Pharmacoeconomics in Pediatrics

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Pharmacoeconomical Aspects of Treating Children with Perinatal Encephalopathy in a Hospital Environment

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This paper shows the results of ABC-VEN (expert) analysis of drugs used to treat children from 7 days to 3 years of age diagnosed with "perinatal encephalopathy" in the psycho neurological department of the Children's city Hospital of Belgorod. The research was conducted taking into account the syndrome approach to diagnosing. It was revealed that in the most costly groups (A and B) almost half of the medicines belonged to categories V and N, and 67.6% of the B group medicines were allocated to the E category. According to the expert VEN-analysis, the greatest number of drugs (34, or 51.5% of the total used) was from group E. Elements of irrational use of medicines are present in the treatment of the central nervous system excitation syndrome and autonomic-visceral disorders. In general it was found that there are some sources for drug therapy optimization in the treatment of each perinatal encephalopathy syndrome.

Keywords*: perinatal encephalopathy, ABC analysis, VEN-analysis.*

Today the level of clinical medicine and pharmacology development confronts the practical physician daily with a very difficult task of selecting the most appropriate medicine [1]. As a rule, the choice is made either in favor of a well-known brand name, or the cheapest one. In this regard, the development of rational methods of treatment which would take into account the economic evaluation of availability of

drugs is very important. The formulary system is a mechanism which makes it possible to ensure the most effective ways of supplying and using drugs [2]. A properly implemented formulary system contributes to positive economic results: first, it would allow to eliminate unsafe and ineffective drugs, which in turn would reduce morbidity and mortality and the duration of treatment and hospital stay. Second, it would reduce the number of purchased drugs, reduce the overall cost of the purchase, or give the opportunity to buy more safe and efficient medicines with the same means. Third, the existence of a final list of drugs in medical organizations would allow to conduct targeted training programs and to collect more complete information about the drug [3].

Despite significant advances in the treatment of perinatal encephalopathy, it remains one of the relevant problems of Pediatrics. Many researchers have reported that perinatal brain damage comprises more than 60% of all childhood diseases of the central nervous system (CNS), is directly involved in the development of diseases such as cerebral palsy, epilepsy, minimal brain dysfunction, etc. [4]. Based on the described, the purpose of this study was the optimization of drug provision for hospitalized children with perinatal encephalopathy, and evaluation of the rationality of expenditures on the provision of medicines for children with this pathology.

Patients and Methods

The study was conducted in the neuropsychiatric department of Children's City Hospital of Belgorod. We studied the medical records of hospitalized patients (histories) of children aged from 7 days to 3 years with the diagnosis "perinatal encephalopathy" for the period of 2006-2009.; Questionnaire surveys of medical experts; official sources of information [5, 6]. The methods of investigation were retrospective analysis of patterns of pharmacotherapy of hospitalized patients with the fixation of all medical drugs prescribed to patients with perinatal encephalopathy; ABC and VEN-analyses [2, 7, and 8].

While carrying out the ABC analysis all drugs were segmented according to their consumption and to their international nonproprietary names. It was found that the drugs of group A (10% of all stocks of the range) provided 80% of the consumption of drugs in the department, group B (15%) - 15%, group C (75%) - 5% of total consumption. A coefficient (Ki) for each drug was calculated in the process of analysis, which is the ratio of the medicine’s consumption to the total consumption of drugs for the treatment of children with perinatal encephalopathy. Further, all drugs were ranked in descending order of Ki to determine the boundaries of consumer groups and segmenting range. Am ABC cost analysis was performed with the calculation of the cost factor (Ks). All consumed drugs were ranked in descending order of Ks and divided into three groups: A - the most

expensive drugs, which consumed more than 80% of the costs, B- up to 15% of the costs, C - no more than 10% of the costs.

