ATCCVR 6538TM).

To perform the growth assay, trypticase soy agar (TSA) were used for *P. aeruginosa* and *S. aureus*, and sabouraud glucose agar (SAB) for *C. albicans* and *A. brasiliensis*.

The test was performed by taking a 1:1000 dilution of 1 g of topical resorcinol in a 0.1% Tween 80 and phosphate buffered saline solution and adding 100 µL of a suspension equivalent to 1×10^3 cfu/mL of every ATCC strain, which were inoculated in TSA or SAB. All tests were done in duplicate and medium lectures were made in 48 hours.

Results The ability of ATCC strains to growth in resorcinol formulation was confirmed under the study conditions. There was mean growth of 17×10^4 cfu/mL for *S. aureus* and 11×10^4 cfu/mL for *P. aeruginosa* in TSA. For *A. brasiliensis* and *C. albicans*, 1×10^4 cfu/mL and 2×10^4 cfu/mL were detected, respectively.

Conclusion and relevance The presented method shows a simplified way to test the microbiological viability of 15% topical resorcinol for quality control.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-003 TERLIPRESSIN PH STABILITY FOR CONTINUOUS INFUSION

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10.1136/ejhp-pharm-2020-eahpconf.50

Background and importance Terlipressin is a synthetic vasoconstrictor peptide similar to desmopressin, used to treat bleeding oesophageal varices and hepatorenal syndrome. Recent publications have shown greater efficacy via continuous infusion (CI) compared with intermittent bolus injection. This could be explained by its pharmacodynamic effect (<4 hours): in 24 hours, with injections every 6 hours, there may be ≥ 8 hours without pharmacological effect. Terlipressin is available in ampoules and is stable only at pH 3–4. It is not currently known if there is a variation in pH after dilution for continuous infusion, and its impact on stability.

Aim and objectives The objective of the study was to determine the pH variation after dilution of terlipressin in different diluents commonly used in clinical practice for administration as a CI.

Material and methods The diluents used were 0.9% NaCl (NS), 5% dextrose (D5W) and 3.3% dextrose–0.3% saline (DS). The initial pH measurement was performed with the commercial ampoule (8.5 mL) after reaching room temperature, as well as with the diluents separately. Subsequently it was diluted to 10, 20, 50, 100, 200, 250 and 500 mL. Triplicate pH measurements were made. The whole process was carried out at 23°C with a precision pH meter WTW inoLab pH level 1.

Results Initial pH values were: 3.94 ± 0.04 terlipressin, 5.62 ± 0.10 NS, 6.14 ± 0.04 D5W and 4.64 ± 0.04 DS. In NS, up to 10 and 20 mL, a slight decrease in pH was observed up to 3.92 ± 0.03 . Subsequently, the value increased exponentially, reaching a pH of 4.11 ± 0.06 in 500 mL of NS. This initial

behaviour was only observed with NS, while with D5W and DS the pH increase was exponential with the increase in volume, until reaching pH values of 4.15 ± 0.01 and 4.13 ± 0.02 , respectively, at 500 mL. In all three cases, a tendency to reach pH values >4 was observed, values in which the stability of the molecule would be compromised.

Conclusion and relevance The results show that pH values are within the terlipressin stability range. This makes it possible to dilute terlipressin with NS, D5W and DS in volumes between 50 and 500 mL (not higher), allowing administration in 24 hours by CI, reducing the dose and number of administrations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-004 PHYSICO-CHEMICAL STABILITY OF CEFEPIME IN POLYPROPYLENE SYRINGES AND IN ELASTOMERIC DEVICES

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10.1136/ejhp-pharm-2020-eahpconf.51

Background and importance Cefepime is a fourth generation cephalosporin used to treat severe infectious. For β -lactam antibiotics, publications have demonstrated that continuous administration is the preferred mode of administration. To the best of our knowledge, no stability data for cefepime solutions at 110 mg/mL in polypropylene syringes or at 50 mg/mL in elastomeric devices have been published.

Aim and objectives The objectives of the study were to assess the stability of cefepime solutions (1) at 110 mg/mL, in 0.9% sodium chloride (0.9% NaCl) or 5% dextrose (D5W), in polypropylene syringes at 20–25°C and (2) at 50 mg/mL, in 0.9% NaCl, in elastomeric devices at 37°C, after preparation and after storage for 6, 24 and 48 hours.

Material and methods Three preparations for each condition were made. For each analysis, one sample was taken from each preparation and analysed by high performance liquid chromatography. The method was validated according to the International Conference on Harmonisation Q2 (R1). Physical stability was evaluated by visual and subvisual inspection with a nephelometer. pH values were measured.

Results

1. In syringes, for each solvent, cefepime solutions at 110 mg/mL retained more than 90% of the initial concentration after 24 hours. No visual modification and no turbidity were observed. After 48 hours, the solutions retained around 83% of the initial concentration and pH values increased with the addition of 1 pH unit compared with the initial value.
2. In elastomeric devices, cefepime solution in 0.9% NaCl at 50 mg/mL retained more than 90% of the initial concentration over a period of 6 hours. After 24 and 48 hours, the solutions retained around 83% and 59% of the initial value, respectively. After 6 hours, visual colour modifications were observed. Under this condition, the initial pH value was 4.81 and 6.18 after 24 hours.

Conclusion and relevance The stability of cefepime in 0.9% NaCl and D5W at 110 mg/mL was demonstrated for 24 hours in syringes at 20–25°C. These stability data provide additional