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THE EFFICACY OF DECASAN ANTISEPTIC AGENT

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Abstract. The work presents the results of study of antimicrobial properties of batch production samples of antiseptic pharmaceutical products Decasan and Myramistin. Experience of clinical use of Decasan in treatment of patients with purulent and inflammatory lesions was summarised.

Key words: antiseptic agents, Decasan, therapeutic efficacy, pneumonia.

Introduction

The aetiological structure of purulent inflammatory disease is dominated by opportunistic organisms, which are characterised by multiple resistance to antibiotics. The horizontal conjugative transmission of genetic determinants of resistance within the microbial population promotes propagation of antibiotic resistance, which develops substantially faster than marketing of new and effective drugs. Along with peculiarities of pharmacokinetics of systemic drugs, which does not allow creating required concentrations of a focus of infection, separated by a wall of inflammation, the above mentioned factor makes local antiseptic agents increasingly important within the therapeutic schedules for local purulent and inflammatory disease.

Compared to the number of antibiotics, the list of contemporary antiseptic agents is quite scarce, containing such agents, known for already a long time, as hydrogen peroxide, nitrofuran compounds, chlorhexidine bigluconate and povidon-iodine. In recent years, the above list was substantially complemented by the products of quaternary ammonium compounds, synthesised in Ukraine, namely, myramistin and decamethoxin.

Surface active cationic detergents, which include decamethoxin and myramistin, are known for a wide range of bactericidal, virucidal, fungicidal action, their ability to reduce adhesive properties of bacteria and to destroy microbial toxins [Paliy, 1997]. Local application of the above agents allows creating the antiseptic regimen in the infective focus, required for fast wound healing and elimination of inflammation, as well as accelerating restoration of homeostasis.

The pharmaceutical product Decasan, a 0.02% isotonic solution of decamethoxin, has received wide acclaim among clinicians during its yet short presence at the market. The batch production of Decasan is performed by the pharmaceutical company Yuria-Pharm (Kyiv). The product is manufactured in vials of 50, 100, 200, 400 mL and plastic containers of 100, 200, 500 and 1000 mL.

The aim of the work: comparative study of antimicrobial activity of Decasan and Myramistin and generalising the existing experience on clinical use of Decasan.

Materials and Methods

During the study we have used batch production samples of Decasan, manufactured by Yuria-Pharm and 0.01% solution of myramistin, manufactured by the pharmaceutical company JSC Darnitsa.

The sensitivity of microorganisms to antiseptic products was assessed with a conventional method of serial double dilutions of the products in a liquid nutrient medium [Volyanskyi et al, 2004]. Comparative assessment of microbial sensitivity to investigational products was performed by the index of minimal bactericidal concentration (MBCC).

The disinfecting efficacy of the finished pharmaceutical products was assessed with a technique of artificially infected cambric test objects. Pieces of cambric 1.0x0.5 cm in size were sterilised in an autoclave and were subject to a 15-minute exposure to the suspension of a daily culture of one of the organisms, which contained 108 colony-forming units (CFU) of bacteria per 1 mL of isotonic solution of sodium chloride (normal saline). Afterwards moisture residue of test objects was removed with sterile filter paper. Infected test objects were introduced into sterile boxes with solutions of one of the investigated products for 15, 30 and 45 sec., and 1, 3, 5, 10. 15, 20. 30, 45, 60 and 120 min. On completion of disinfecting exposure test objects were washed from antiseptic residue for 5 minutes in 10 mL of sterile isotonic solution of sodium chloride and transferred into a test-tube with 5 mL of meat peptone broth. The conclusion on the efficacy of disinfection was made based on the presence or absence of microbial growth in a nutrient medium after 48 hours of incubation at the temperature of 37°C. The values of each index were determined by the results of a triple experiment.

Clinical efficacy of Decasan was assessed in course of treatment of 650 in-patients with purulent inflammatory lesions, which were treated at the Clinic of Vinnitsa Pirogov Memorial National Medical University at the facilities of Central Clinical Hospital No. 1 of. Vinnitsa and 150 patients with nonspecific inflammatory diseases of the urinary tract, treated in the hospital setting of Kamenetz-Podolsk City Hospital No. 1 during 2001-2007.

