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THE RESULTS OF EXPERIMENTAL AND CLINICAL STUDY OF THE EFFICACY OF THE ANTISEPTIC PRODUCT DECASAN

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Key words: antiseptics, Decasan, local bacterial infections

Introduction

Contemporary epidemiological situation is characterized by increased proportions of local inflammatory disease, caused by antibiotic-resistant opportunistic microflora. Using the modern systemic antimicrobial agents, such as fluorquinolones, cephalosporin and carbapenem antibiotics for the treatment of these diseases is costly and unpractical. Therapy with antiseptic agents is the most available and effective treatment for local infections. Unfortunately the selection of antiseptic agents available to the healthcare settings is outdated and fails to meet the contemporary challenges. In the National List of the principal (vital) medications and medical products, approved by the Decree of the Cabinet of Ministers of Ukraine dated 16 November 2001 No. 1482, the group of antiseptic agents includes such products, as boric acid, iodine-based products, hydrogen peroxide, potassium permanganate, ethanol and brilliant green. In fact, this list has migrated to the present from the 19th century. The only contemporary agent in the above list is chlorhexidine bigluconate, supplied by domestic manufacturers only as 0.05% solution in special containers, intended for prevention of sexually-transmitted disease. The inter-hospital pharmacies attempt to meet the demands of healthcare settings for antiseptic agents by preparing the solution of Furacilin. However, there are almost no Furacilin-susceptible organisms left in the nature; certain species even manage to utilize it. Due to this fact the above mentioned product has become a known reservoir of the microbial agents, causing nosocomial purulent and inflammatory infections. Given the unfavourable situation with the supply of antiseptic agents, outlined above, a positive step was made by domestic pharmaceutical industry. In 2002 the pharmaceutical company 'Yuria-Pharm' had launched batch-scale production of the ready-to-use liquid dosage form of an antiseptic, the Decasan product. The product is supplied as vials of 100 mL, 200 mL and 400 mL volume. The aim of this study was to perform comparative efficacy study of Decasan and a number of widely known antiseptic agents.

Materials and methods.

Batch-scale production product Decasan, manufactured by the pharmaceutical company Yuria-Pharm was used during the study. The product had the following composition: decamethoxin (FS 42U046-152-97) – 0.2 g; sodium chloride (FS 42-2572-88) – 9.0 g; water for injections (FS 42-2620-89) – up to 1 L. The therapeutic efficacy of Decasan was studied using the experimental model of pneumonia in rats. Pneumonia was caused by intra-tracheal administration of 1 mL of the suspension of the daily culture of Kl. pneumoniae, which contained 1 x 103 of bacteria. Decasan was used as an, aerosol, which was obtained using a household air humidifier in a specially designed chamber. The supply mode was adjusted taking into consideration the rate at which the solution was fed into the chamber, the respiratory rate, the depth of breathing and the respiratory volume of the animals, which allowed calculating the amount of the product entering the airway. The treatment of the infected animals was started in 12 hours after infecting. Inhalations were performed 2 times a day 20 minutes each. The experiment was performed in 20 rats. The control group included 20 animals, which received inhalations of sterile isotonic sodium chloride. The therapeutic efficacy of the drug under experimental conditions was assessed by comparing survival rates and overall survival times of the investigational and control animals. Clinical study of therapeutic efficacy of Decasan was performed by observing the group of 58 paediatric patients, age between 2 and 8 years. All children with chronic obstructive bronchitis were admitted to hospital during exacerbation. The first group of observation was made of 30 patients, which received antibiotics, broncholytics and physical therapy. The second group of children under observation consisted of 28 subjects, which, in addition to the above therapies, received Decasan. The latter was administered via inhalation in the volume of 5-10 mL using an ultrasound nebulizer.

The therapeutic efficacy of Decasan in patients with surgical disease was studied by observing the patients treated in a surgical hospital setting for post-injection abscess, carbuncles and cellulitis, affecting soft tissues. The first group included 30 patients in which local treatment of wounds was performed using hydrogen peroxide, Furacilin and hypertonic solution of sodium chloride; the second group included 29 patients, in whom the wounds were treated with Decasan. Surgical debridement of the purulent site in all patients involved broad tissue excisions, opening of all pouches and purulent leakages. Wound cavity was irrigated by one of the applicable solutions. Small cavities were filled with small gauze napkins, soaked with the same solution. Perforated drainage tubes were introduced into larger cavities; the tubes were subsequently used for irrigation with the investigational antiseptics. Wound dressing and wound irrigations were performed daily until complete clearance of wounds.

Results and Discussion.

Observation of animals with experimental Klebsiella-induced pneumonia has indicated that in all experimental animals the respiration was changed, dyspnoea was observed, the rats refused food; all animals had nasal discharge and conjunctivitis. In one day after the onset of treatment with Decasan aerosol the condition of the rats has improved: dyspnoea had relieved, the amount of nasal discharge had decreased; compared to untreated animals, the treated counterparts were consuming food. In 5-7 days after the onset of the disease the rats receiving inhalation therapy were not different from healthy animals in terms of appearance. Most of the animals in the control group have died by that time.

The results concerning survival and overall survival time assessments in the investigational and control animals are given in Table 1.

Table 1. The results concerning survival rate and overall survival time assessments in the investigational and control animals

Product	n	Survival	
		abs.	%
Isotonic sodium chloride solution	20	6	30
Decasan	20	17	85

*the maximum possible life span of the animals

The data in table 1 are evident of the fact that using Decasan as an aerosol ensured survival of 85% of rats with pneumonia, whereas survival rate was only 30% among the untreated animals, which is 2.8 times less compared to the investigational group.