The peer approach was used for the VEN-analysis, by using the Delphi technique, which involves multiple tours of the survey procedure [9]. Working (3 persons) and expert (13) groups were created. All involved professional experts had the highest qualification category in the field of "neuroscience" and "neonatology". Individual interviews were conducted with questionnaires developed anonymously, i.e. personal contacts between experts and group discussions were excluded. The received responses were compared by the members of working group, and results were sent back to the members of the expert group. Experts, remaining anonymous, continued the further sampling. After a convergence of views started to emerge, the results were used as a prediction. In the first section of the questionnaire the expert was offered to indicate his/her professional affiliation (work experience, qualification category and the degree), characterizing him/her as a professional and reflecting objective competence; in the second section he/she was asked to estimate the incidence of syndromes for each type of perinatal encephalopathy according to the clinical classification, in the third – to specify the motivating factor that influenced the assessment of drugs. The analysis included drug groups A and B of the ABC analysis. The proposed range of drugs has been divided according to the syndrome approach to diagnosis. The obtained data was subjected to statistical questionnaires to determine the "average" scoring of every medicine out of the whole range of drugs. For each drug scorecards were compiled taking into account the competence of the expert. Given the "weighted average" assessment of each drug the boundaries of their meanings were identified determining the distribution of the following groups: vital (V), the necessary (E) and secondary (N).

In the course of this study, it was decided that the use of such terms as "vital medicines" in its correct sense i.e. when the removal of drugs leads to death is not acceptable in the treatment of perinatal encephalopathy. In this regard, we consider it more appropriate to use the term "basic drugs" for group V, meaning that it’s not possible to treat the nosology without them and their use will significantly improve the prognosis and course of the disease. Drugs that markably improved the course of the disease were included into category E. Erroneously attributed drugs or drugs with a low efficacy were included into group N.

Results and Discussion

A retrospective analysis of 504 medical records showed that among all patients undergoing treatment with a perinatal damage of the CNS, there were 421 (83.5%) children aged from 7 days to 1 year and 83 (16.5 %) from 1 year to three years of age. The diagnosis of combined ischemic and hemorrhagic CNS damage (no

traumatic) (according to "Classification of perinatal damages of the nervous system and their impact on children of the first year of life," MKB-10) was present for 483 (95.8%) children, the hypoxic nature of the damage - in 14 (2.7%), traumatic injuries of the nervous system - in 7 (1.4%) [10]. The average length of stay of children in hospital was 15 ± 2, 35 bed-days.

During the ABC consumption analysis group A with the boundaries of Ki from 18.0 to 1.2 consisted of 14 medicines (32.5% of all names): diuretics - 3, psycho stimulants and nootrops - 3, mineral supplements – 2; antiepileptic – 1; anxiolytics – 1; other drugs for the treatment of the nervous system – 1; electrolyte solutions – 1; hypnotics and sedatives - 1; antidiarrheal of biological origin - 1. Group B with the boundaries of Key 0,89-0,03 28 consisted of 28 drugs(65.1% of all names): antiepileptic – 3; antidiarrheal, intestinal, anti-inflammatory and antimicrobial – 3; psycho stimulators and nootrops – 3; other drugs for the treatment of diseases of the nervous system – 2; vitamins – 4; drugs for the treatment of functional disorders of the gastrointestinal tract – 2; digestive - 2; mineral supplements – 2; drugs used in conditions associated with impaired acid - 1; laxatives - 1; for the treatment of diseases of the gastrointestinal tract and metabolism – 1; for the treatment of hear diseases – 1; other hematologic drugs - 1; muscle relaxants – 1;peripheral vasodilators - 1. Group C consisted of two drugs (4.6% of all names): furosemide (Lasix) (Sopharma AD, Bulgaria) and Hilak forte (Ratiopharm RUS Ltd., Russia). Duing the ABC cost analysis, the results turned out to be comparable. Group A, with the boundaries of Ks from 9.8 to 1.1 had 14 drugs (32.5% of all titles), group B with the boundaries of Ks from 0.4 to 0.02 - 28 (65.1%), group C with 0.008 Ks had 1 drug (2.4%) - Forte Hilak (Fig. 1). In the most expensive groups (A and B), almost half belonged to the categories V and N, and 67.6% of B group was transferred to E group (Table 1).

Expert VEN-analysis revealed nine drugs of category N, indicating the inexpediency of their use (13.6% of the total number of names of drugs) (see Table. 1). Category V had 23 drugs (35%). The greatest number of drugs - 34 (51.5%) - was in the E group. From secondary products only 8 had a confirmed clinical efficacy (antiepileptic, psyholeptics, antidiarrheal, intestinal anti-inflammatory and antibacterial), all the rest were used according to the traditions of clinical practice (Nicergoline, Cavinton, Cinnarizine, Riboksin, alpha-tocopherol acetate, etc.).