Results and Discussion

The index of minimum bactericidal concentration reflects the sensitivity of a given strain of organisms to the principal active ingredient of the pharmaceutical product when culturing under artificial conditions and is taken into consideration when selecting the concentration of the antimicrobial agent within the finished pharmaceutical product. By comparing the MBCC of the principal active ingredient for the specific microbial strain and the concentration of the pharmaceutical in a finished dosage form, a rough predication of drug's efficacy can be made. However, under clinical conditions the activity of an antiseptic compound is decreased under the influence of biological fluids, sorption properties of body tissues and other factors, which calls for a substantial safety margin concerning the concentration of substances in a finished dosage form as compared to MBCC.

Table 1 presents the results of studying the sensitivity of clinical strains of microorganisms to Decasan and Myramistin.

Analysis of the results obtained indicates the high sensitivity of a wide spectrum of opportunistic organisms to the investigational antiseptic products. However, the sensitivities of individual species to each of the products were substantially different. 1).

S. aureus was killed in the presence of 4.68 mcg/mL of Decasan. To kill these organisms, a 3.5 times higher concentration of Myramistin is required. The activity of Decasan against S. epidermalis was 11.1 times higher than that of Myramistin.

Table 1. *The characteristics of antimicrobial activity of batch production samples of Decasan and Myramistin*

Microorganisms	The number of strains	Antiseptic product		The multiplicity of difference
		Decasan	Myramistin	
		MBCC (μg/mL)		
S. aureus	3	4.68±1.56	16.50±4.25	3.5
S. epidermidis	13	1.74±0.58	19.35±7.06	11.1
E. coli	5	3.64±0.85	12.67±3.14	3.5
P. vulgaris	3	12.75±2.86	26.36±5.02	2.1
P. aeruginosa	3	91.67±33.3	78.13±39.12	1.1
A. fecalis	3	41.61±8.33	83.33±16.66	2.0
M.uretralis	3	1.56±0.0	3,13±1.56	2.0

Table 2. *The results of evaluating the disinfecting efficacy of Decasan and Myramistin.*

Microorganisms	Antiseptic product		The multiplicity of Decasan superiority
	Decasan	Myramistin	
	Time to disinfect the objects		
S. aureus	0.25	30	120
S. epidermidis	0.25	10	40
E. coli	60	120	2
M. uretralis	10	30	3
C. albicans	20	120	6

The Gram-negative bacteria of the Enterobacteriaceae family proved to be 2.1-3.5 times more resistant to Myramistin, than to Decasan.

In the recent years the increasing proportion of nosocomial pathogens belongs to non-fermentative aerobic gram-negative bacilli of genera Pseudomonas, Alcaligens and Moraxella. The analysis of the sensitivity of that group of bacteria allowed detecting the advantages of Decasan.

The investigated strains of Pseudomonas were much more resistant to antiseptics than Staphylococci and Enterobacteriaceae. The representatives of Pseudomonas were found to have low sensitivity to Myramistin (MBCC 78.13±46.88 μg/mL). However, the finished dosage form of the latter product, a 0.01% solution (100 μg/mL), had insufficient concentration to ensure the killing effect concerning any representative of the Pseudomonas genus, even within standard deviations of sensitivities of certain strains of Pseudomonas during our study. In clinical situations, the expected efficacy of 0.01% solution of Myramistin against Pseudomonas aeruginosa will be even lower, given partial inactivation of the drug via interaction with the factors of bacterial ambient. In that regards, Decasan appears to be attractive, since it contains 200 μg of antiseptic agent in 1 mL, which is twice the required minimum bactericidal concentration.

The representatives of the genus Alcaligens and Moraxella had greatest sensitivity to decamethoxin (MBCC 41.61±8.33 μg/mL and 1.56±0.0 μg/mL, respectively), twice as low as the same indices for Miramistin (MBCC 83.33±16.66 μg/mL and 3.13±1.56 μg/mL).

