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Research Article

Clinical Effectiveness and Tolerability of VANCOMYCIN-Belpharm in the Treatment of Surgical Soft Tissue Infections

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ABSTRACT

A randomized comparative study of the clinical effectiveness and tolerability of the locally produced drug «Vancomycin-Belpharm» (produced by IP LLC «BELPHARM», Uzbekistan) in comparison with the reference drug «Vancomycin» (LLC «Farmkontsept», Russia) in the treatment of surgical soft tissue infections (SSTI) was conducted. Effectiveness was evaluated based on a three — point scale (clinical symptoms, pathogen eradication, dynamics of laboratory parameters), tolerability-on a four-point scale (objective and subjective signs of adverse reactions). The results showed a comparable high clinical efficacy of both drugs: a significant decrease in body temperature (up to 36.8°C), a marked reduction in pain and signs of local inflammation, and cleaning of the wound process (from 3.0 to 1.13–1.25 points). The average efficiency score was 2.9±0.54 in the main group and 2.70±0.92 in the control group. Tolerance was also high and comparable: 3.9±0.7 and 3.73±1.01 points, respectively. Cases of intolerance (chills, hyperthermia that required withdrawal) were rare in two patients of the main group and in one patient of the control group. Vancomycin-Belpharm demonstrated clinical effectiveness, safety, and tolerability fully comparable to the original (reference) drug. The drug can be recommended for inclusion in standard chemo therapy regimens, which is especially important in the context of import substitution, increasing the availability of treatment and supporting local production in the Republic of Uzbekistan.

Key words: *vancomycin, surgical soft tissue infections, clinical efficacy, tolerability, comparative study, import substitution, complications.*

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INTRODUCTION

Surgical soft tissue infections remain one of the leading causes of hospitalization and complications in surgical practice, especially against the background of concomitant diseases such as diabetes mellitus [1,3,11,24]. According to the World Health Organization (WHO), millions of surgical-related infections are reported annually, resulting in longer treatment times, higher health care costs, and an increased risk of antibiotic resistance [2,4,9,10]. The treatment of staphylococcal infections is based on the use of antibiotics that interfere with cell wall synthesis, such as beta-lactam drugs [5,6,7,22]. Vancomycin, as a glycopeptide antibiotic, plays a key role in the treatment of gram-positive infections resistant to other drugs [12,13,21].

In the Republic of Uzbekistan, where the number of patients with surgical infectious complications also continues to grow, it is urgent to search for effective and affordable antibiotics that can provide rapid eradication of pathogens without significant side effects, with an economic effect [14, 15].

Research on domestic analogues, such as Vancomycin-Belpharm, produced in Uzbekistan, promotes import substitution and increases the availability of treatment, which is especially important in the context of a global pandemic of resistant bacterial strains [16, 17, 23]. Localization of drug production contributes to a significant reduction in procurement costs by eliminating currency risks, reducing logistics costs and gaining access to state preferences. This makes it possible not only to optimize budget expenditures, but also to increase the physical and economic availability of vital medicines for the population.

RESEARCH OBJECTIVE

To study the clinical efficacy and tolerability of the drug Vancomycin-Belpharm (produced by IP LLC «BELPHARM», Uzbekistan) in comparison with the drug Vancomycin (produced by LLC «Farmkontsept», Russia) for the treatment of patients with surgical soft tissue infections (SSTI).

RESEARCH MATERIAL AND METHODS

The study was conducted in a multidisciplinary clinic of the Tashkent Medical Academy and included 60 patients divided into two groups of 30 people each. The control group consisted of patients who were prescribed Vancomycin (manufactured by Pharmconcept LLC, Russia) and the main group of patients who received Vancomycin-Belpharm (manufactured by IP BELPHARM LLC, Uzbekistan).

The groups were comparable in gender, age, and diagnosis. In the control group, the average age of men was 53.1 years, women-48.2 years. In the main group, 55.2 and 49.5, respectively.