The results of the ABC and VEN-analyses are summarized in table 2. According to the expert VEN-analysis accounting for the predominant clinical syndrome it was found that for the treatment of the central nervous system excitation syndrome (R91.3) five drugs were assigned, which have been categorized under N (45,4% of all the names used for this syndrome) - in the

majority from the anticonvulsants group. Three drugs were included in the category of V and E (27.3%). Particular attention was drawn to the distribution of carbamazepine (Finlepsin, AWD pharma GmbH, Germany) into category N - the sole representative of this category which entered group A based on costs (see Table. 2). Pharm economical analysis of the average cost of drug therapy per patient per course of treatment showed that the treatment of central nervous system excitation syndrome (R91.3) cost 485.6 rubles. Given the limitations of the use of drugs from the N group, costs could have been reduced by two times.

In the treatment of seizures (P90), symptomatic seizures and situational paroxysmal disorders (R56.0; R56.8) nine medicines were used, which the experts had uniformly distributed across categories. The base drug was phenobarbital (Tatkhimpharmpreparaty, Russia). There were no N reserve drugs in group A for consumption and costs. For group B the experts named carbamazepine, diazepam (Sibazon) (Virion, Russia), Valproic acid (Depakine) (Sanofi-Aventis, France) according to the consumption and costs as a reserve (E). In the treatment of seizures (P90), symptomatic seizures and situational paroxysmal disorders (R56.0; R56.8) the average cost of drug therapy per patient was, respectively, 887.95 and 880.65 rubles. Based on this data we can conclude that a rational use of drugs and the optimal choice were made.

In the analysis of drug therapy of the intracranial hypertension syndrome (R91.8) and benign intracranial hypertension (G93.2) there were no drugs in category N. However, the basic drug furosemide joined group C when it was evaluated according to consumption. The other drugs (4) were all in group A. The average cost of drug therapy was 617, 56 rubles. Thus, in general, there has been quite rational drug consumption and optimal assignment.

In the treatment of the autonomic-visceral disturbances syndrome (R91.8) and the autonomic nervous system disorders (G90.5) 25 different drugs were used (see Table. 1). The basic amount of designated drugs (16) was from the reserve category (E), four drugs (16% of all appointed for this syndrome) comprised the base category (V), of which only etilmetilgidroksipiridin succinate (Meksidol) (Farmasoft SPC Ltd., Russia) came into Group A; the other drugs were included into group B according to their consumption and cost. Group C had a reserved drug - Hilak forte. As experts determined, category «N» was composed of five drugs (20% of all appointed for this syndrome). It is interesting, that three of the medicines in this category were part of group A (see Table. 1). The average cost of drug therapy was 556.7 rubles. Concerning the drugs of group N, we can say the following. It’s necessary to substantially limit or revoke medicines such as activated charcoal, dried bifid bacteria, calcium gluconate and calcium

glycerophosphate and magnesium sulfate with this syndrome, because their use is not pathogenically justified, and only increases the cost of treatment.

In the treatment of the syndrome of motoric disturbances (R94.8), the CNS depression syndrome (R91.4) and delayed motoric development (F82) there were no N category medicines identified (see Table. 1). Two reserve drugs (E) included in the treatment of CNS depression syndrome belonged to Group A: - polypeptides of the cerebral cortex (Cortexin, Geropharm Ltd., Russia) and Vinpocetine (Cavinton, Gedeon-Richter, Hungary), and such drugs as choline alfostserat (Gliatilin, Italfarmako, Italy) and Actovegin (Nycomed, Norway), from the category of the base drugs (V) comprised group A according to costs and to group B according to consumption. Vinpocetine, used in the treatment of delayed psychomotor development, belonged to group A according to consumption and costs. According to the results of the pharmacy-economical analysis the most expensive was the pharmacotherapy of motor development delays (F82) - 1185, 4 rubles. According to the ABC and VEN-analyses, evidence of irrational spending of medicines under these syndromes has not been identified.