Liquid dosage forms of antiseptic agents have to be used taking into consideration the fact that their killing effect on microorganisms is exerted only in direct contact with contaminated surface, e.g. in wound irrigation and until drying of dressing material, moistened with an antiseptic agent. Therefore, an important characteristic of the efficacy of an antiseptic agent is time of exposure, required to exterminate the microorganisms on the contaminated object. The results of assessments of this characteristic for batch production samples of Decasan and Myramistin in artificially contaminated cambric test objects are presented in Table 2.

The data in Table 2 illustrate the significant differences concerning the rate of impact of the investigational antiseptic agents on various types of organisms.

Thus, S.aureus was killed in exposure of Decasan, which was 120 times shorter than the exposure required for batch production samples of Myramistin. The effective exposures of Decasan were significantly shorter than those of Myramistin concerning test objects, infected with Gram-negative bacilli and yeast-like fungi of the genus Candida.

When generalising the results of antimicrobial efficacy study of the products it should be noted that Decasan and 0.01% solution of Myramistin are substantially different in terms of antimicrobial activity with a substantial superiority of Decasan. The vast majority of studies of opportunistic microorganisms found significantly higher sensitivity to decamethoxin compared to myramistin. Concentration of decamethoxin in Decasan is twice as high as the concentration of miramistin in its finished dosage form. On the whole, Decasan provides much faster disinfection and a safety margin of antimicrobial activity, mandatory under clinical conditions due to potential partial inactivation by biological fluids.

The high antiseptic therapeutic activity of Decasan has been confirmed by the results of numerous clinical observations. Septic surgery is the field where Decasan is used in the widest way for local therapy of purulent lesions of soft tissues of various locations. Prior to use, Decasan was warmed to 37-38°C; the product was used for wound irrigation after lancing of abscesses, cellulitis, carbuncles, furuncles, felons and paraproctitis. After irrigation with Decasan an aseptic dressing was put in place. Dressing change and irrigation of septic cavities with Decasan were performed on a daily basis.

Using the product allowed reducing the time to wound clearance from purulent necrotic masses and elimination of inflammatory reactions. The duration of the hydration stage of wound process was reduced to 5.7 days as compared to 8.4 days in patients, in whom the wounds were irrigated with Furacilin and hydrogen peroxide. The time to complete wound healing was 2.5 days shorter. Hospital stay in patients with cellulitis and abscess reduced from 14.97 and 15.18 days to 12.33 and 10.8 days, respectively.

Decamethoxin was proved to possess anti-inflammatory activity; the mechanism behind the latter is related to inhibition of serotonin synthesis by the cells, anti-exudative and anti-oedema effects [Polyachenko, 1995]. Clinicians consider the above to determine reduction of discharge from the lanced septic cavity already by Day 1-2 of Decasan application; the high antiseptic efficacy explains the possibility to discontinue systemic antibiotic therapy already at Day 5 [Fomin et al., 2006].

There is a positive experience of eliminating acute cholangitis by intra-choledochal administration of Decasan in course of minimally invasive endoscopic treatment of choledocholithiasis. Using the product allowed reducing bacterial contamination of bile by 2.7 times and accelerating the time

to sanitation of biliary tract [Nechytaylo et al, 2006]

High prophylactic efficacy of Decasan in abdominal surgery was demonstrated by the specialists of Feofaniya Clinical Hospital (Kyiv). After applying digestive anastomoses, prolonged drip irrigation of the anastomosis zones by Decasan was performed via a dedicated two-lumen tube. Such approach allowed avoiding the complications associated with leakage of digestive anastomoses [Kozan et al, 2006].

The product is also used in neurosurgery during primary surgical debridement of wounds, in multi-modality treatment of purulent neurosurgical disease and in perforated meningocele [Pedachenko et al., 1991].

Substantial positive experience of using Decasan has been accumulated in Dentistry, Otolaryngology, Gynaecology, Urology and other fields of medical practice. In Dentistry the product is used to treat stomatitis, ulcer-necrotic gingivitis and exacerbated periodontal disease. Decasan rinses are used to treat catarrh, as well as acute and chronic tonsillitis.