The study included patients older than 18 years of age of both sexes, who are undergoing inpatient treatment with a verified diagnosis of SSTI, and who gave written informed agreement. The treatment regimen consisted of double administration of 1.0Vancomycin, which was diluted in 200.0 saline solution and administered 2 times, for five days. The main group received Vancomycin-Belpharm 1000 mg, and the control group received Vancomycin (Russia) according to a similar scheme. All patients received basic therapy. The effectiveness was evaluated on a 3-point scale, where 3 points were evaluated as high efficiency (Significant reduction in the severity of disease symptoms (sum of points 0-3), pathogen eradication 81-100% and normalization of laboratory parameters), 2 points — moderate (moderate reduction in the severity of disease symptoms (sum of points 4-6), moderate pathogen eradication 60-80%, significant improvement in laboratory parameters); 1 point - low (a slight decrease in the severity of symptoms of the disease (the sum of points 7-9), insignificant eradication of the pathogen up to 50%, a slight improvement in laboratory parameters.) effectiveness and at 0 points it was absent.

Tolerability was assessed on a 4-point scale. 4 points - during an objective examination and / or laboratory studies in dynamics, no pathological changes or clinically significant deviations were detected and/or the patient did not notice adverse reactions; 3 points - during an objective examination and/or laboratory studies in dynamics, minor changes were detected that are transient and did not require a change in the treatment regimen. 2 points - during an objective examination and / or laboratory tests, significant changes were detected in the dynamics that did not require additional measures and/or the patient noted manifestations of an adverse reaction that had a negative effect on his condition, but did not require discontinuation of the drug 1 point - objective examination and / or laboratory tests revealed significant changes in the dynamics, and / or the patient noted manifestations of an adverse reaction that has a negative effect on his condition and requires discontinuation of the drug. If an objective examination and / or laboratory tests revealed significant changes in the dynamics, and / or the patient noted manifestations of an adverse reaction

that required discontinuation of the drug and additional medical measures, 0 points were awarded.

RESULTS

As noted earlier, the main criterion for the effectiveness of treatment is clinical signs. The temperature response, pain in the area of the wound process, which is accompanied by local hyperthermia and hyperemia, as well as the nature of the wound process itself were studied.

Analyzing the temperature response of patients, it was found that it significantly decreased. Thus, the average temperature before admission was at the level of 37.8±0.60C, while against the background of treatment with Vancomycin (Belpharm), it decreased to 36.8± 0.30C, which indicated the effectiveness of the treatment. Speaking about pain and perifocal inflammation, it was found that local pain and other signs of inflammation averaged 2.82±0.55 in the control group and 2.87±0.35 in the main group before the start of treatment, while at the end of treatment this indicator was at the level of 0.29±0.66 and 0.47±0.73, respectively, which also confirms the effectiveness of the drug

Analysis of the nature of the wound process showed that before the start of treatment, all patients were admitted with a purulent process, and its indicator was 3, against the background of the treatment, the average indicator in the control group was 1.25±0.52 and in the main group 1.13±0.43.

A study of the dynamics of changes in laboratory parameters in both groups showed that during the treatment, the indicators of hemoglobin, bilirubin, white blood cells, urea and creatinine were within normal values. That is, there was no adverse effect of drugs on these indicators.

A study of the comparative efficacy and tolerability of the drug among patients of both groups showed that it was satisfactory in all cases. Only one patient of the control group and two patients of the main group had intolerance, manifested by the appearance of chills and hyperthermia, which required the withdrawal of drugs.

The final stage of the study was to analyze the effectiveness and tolerability of the studied drugs. As can be seen from the presented data, the point gradation in both efficacy and tolerability is the same in both groups, which indicates the satisfaction of drugs in both groups.

CONCLUSION

Thus, the drug Vancomycin-Belpharm, produced by IP LLC «BELPHARM», UZBEKISTAN, had a positive clinical effect comparable to the reference drug, which was manifested by the relief of inflammatory phenomena, due to the cleansing of the wound process. The inclusion of this drug in the standard treatment regimen for patients with surgical soft tissue infection revealed good efficacy, tolerability and safety of this drug. Drug intolerance was rarely observed, which is consistent with the literature data. The advantages of a domestic drug are the availability and support of local production, as well as the cost of the product.

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Yumshoq to'qimalarining jarrohlik infeksiyalarini davolashda VANCOMYCIN-Belpharm dori vositasini qo'llash: klinik samaradorligini baholash va qiyosiy tasxishlash.