Conclusions:

1. In general, based on ABC and VEN-expert analysis criteria, medicines are spent rationally while treating perinatal encephalopathy at children in the Children's City Hospital of Belgorod.

2. In the treatment of the central nervous system excitation syndrome, the syndrome of autonomic-visceral disorders, disorders of the autonomic nervous system there is a tendency for the appointment of drugs with little or unproven efficacy. This group of drugs are: antiepileptic (carbamazepine, valproic acid, phenytoin), mineral supplements (calcium glycerophosphate, calcium gluconate, magnesium sulfate), antidiarrheal, probiotic means (activated carbon, Bifid bacterium bifid), which on one hand create excessive drug load on the child's body and on the other lead to unnecessary hospital spendings. A sensible approach to drug designation will reduce the cost of drug therapy by two times.

3. In the treatment of each syndrome there are certain reserves for drug use optimization, primarily due to terminating and reducing secondary drug prescriptions (group E and N).

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Fig. A. The distribution of medicines based on costs according to ABC-analysis

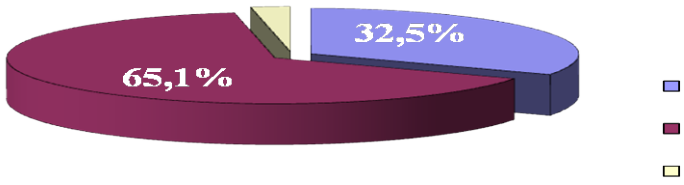

Table 1: The distribution of drugs according to cost for groups A, B, and C (the results of ABC analysis) and categories V, E, N (results of expert VEN-analysis)

Group	Total number of drugs, abs.	From them					
		V		E		N	
		Abs.	%	Abs.	%	Abs.	%
A	27	13	56,5	10	29,4	4	44,4
B	38	10	43,5	23	67,6	5	55,5
C	1	-		1	2,9	-	
Total	66	23	100	34	100	9	100

Table 2: The results of the ABC and VEN-analyzes of drugs used in the treatment of perinatal CNS lesions in newborns and infants in the hospital

№	International generic name	Trade name, form of release, manufacture, country	ABC-analysis		VEN-analysis	
			Ki-consumption /group	Ki cost/ group	"Weighted average" score	Group
1	2	3	4	5	6	7
Excitation of the central nervous system syndrome (**(P91.3)**						
1	Gopantenovaya acid	Pantogam in tablets. (Pik-pharm, Russia)	0,1 / B	0,3 / B	4,9	V
2	Magnesium sulfate	Magnesium sulfate in ampullas, (Biosynthesis, Russia)	5,0 / A	1,1 / A	4,5	V
3	Phenobarbital	Phenobarbital in tablets. (Tathim-pharmaceuticals Inc., Russia)	8,6 / A	0,1 / B	4,5	V

4	Magne B 6	Magne B 6 in tablets (Sanofi-Aventis, France)	0,1 / B	0,3 / B	3,6	E
5	Phenylbutyric acid hydrochloride	Phenibut in tablets(Olaine Farm, Latvia)	3,1 / A	0,4 / B	3,6	E
6	Diazepam	Sibazon in ampulla (Federal State Unitary Enterprise Moscow Endocrine Plant, Russia)	0,1 / B	0,07 / B	3,0	E
7	Tolperizon	Tolperizon Mydocalm in tablets (Gedeon-Richter-Rus, Russia	0,1 / B	0,1 / B	1,7	N
8	Carbamazepine	Finlepsin in tablets (AWD pharma GmbH Germany)	0,89 / B	1,3 / A	1,7	N
9	Valproic acid	Depakine, syrup (Sanofi-Aventis, France)	0,2 / B	1,4 / B	1,0	N
10	Phenytoin	Diphenin in tablets (Akrihin, Russia)	0,7 / B	0,1 / B	1,0	N
11	Calcium glycerophosphate	Calcium glycerophospha te in tablets	0,25 / B	0,02 / B	1,0	N