The recently discovered property of decamethoxin to inactivate influenza viruses opens the perspectives for prophylactic and therapeutic use of Decasan during flu epidemics [Gridina et al, 2008]. Decasan is successfully used in Pulmonology to treat lung abscesses, in bronchiectasis for endobronchial lavage of airway and for sanitation of pleural cavity. Taking into consideration that Decasan possesses an anti-spasmodic effect; inhalations in children with exacerbated chronic obstructive pulmonary disease have proved to be highly effective. Clinical observations have confirmed that multi-modality treatment including Decasan inhalations in the above category of patients allows for a substantial reduction of duration of febrile reactions, prompt eliminating dyspnoea and cough, as well as reducing hospital stay by four days, compared to patients treated with antibiotics and broncholytics alone.

Decasan is used in Gynaecology to treat candidiasis of vaginal mucosa, Trichomonas-related and Chlamydia-related vaginitis, vaginosis and post-abortion endometritis. The product is used with prophylactic intent in prenatal period for antiseptic preparation of the passages. In treatment of postpartum endometritis application of Decasan allowed achieving rapid restoration of the endometrium; in terms of therapeutic efficacy Decasan was superior to chlorhexidine bigluconate.

The product exerts potent spermicidal action and may be used as douching (syringing) to prevent unwanted pregnancy with concomitant prophylaxis of sexually-transmitted disease [Dzys, 1997].

In Urology the product is used as soakings in balanoposthitis, instillations into urinary bladder and irrigations of post-adenomectomy prostatic bed to prevent suppuration. Using Decasan in multi-modality therapy of acute epididymitis allowed for a prompt elimination of pain syndrome and accelerating elimination of inflammatory infiltration of the epididymis [Zaritskyi et al, 2007].

The high disinfecting activity of Decasan, confirmed by the above results of experimental studies, opens the prospects of using the product for reliable disinfection of skin of the hands of medical personnel and rubber gloves in patient assessments and medical interventions. Considering the above aspect, the results of experimental studies concerning antiviral activity of Decasan are especially important. Prophylactic use of the product allows limiting the spread of HIV infection, Hepatitis B and C viruses and Herpes virus [Fedchuk et al., 2003]. The chemical inertness of Decasan eliminates the risk for damaging diagnostic equipment made of metal, glass and polymer materials in course of disinfection.

Comprehensive experimental assessment and numerous studies of clinical efficacy of the domestically produced antiseptic agent Decasan are evident of its high therapeutic efficacy. The product is well tolerated by the patients and does not cause adverse reactions. Application of the product in purulent inflammatory disease allows reducing the volumes of systemic antibiotic therapy, which substantially increases the cost efficacy of treatment. The efforts of the pharmaceutical company Yuria-Pharm have to be complemented, which are aimed at meeting any consumer needs by supplying the product in a convenient packaging range from 50 mL up to 1 L. Medical use of Decasan allows increasing the efficacy of treatment of patients with purulent inflammatory disease of various location.

Conclusions and prospects of further developments.

1. The antiseptic pharmaceutical product Decasan possesses high antimicrobial activity against a broad spectrum of pathogenic and opportunistic organisms and exerts potent disinfecting action; therefore, Decasan is recommended to be used for prevention and treatment of diseases of microbial origin.

2. The experience of clinical application of Decasan is evident of high therapeutic efficacy of the product in purulent and inflammatory lesions of various locations, the absence of adverse events and cost-efficacy of its wide medical use.

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EFFECTIVENESS OF THE ANTISEPTIC PREPARATION DECASANUM (Author's English abstract)

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Summary. Research results of the antiseptic medicinal preparation decasanum and miramistinum serial samples antimicrobial properties were brought in work. Decasanum clinical usage experience during treatment of patients with purulent-inflammatory diseases was summarized.

Key words: antiseptic drug, Decasanum, medicinal effectiveness, pneumonia.