

# Combination Therapy with Clindamycin and Rifampicin for Hidradenitis Suppurativa: A Series of 116 Consecutive Patients

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## Key Words

Hidradenitis suppurativa · Rifampicin · Clindamycin · Sartorius score · Quality of life

## Abstract

**Background:** Antibiotics are frequently used to treat hidradenitis suppurativa (HS); however, few data on their efficacy are available. **Objective:** To evaluate the efficacy of a combination of systemic clindamycin (300 mg twice daily) and rifampicin (600 mg daily) in the treatment of patients with severe HS. **Methods:** Patients (n = 116) who received this combination were studied retrospectively. The main outcome measure was the severity of the disease, assessed by the Sartorius score, before and after 10 weeks of treatment. **Results:** The Sartorius score dramatically improved at the end of treatment (median = 29, interquartile range = 14.5, vs. median = 14.5, interquartile range = 11; p < 0.001), as did other parameters of severity as well as the quality of life score. Eight patients (6.9%) stopped the treatment because of side effects. **Conclusion:** The combination of clindamycin and rifampicin is effective in the treatment of severe HS.

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## Introduction

Hidradenitis suppurativa (HS) is a chronic inflammatory disease, characterized by painful nodules and draining sinus tracts, affecting apocrine areas of the skin. The prevalence of HS has been estimated to be 1% of the general population [1, 2]. Management of HS is difficult; relapses and chronicity contribute to produce a severe impact upon the quality of life [3]. Numerous treatments, such as topical and systemic antibiotics, oral zinc, hormonal therapies, oral retinoids, immunosuppressant agents, anti-tumour-necrosis-factor biologicals and surgical interventions have been used, but their efficacy has seldom been assessed.

HS is not primarily an infectious disease, although bacterial infection is often present. A large variety of micro-organisms has been isolated from the lesions; the most frequently isolated pathogens are *Staphylococcus aureus*, Gram-negative rods [4–6] and anaerobic bacteria [5, 7]. Unfortunately the clinical significance of superficial and even deep bacterial sampling is very low in the clinical setting [8]. Representative flora has been identified using carbon dioxide laser evaporation with bacterial sampling at each level but this is not convenient in common practice [9]. Accordingly the choice of an antibiotic combination cannot be based on bacterial sampling.

**Table 1.** Sartorius score modified by J.E. Revuz

	Number	Coefficient	Total
1 Anatomical region involved: armpit, breast, inguinofemoral, perianal and perineal areas		× 3	
2 Lesions: – nodules		× 2	
– abscess or fistulas		× 4	
– hypertrophic scars		× 1	
– others (folliculitis, pustules, ...)		× 0.5	
3 The longest distance between two relevant lesions or size if there is only one lesion (<5 cm = 2; <10 cm = 4; ≥10 cm = 6; no active lesions = 0)		× 1	
4 Are all lesions clearly separated by normal skin? (yes = 0; no = 6)		× 1	
	Total		

Short clinical series have claimed the efficacy of the combination of systemic clindamycin and rifampicin in folliculitis decalvans [10] and, subsequently, in 10 patients with HS [11]. In our centre, this combination is widely used for severe HS, using a treatment cycle of 10 weeks. The aim of our study was to evaluate retrospectively the efficacy of this combination of antibiotics in our cohort of patients with HS.

## Methods

### Patients

Consecutive patients with HS were examined in our centre by the same investigator (J.R.), from September 2003 to September 2007 (n = 373). Diagnostic criteria were: (1) presence of typical lesions, i.e. deep-seated nodules (blind boils), abscesses and/or fibrosis, (2) location in typical areas, i.e. armpit and groin (and, secondarily, breast, buttocks and perineum), and (3) evolution, with relapses and chronicity. The above 3 criteria were considered necessary to establish the diagnosis.

At the first visit (week 0, W0), a standardized form was used to prospectively record demographic characteristics, socioprofessional data, smoking habits, history of the disease and a family history of HS. The body mass index (BMI) was computed. Active acne at the time of examination and a personal history of severe acne were both recorded separately. The anatomical zones which had been involved at least once in the history of the patient were recorded: 'typical locations', i.e. axillae, breast, genitofemoral area, buttocks, perianal and perineal areas; 'atypical locations', i.e. ears, chest, and associated follicular diseases, such as dissecting folliculitis of the scalp and pilonidal cysts. The type of lesions, e.g. nodules, abscesses/sinus/fistulas, hypertrophic scars or folliculitis, was described.

Patients treated with the combination of rifampicin and clindamycin were extracted from our database. The decision to use this treatment was taken by one of us (J.R.), based on the degree of severity and inflammation present. The regimen was clindamycin 300 mg twice daily and rifampicin 600 mg once dai-

ly in the morning during a period of 10 weeks. Women using contraceptive pills were systematically informed at the first visit that they had to use mechanical contraception.