		(HFZ Lugansk, Ukraine)				
1	2	3	4	5	6	7
Seizures of newborn (P90) Symptomatic seizures and paroxysmal disorders caused by paroxysmal disorders (R56.0; R56.8)						
1	Calcium Gluconate	Calcium Gluconate in ampulla (Darnitsa-(Russia)	7,5 / A	4,4 / A	4,9	V
2	Magnesium sulfate	Magnesium sulfate in amp.	5,0 / A	1,1 / A	4,9	V
3	Phenobarbital	Phenobarbital in tablets	8,6 / A	0,1 / B	4,6	V
4	Carbamazepine	Finlepsin in tablets	0,89 / B	1,3 / A	3,9	E
5	Diazepam	Sibazon in ampulla	0,1 / B	0,07 / B	3,8	E
6	Valproic acid	Depakine syrup	0,2 / B	1, 4 / B	3,4	E
7	Phenytoin	Diphenin in tablets	0,7 / B	0,1 / B	1,6	N
8	Tolperizon	Mydocalm in tablets	0,1 / B	0,1 / B	1,4	N
9	Calcium glycerophosphate	Calcium glycerophosphate in tablets	0,25 / B	0,02 / B	1,2	N
The syndrome of intracranial hypertension (R91.8) Benign intracranial hypertension (G93.2)						
1	Acetazolamide	Diakarb in tablets (Akrihin, Russia),	2,2 / A	2,6 / A	4,9	V
2	Asparaginat Mg and K	Asparcam in tablets (HFZ Lugansk, Ukraine)	1,6 / A	0,1 / B	4,9	V
3	Furosemide	Lasix in amp.	0,02 /	0,01 / B	4,6	V

		(Sopharma Inc. Bulgaria)	C			
4	Hydrochlorothiazide + Trimateren	Triampur com-pozitum in tablets (AWD pharma GmbH Germany)	1,2 / A	2,1 / A	4,0	V
5	Magnesium sulfate	Magnesium sulfate in ampulla	5,0 / A	1,1 / A	3,7	E
The syndrome of visceral autonomic disturbances (R91.8) Autonomic disorder of autonomic nervous system (G90.9)						
1	Cinnarizine	Cinnarizine in tablets (Darnitsa, Russia)	0,7 / B	0,1 / B	4,2	V
2	Levocarnitine	Elkar solution (Pik pharm Russia)	0,5 / B	2,1 / A	4,2	V
3	Etilmetilgid roksipiridina succinate	Meksidol in ampulla (Farmasoft SPC Ltd., Russia)	2,0 / A	5,1 / A	4,2	V
1	2	3	4	5	6	7
4	Nicergoline,	Nicergoline in tablets (Moschim-pharmaceuticals named after Semashko, Russia)	0,1 / B	0,2 / B	4,1	V
5	Nicergoline	Nicergoline in ampulla	1,2 / A	4,1 / A	3,5	E
6	Vitamin E	Alpha-tocopherol acetate, oral solution (St. Peters-burg	0,2 / B	0,1 / B	3,5	E

		NIIVS, Russia)				
7	Vinpocetine	Cavinton in tablets (Gedeon Richter, Hungary)	4,2 / A	2,2 / A	3,4	E
8	Actovegin	Actovegin in ampulla (Nycomed, Austria)	0,1 / B	1,5 / A	3,4	E
9	Riboksin	Riboksin in ampulla (Moskhim pharmaceuticals named after SeMashkov, Russia)	0,3 / B	0,2 / B	3,2	E
10	Peppermint Leaf oil + Phenobarbital + etilbromizo valerian	Corvalol drops (Pharmstandard -Medicines JSC, Russia)	1,4 / A	0,2 / B	3,2	E
11	Drotaverine	No-spa in amp. (Hinoin, Hungary	0,7 / B	2,3 / A	3,2	E
12	Linex	Linex in capsules (LEK,	0,3 / B	0,7 / B	3,0	E
13	Simethicone	Espumizan emulsion (Berlin-Chemy, Germany)	0,3 / B	0,6 / A	3,0	E
14	Lactulose	Duphalac syrup (Solvay-Pharma, The Netherlands)	0,1 / B	0,2 / B	3,0	E
15	Hilak forte	Hilak forte	0,008 /	0,008 / C	2,9	E

		drops (Ratio-pharm RUS Ltd., Russia)	C			
16	Pancreatin	Mezim Forte in tablets (Berlin-Chemy, Germany),	0,4 / B	0,5 / B	2,8	E
17	Pancreatin	Creon in capsules, (Abbott, Germany)	0,03 / B	0,1 / B	2,8	E