The results of clinical assessment of the efficacy of Decasan as aerosol therapy are given in table 2.

The analysis of data in Table 2 is indicative of the fact that children treated with Decasan inhalations tend to have earlier relief of catarrh, shorter duration of febrile reaction, faster relief of dyspnoea, rales and cough. Due to the high therapeutic efficacy of inhalations with Decasan hospital stay is reduced by 4 days.

In order to perform clinical assessment of the efficacy of local treatment for surgical purulent and inflammatory lesions of soft tissues, the duration of hydration phase and hospital stay were compared in patients of Group 1 and Group 2.

In group 1 the duration of the hydration phase was 8.4 ± 0.7 days; in Group 2 it was 5.7 ± 0.5 days. Hospital stay in the surgical setting in Group 1 and Group 2 was 12.6 ± 1.0 and 10.1 ± 0.8 days, respectively.

Thus, the results of the experimental study and clinical observations indicate the high therapeutic efficacy of batch-scale samples of the novel domestically-produced antiseptic product Decasan in the treatment of local inflammatory diseases of microbial origin in various locations.

Table 2. The influence of the methods of treatment used on the duration of clinical manifestations of obstructive bronchitis (days).

The symptoms of the disease	The group of children receiving inhalations of decamethoxin	Control group	p
	M ± m		
Febrile reaction	1.8 ± 0.31	2.4 ± 0.41	>0.05
Dyspnoea	2.38 ± 0.21	4.41 ± 0.32	<0.05
Cough	4.94 ± 0.73	8.2 ± 0.56	<0.05
Dry rales	3.2 ± 0.41	5.1 ± 0.27	<0.05
Moist rales	4.5 ± 0.52	7.6 ± 0.43	<0.05
Catarrhal changes in the nasopharynx	5.6 ± 0.48	8.2 ± 0.74	<0.05
Hospital stay	7.8 ± 0.56	11.8 ± 0.34	<0.05

The principal active ingredient of the investigational product Decasan is the domestically produced antiseptic agent decamethoxin, the unique polytropic therapeutic properties of which are widely known.

First of all, a broad antimicrobial spectrum of the product has to be noted. Decasan possesses bactericidal, fungicidal, virucidal and anti-protozoal actions. The minimal bactericidal concentration (MBC) of the drug against Staphylococci is 0.9 μg/mL; the drug is bactericidal against the representatives of the Enterobacteria family at 7.8 – 31.2 μg/mL. The yeast-like fungi of genus Candida are killed in the presence of 7.8 μg/mL of decamethoxin. Pseudomonas aeruginosa, the most decamethoxin-resistant species, is killed in decamethoxin concentrations over 125 μg/mL [Paliy et al., 1997]. Thus, Decasan, which maintains the concentration of decamethoxin at 200 μg/mL, covers the entire spectrum of pathogens and opportunistic infections with its bactericidal action.

The aggregate of aetiological and pathogenetic links of the development of inflammatory disease, caused by microbial agents, calls for utilization of immune-modulating and desensitizing agents, among others, in addition to antimicrobial agents. The weakened system of the patient often fails to cope with extensive pharmacological burden, which produces drug intolerability and worsens the course of the disease. Therefore, the drugs with polytropic action and favourable impact on various links of pathogenesis of the disease are especially valuable.

Apart from antimicrobial effect, Decasan has a positive influence on natural and specific immunological reactivity, causes statistically significant increase of complement titre. The desensitizing action of the drug is manifested as delayed development of anaphylactic shock in experimental animals [Paliy, 1973].

Decasan was proven to possess anti-inflammatory action, whose mechanism of action is related to inhibition of cellular serotonin production and the related anti-oedema effect [Polyachenko, 1995].

In studies of diphtheria agents subject to Decasan influence, the sub-bacteriostatic concentrations of the drug were demonstrated to inhibit the formation of exotoxin. This property, along with a powerful antimicrobial action, allowed the Ministry of Health to recommend Decasan to control the epidemics of diphtheria in 1994 [Volyanskyi et al., 1994].

A useful property of Decasan is its ability to increase susceptibility of microflora to antibiotics. The presence of sub-bacteriostatic doses of Decasan potentiates the effect of kanamycin, gentamycin, streptomycin, erythromycin, penicillin, tetracycline et al. [Rakovska et al., 1979].

The experiments on isolated fragments of the intestine have revealed a marked anti-spasmodic effect of Decasan, which approximates that of No-Spa (drotaverine). It is evident that this effect, in addition to anti-microbial action, determines the high efficacy of Decasan in patients with chronic bronchitis and bronchial obstruction syndrome [Biktimirov, 1995].

Positive experiences of Decasan utilization were accumulated in the fields of Dentistry, ENT, Gynaecology, Proctology, Urology and other fields if medical practice.

Taking all of the above into consideration, it is important to stress once again that given the lack of highly efficient antiseptics at the pharmaceutical market, the launch of production of the first locally produced pharmaceutical of this kind by domestic pharmaceutical industry is a significant achievement, which may solve a number of current problems in the therapy of diseases, caused by microorganisms.

It should be also stressed, that Decasan should be included into the aforementioned National List of the principal (vital) medications and medical products.

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Abstract

The article presents the results of experimental study and clinical observations of therapeutic efficacy of a novel domestically-produced antiseptic product, namely Decasan. The results of treatment in patients with chronic bronchitis using inhalations with Decasan are presented. High efficacy of using Decasan in surgical treatment of patients with purulent inflammatory disease affecting soft tissues is demonstrated.

Key words: Antiseptics, Decasan, local bacterial infections