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Annotatsiya

Yumshoq to'qimalarining xirurgik infeksiyalarini (YTXI) davolashda mahalliy «Vancomycin-Belpharm» preparatining (BELPHARM MChJ, O'zbekiston tomonidan ishlab chiqarilgan) klinik samaradorligi va qo'llash bo'yicha randomizatsiyalangan qiyosiy tadqiqot o'tkazildi. Tadqiqotda «Vancomycin» (PharmConcept MChJ, Rossiya) referent preparati bilan taqqoslandi.

Samaradorlik uch balli shkala bo'yicha baholandi (klinik alomatlar, patogen mikroflorani yo'q qilish, laboratoriya parametrlarining dinamikasi) va qabul qilish to'rt balli shkala bo'yicha baholandi (nojo'ya reaktsiyalarning ob'ektiv va sub'ektiv belgilari).

Natijalar ikkala preparatning ham yuqori klinik samaradorligini ko'rsatdi: tana haroratining sezilarli darajada pasayishi (36,8°C gacha), og'riq va mahalliy yallig'lanish belgilarining sezilarli darajada kamayishi va yaralarning bitishi (3,0 dan 1,13–1,25 ballgacha). O'rtacha samaradorlik balli asosiy guruhda 2,9±0,54 va nazorat guruhida 2,70±0,92 ni tashkil etdi. Qabul qilish ham yuqori va o'xshash edi: mos ravishda 3,9±0,7 va 3,73±1,01 ball. Nojuya tasir holatlari (titroq, gipertermiya, to'xtatishni talab qilish) kam uchradi - tadqiqot guruhidagi ikkita bemorda va nazorat guruhidagi bitta bemorda.

Vankomitsin-Belpharm klinik samaradorligi, xavfsizligi va qabul qilish asl (referent) preparat bilan to'liq taqqoslash mumkinligini ko'rsatdi. Preparatni YTXI davolash standart rejimlariga kiritish uchun tavsiya qilish mumkin, bu ayniqsa import o'rnini bosish, davolash imkoniyatlarini yaxshilash va O'zbekiston Respublikasida mahalliy ishlab chiqarishni qo'llab-quvvatlash nuqtai nazaridan muhimdir.

Kalit so'zlar: vankomitsin, yumshoq to'qimalarining jarrohlik infeksiyalari, klinik samaradorlik, qiyosiy tadqiqot, import o'rnini bosish, asoratlar

Клиническая эффективность и переносимость «ВАНКОМИЦИНА-Belpharm» в лечении хирургических инфекций мягких тканей: результаты сравнительного исследования.

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Аннотация

Проведено рандомизированное сравнительное исследование клинической эффективности и переносимости отечественного препарата «Ванкомицин-Belpharm» (производства ИП ООО «BELPHARM», Узбекистан) в сравнении с референтным препаратом «Ванкомицин» (ООО «ФармКонцепт», Россия) при лечении хирургических инфекций мягких тканей (ХИМТ).

Оценка эффективности проводилась по трёхбалльной шкале (клиническая симптоматика, эрадикация возбудителя, динамика лабораторных показателей), переносимости — по четырёх балльной шкале (объективные и субъективные признаки нежелательных реакций).

Результаты показали сопоставимую высокую клиническую эффективность обоих препаратов: достоверное снижение температуры тела (до 36,8°C), выраженное уменьшение болевого синдрома и признаков локального воспаления, очищение раневого процесса (с 3,0 до 1,13–1,25 балла). Средний балл эффективности составил 2,9±0,54 в основной группе и 2,70±0,92 в контрольной. Переносимость также была высокой и сопоставимой: 3,9±0,7 и 3,73±1,01 балла соответственно. Случаи непереносимости (озноб, гипертермия, потребовавшие отмены) отмечены редко — у 2 пациентов основной группы и у 1 пациента контрольной.

Ванкомицин-Belpharm продемонстрировал клиническую эффективность, безопасность и переносимость, полностью сопоставимые с оригинальным (референтным) препаратом. Препарат может быть рекомендован для включения в стандартные схемы терапии ХИМТ, что особенно важно в контексте импортозамещения, повышения доступности лечения и поддержки локального производства в Республике Узбекистан.

Ключевые слова: ванкомицин, хирургические инфекции мягких тканей, клиническая эффективность, переносимость, сравнительное исследование, импортозамещение, осложнения.