1	2	3	4	5	6	7
18	Smectite dioctyl	Smecta oral powder (Beaufour-Ipsen, France)	0,06 / B	0,06 / B	2,8	E
19	-	Almagel, susp. (Balkanfarma, Bulgaria)	0,04 / B	0,02 / B	2,8	E
20	Procaine	Novocain in ampulla (Veropharm, Russia)	0,3 / B	0,05 / B	2,6	E
21	Coal-centered activated	Coal-centered activated in tablets (Aspfarma, Russia)	0,3 / B	0,009 / B	2,0	N
22	Bifid bacterium bifid	Bifid bacterium bifid oral lyophilized(Vita-Pharma, Russia)	18,0 / A	8,7 / A	1,4	N
23	Calcium gluconate	Calcium gluconate in amp	7,5 / A	4,4 / A	1,4	N
24	Calcium glycerophosphate	Calcium glycerophosphate in tablets	0,25 / B	0,02 / B	1,4	N

25	Magnesium sulfate	Magnesium sulfate in amp.	5,0 / A	1,1 / A	1,4	N
The syndrome of motor disturbances (R94.8)						
1	Actovegin	Actovegin in amp	0,1 / B	1,5 / A	4,4	V
2	Pyridoxine	Pyridoxine Hydrochloride in amp (Veropharm, Russia)	0,8 / B	0,1 / B	3,9	E
3	Thiamine	Thiamine Chloride in amp. (Mosch-pharmaceuticals named after Semashko Inc., Russia)	0,2 / B	0,03 / B	3,9	E
4	Riboflavin	Riboflavin in tablets (Altayvi-Tiamines, Russia)	0,2 / B	0,03 / B	3,8	E
5	Magne B6	Magne B6 in tablets	0,1 / B	0,3 / B	3,7	E
Syndrome of CNS depression (91.4 F)						
1	Piracetam	Piracetam in amp Pharmstandard, Russia)	0,2 / B	0,05 / B	4,1	V
2	Choline alfostserat	Gliatilin in amp. (Italfarmako, Italy)	0,4 / B	1,8 / A	4,0	V
1	2	3	4	5	6	7
3	Cinnarizine	Cinnarizine in tablets	0,7 / B	0,1 / B	4,0	V
4	Actovegin	Actovegin in amp	0,1 / B	1,5 / A	4,0	V

5	Polypeptides of the cortex of brain	Cortexin in amp (Geropharm Ltd., Russia)	1,5 / A	9,8 / A	3,5	E
6	Levocarnitine	Elkar solution	0,5 / B	2,1 / A	3,5	E
7	Gopantenovaya acid	Pantogam syrup	0,1 / B	0,2 / B	3,5	E
8	Vinpocetine	Cavinton in tablets	4,2 / A	2,2 / A	3,0	E
9	Vitamin E	AlphaTokoferoll acetate oral sollution	0,2 / B	0,1 / B	2,9	E
Delayed motor development (F82)						
1	Actovegin	Actovegin in amp	0,1 / B	1,5 / A	4,8	V
2	-	Cerebrolysin in amp.	2,0 / A	9,5 / A	4,2	V
3	Gopantenovaya acid	Pantogam in tablets	0,1 / B	0,3 / B	4,1	V
4	Polypeptides of the cerebral cortex	Cortexin in amp	1,5 / A	9,8 / A	4,1	V
5	Piracetam	Piracetam in amp	0,02 / B	0,03 / B	4,0	V
6	Glycine	Glycine in tablets	2,3 / A	0,4 / B	3,9	E
7	Pyridoxine	Pyridoxine Hydrochloride in amp	0,8 / B	0,1 / B	3,9	E
8	Cinnarizine	Cinnarizine	0,7 / B	0,1 / B	3,5	E
9	Vinpocetine	Cavinton in tablets	4,2 / A	2,2 / A	3,0	E