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# The effects of Ibuprofen-releasing foam dressing on wound pain in leg ulcers

## Učinci obloge s ibuprofenom na bol u bolesnika s vrijedom potkoljenice

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**Abstract. Aim:** Ulcus cruris represents one end-point of complications linked to the venous hypertension of lower extremities, as inadequately supplied sclerotic tissue breaks down and healing is largely impaired. Today the advanced leg ulcer treatment is based on wound dressing that can contain analgesics in order to diminish pain. The aim of this non randomized one year study was to analyze the effects of ibuprofen-releasing foam dressing on wound pain in leg ulcers in order to ameliorate the quality of life in patients. **Methods:** In this one-year study 288 patients with leg ulcers were analyzed, among which 28 patients were prescribed ibuprofen-releasing foam dressing without peroral analgesic therapy, while 30 patients continued peroral analgesic therapy with silver-releasing foam dressing as a control group. The primary endpoint was to determine wound pain relief in the first two days among patients treated with. **Results:** We observed a statistically significant decrease of pain intensity in the first two days of therapy, but not a significant different rate of ulcer healing compared to the control group. **Conclusion:** Based on these results we concluded that foams with analgesics could be a treatment of choice for chronic leg wounds with intense pain.

**Key words:** ibuprofen-releasing foam, leg ulcer, wound pain

**Sažetak. Cilj:** *Ulcus cruris* krajnja je posljedica komplikacija povezanih s venskom hipertenzijom donjih ekstremiteta, a nastaje zbog nemogućnosti cijeljenja nedovoljno opskrbljenog sklerotičnog tkiva. Danas se napredno liječenje vrijeda potkoljenice bazira na oblogama za rane koje mogu ili ne moraju sadržavati analgetike da bi umanjile bolove. Cilj ove jednogodišnje studije bio je analizirati učinke obloge s ibuprofenom na bolove u bolesnika s vrijedom potkoljenice u svrhu poboljšanja njihove kvalitete života. **Metode:** U ovoj jednogodišnjoj studiji obradili smo 288 bolesnika; 28 bolesnika koristilo se oblogama s ibuprofenom bez peroralne analgetske terapije, dok je 30 bolesnika primalo peroralnu analgetsku terapiju s oblogama sa srebrom kao kontrolna skupina. **Rezultati:** Uočili smo statistički značajan pad intenziteta bola u prva dva dana liječenja, ali ne značajan u odnosu na cijeljenje ulkusa u kontrolnoj skupini. **Zaključak:** Na osnovi ovih rezultata zaključujemo da bi obloge s analgeticima mogle biti lijek izbora za kronične nožne ulkuse s intenzivnim bolovima.

**Ključne riječi:** bol, obloga s ibuprofenom, vrijed potkoljenice

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## INTRODUCTION

Ulcer cruris represents one end-point of complications linked to venous hypertension, as the inadequately supplied sclerotic tissue breaks down and healing is largely impaired (Figure 1 and 2). About 40% of venous ulcers are associated with superficial (epifascial) venous insufficiency and can be treated by relatively simple measures. The rest are associated with deep venous impairment, usually the post-thrombotic syndrome, and are much more troublesome. The most common site of venous ulcers is the median aspect of the leg at the level of around the ankle, then the middle and the lower part of shins. A chronic wound is defined as a break in the skin of long duration (more than 6 weeks) or frequent recurrence<sup>1,2</sup>. Approximately 1%-2% of population suffers from ulcer on shins throughout lifetime, and the incidence enlarges with age<sup>3-5</sup>. According to some authors, the disease is present in 1% of population younger than 60 years of age, in 13% of population older than 70 years of age, and in 20% in older than 80 years of age<sup>6</sup>. Chronic wounds are often accompanied with pain, infections, inflammation of joints and restricted mobility that results with changes in individual psychological status. The most common changes are depression, anxiety, aggressiveness and frustration, followed by concern for the effectiveness of treatment and fear that the wound would not heal, as well as the insecurity due to restricted mobility<sup>7</sup>. Today the advanced leg ulcer treatment is based on wound dressings. They promote debridement, reduce the number of bacteria and stimulate granulation. Newer hydrocolloids contain some additives like analgesics which can diminish the pain in leg ulcer patients.

The aim of this study was to analyze the effects of ibuprofen-releasing foam dressing on wound pain in leg ulcers in order to ameliorate the quality of life in those patients, as today even younger, working people suffer from leg ulcers.

