AUTOMATION OF PARENTERAL NUTRITION COMPOUNDING

RESULTS OF GRAVIMETRIC QUALITY CONTROL BEFORE AND AFTER ITS IMPLEMENTATION

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BACKGROUND

The equipment for automated compounding systems (ACS) for parenteral nutritional (PN) admixtures are increasingly being used. Gravimetric control is a quality assurance test used in the preparation of nutritional admixtures. The international guidelines recommend this control to the final product and stated that the variation should be within 5%, ensuring an appropriate accuracy and safety of these parenteral solutions. However, it is recommended a 3% variation, mainly for pediatric parenteral nutrition.

OBJECTIVES

Impact evaluation of the ACS implementation on the quality of coumpounding parenteral nutrition solutions.
Testing the possibility of reducing the acceptable variation limit from 5% to 3%.

STUDY DESIGN

Statistical evaluation of the gravimetric quality control results of PN admixtures before (manual method and semi-automated method) and after ACS implementation.
Three samples of 580 PN admixtures for each specified compounding method were used.

Image 1 – Manual method

Image 2– Semi-automated method (Medimix®)

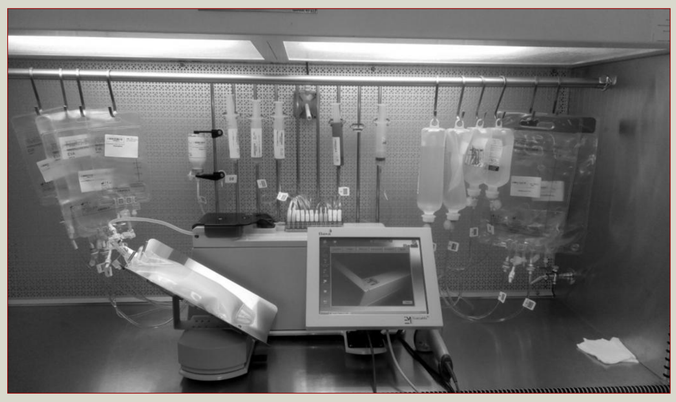

Image 3 - Automated compounding system (Baxa ExactaMix® 2400)

RESULTS

Deviation Interval (%)	Semi-automated method (Medimix®)	Manual Method	Automated method (Baxa Exactamix® 2400)
>5%	1	0	0
4-4,99%	1	0	0
3%-3,99%	0	9	0
2%-2,99%	11	26	0
1%-1,99%	75	202	6
0%-0,99%	219	263	361
-0,01% a -0,99%	151	63	211
-1% a 1,99%	59	12	1
-2% a 2,99%	33	0	0
-3% a -3,99%	19	2	0
-4% a -4,99%	8	3	0
<-5%	3	0	0
RESULTS			
Total PN admixtures	580	580	579
Mean deviation	-0,20	0,78	0,10
Standard deviation	1,44	0,91	0,39
PN admixtures within 3% interval/range	548	566	5
PN admixtures out 3% interval/range	32	14	0
Maximum positive deviation	8,95	3,51	1,5
Maximum negative deviation	-7,9	-4,35	-1,09

Table 1 – Summary of results

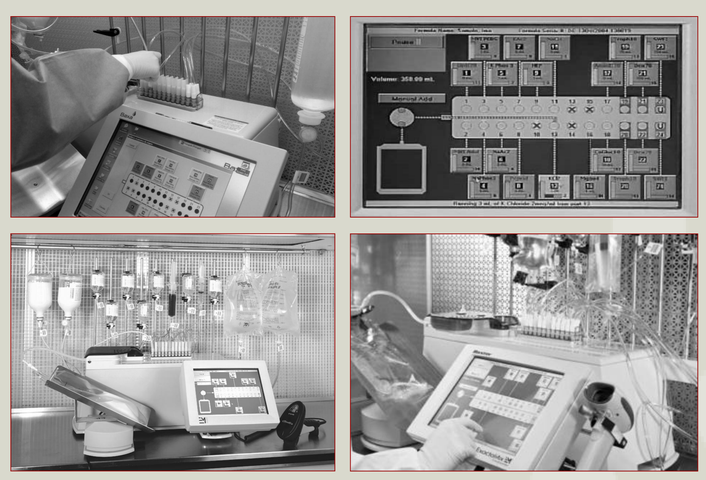

Image 4, 5, 6 and 7 – Automated compounding system (Baxa ExactaMix® 2400)

CONCLUSIONS

The automated compounding method was related to the lower mean for the theoretical weight deviation, as well as lower standard deviation, which indicates a lower error percentage but also a lower dispersion of the results for this method. Thus the implementation of ACS improved the accuracy of results for the gravimetric control of the PN admixtures, reducing to zero the number of solutions that exceed the acceptable range, thus increasing the safety of the admixtures produced and consequently, the safety of the patient.
The number of PN admixtures that exceeded the 3% margin, recommended for pediatric nutrition, was zero, so we concluded that we could reduce our test specification to 3%.

References:

1. ASHP Guidelines on the Safe Use of Automated Compounding Devices for the Preparation of Parenteral Nutrition Admixtures (2000). 57:1343-8;
2. Crill, Catherine. Accuracy of parenteral nutrition solutions compounded with automated systems and by hand. AJHSP, (2005) vol 62 Nov 15.
3. Cardona Pera D et al. Consenso Espanol sobre la preparacion de mezclas nutrientes parenterales 2008. Fam Hosp, (2009) 33 (sup 1), 81-107.

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