## MATERIALS AND METHODS

In this one-year study 288 patients with leg ulcers were analyzed at out-patient Department of phlebology, Clinical Hospital Centre Rijeka Croa-

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Patients with a leg ulcer had adverse quality of life changes that were as severe as those in people with obstructive lung disease, angina or arthritis.

tia. According to intense wound pain, 58 patients were further analyzed. They were undergoing peroral analgesic therapy and silver-releasing foam dressing for treatment of leg ulcer. Among them, 28 patients were prescribed ibuprofen-releasing foam dressing without peroral analgesic therapy, while 30 patients continued peroral analgesic therapy with silver-releasing foam dressing as a control group. The primary endpoint was to determine wound pain relief in the first two days



Figure 1. *Ulcer cruris*



Figure 2. Ulcus cruris

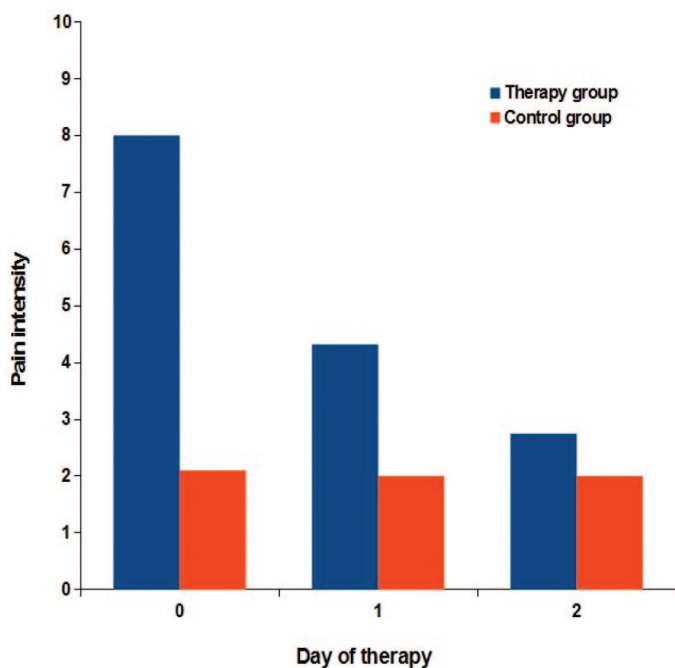


Figure 3. Pain intensity in patients treated with ibuprofen-releasing foam dressing (Therapy group) and those treated with silver-releasing foam dressing (Control group).

among patients treated with. Before and during the therapy, type and intensity of pain were assessed using a standardized questionnaire and the 0-10 Numeric Pain Assessment Scale. Based on this scale, 0 represents the absence of pain, 1-3 tolerable, 4-6 moderate, 7 severe/intense and 10 intolerable pains. Results were statistically analyzed using the Friedman test and the  $\chi^2$  test.

## RESULTS

After the first day of therapy, patients with ibuprofen-releasing foam dressing reported a reduction in pain intensity from a mean value of 8.0 to 4.32 ( $p < 0.001$ ). After the second day of treatment the pain score further decreased to a mean value of 2.75 ( $p < 0.01$ ) (Figure 3). In the control group of 30 patients treated with peroral analgesics and local silver releasing foam dressing, the maximal pain before local therapy alone was 3 (tolerable pain). During the first two days the pain did not change significantly, and the patients successfully managed it using analgesics, antipyretics or NSAID. Also, we focused our observations to the complete resolution of ulcers in 3 to 6 months of therapy. Of 28 patients treated with ibuprofen-releasing foam dressing, complete resolution was seen in 9 (32.14%). In the control group there was a higher percentage of resolution but not statistically significant (11 of 30 patients – 36.66%). While the difference was not significant, the quality of life of patients treated with ibuprofen-releasing foam dressing was evidently better.

## DISCUSSION AND CONCLUSION

Leg ulcers should not be taken lightly. Good care and treatment, with or without healing, improves the quality of life<sup>8</sup>. Today the treatment of leg ulcers is mainly based on wound dressings, as dressings have proved their efficacy on wound bacteria and wound healing<sup>9,10</sup>. New guidelines for treating leg wounds appear as the technology and science of wound dressings develop<sup>11</sup>. Pain is the most important factor in determining the quality of life in leg ulcer patients<sup>12</sup>. The Arapoglu study shows the efficacy of ibuprofen-releasing foam dressing in examined patients on wound pain versus best local treatment<sup>13</sup>. Other studies

found a correlation between the stage of chronic venous diseases and the impairment of the quality of life, which was mild for varicose veins but significant for trophic changes. Patients with a leg ulcer had adverse quality of life changes that were as severe as those in people with obstructive lung disease, angina or arthritis<sup>14</sup>. In the Hareendran study (2005), the adverse change in quality of life was particularly significant in elderly people and patients with painful ulcer that was refractory to treatment<sup>15</sup>. Generic and specific questionnaires are now available to evaluate the impairment of quality of life, both during the disease and for validation of treatment. From now on, this approach should be integrated into new epidemiological and therapeutic trials in the study of venous diseases. It should also be taken into consideration by health economists. Although this was not a randomized study and the control group had a lower pain score, this 1-year study shows a statistically significant decrease of pain intensity in examined patients. Some of these patients felt no pain in just one day of therapy with ibuprofen releasing foam, as described. According to our results, one can conclude that foams with analgesics could be a treatment of choice for chronic leg wounds with intense pain.

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