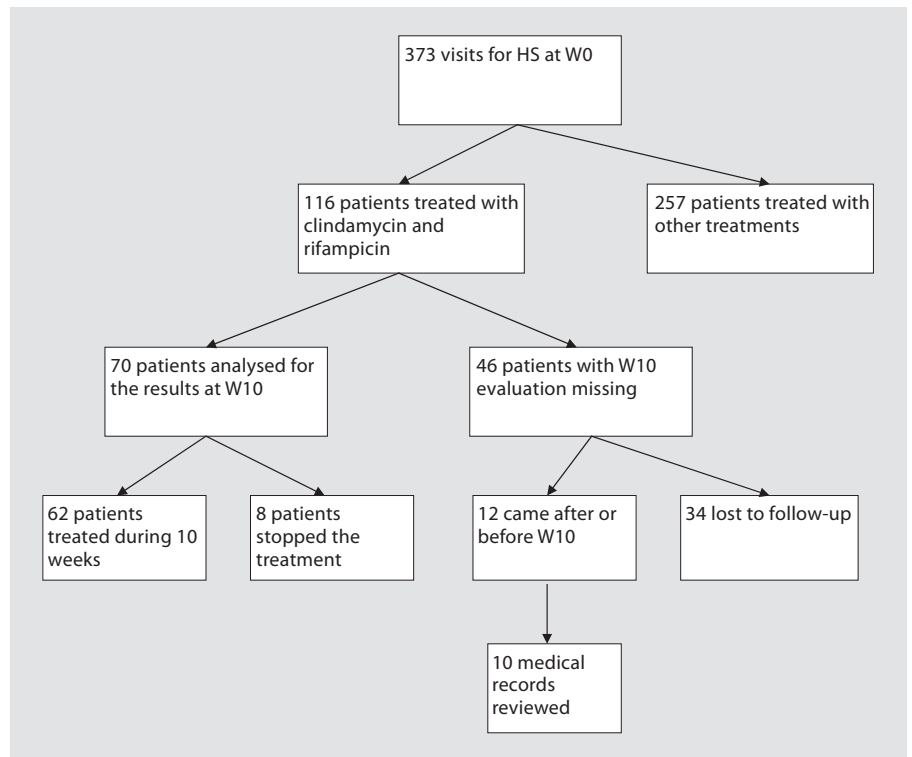
### Data Collection

A standardized form was used to collect data before the antibiotic treatment was initiated (W0) and at the end of the 10-week treatment (W10). Disease activity was systematically assessed by the Sartorius severity score [12, 13] (table 1). Hurley's classification [14] (table 2) was assessed for each zone involved; the final grade was the grade of the most severely affected zone. Maximal pain score and maximal suppuration score were assessed by the patient for the period of the preceding month, with a numerical scale from 0 to 10. The number of painful days per month and the number of days with suppuration were evaluated by the patient, with the result being recorded in 4 categories: none, <15 days, ≥15 days or permanent. The patient's quality of life was assessed using a skin-disease-specific tool, the Skindex-France questionnaire [3]. However, as this tool was only introduced belatedly, this assessment involved only the patients included later in the database.

The treatment was also assessed by the patients: at W10, they were asked for their perception of the result of the treatment on HS symptoms (i.e. very good, good, stable, worse). Finally, they were asked about potential side effects during the treatment, i.e. diarrhoea, abdominal pain or others.

### Statistical Analysis

Initial characteristics and disease activity of the 116 patients who used the combination therapy were described and compared to those of patients who had been treated with another therapy. Patients whose W10 evaluation was missing (n = 46) were also compared with the 70 patients whose W10 data were available. Continuous data are presented as means (±1 standard deviation) or medians (with interquartile range, IQR = Q3–Q1) for non-normally distributed variables and were compared by using the Student t test or the non-parametric Wilcoxon-Mann-Whitney U test, as appropriate. Categorical data are presented as numbers (with percentages) and compared by using the  $\chi^2$  or Fisher exact test, as appropriate.



**Fig. 1.** Flow chart.

The main measure of outcome was the severity of the disease as assessed by the Sartorius score; the secondary outcome measures were Hurley's classification, intensity and duration of pain and suppuration, and quality of life scores. The measures before and after treatment were compared using the Wilcoxon matched-pair signed-rank test or test of marginal homogeneity (Stuart-Maxwell) for paired data, as appropriate. As data of 46 patients were not available at W10, we also analysed the main outcome measure using the 'worst-case hypothesis', i.e. assuming that these 46 patients had no improvement of the Sartorius score.

All comparisons were two-sided, and a  $p$  value  $<0.05$  indicated a statistically significant difference. Data were analysed using the Stata Statistical software (Stata Corp. 2003, release 8.2; College Station, Tex., USA).

## Results

### *Patient Characteristics*

Among the 373 patients registered in the database, 116 (31%) received the combination therapy. W10 assessment was missing for 46 patients: 34 lost to follow-up and 12 whose evaluation was performed before or after W10. Therefore, data before and after treatment were available for 70 (60%) patients (fig. 1).

Table 3 describes the initial clinical characteristics of patients treated by combination therapy of clindamycin-

**Table 2.** Hurley's classification [14]

Grade I	Abscess formation, single or multiple, without sinus tracts and cicatrization
Grade II	Recurrent abscesses with tract formation and cicatrization; single or multiple, widely separated lesions
Grade III	Diffuse or near-diffuse involvement, or multiple interconnected tracts and abscesses across entire area

rifampicin. Thirty-one men and 85 women were included (sex ratio 0.4); their mean age was 33 years ( $\pm 10$ ). The mean BMI was 27 ( $\pm 7$ ). The percentage of active cigarette smokers was 79. The mean self-reported disease duration was 11 years ( $\pm 9$ ). The median score of the numerical scale for pain and suppuration was 7 (IQR = 3). The median Sartorius score was 28 (IQR = 14.5). There was no significant difference in the baseline characteristics, including the clinical severity as assessed by the Sartorius score, Hurley's classification, and intensity and duration of pain and suppuration recorded at the first visit, between the 70 patients who were followed up and the 46 who were not (data not shown).

**Table 3.** Comparison of initial characteristics of patients treated with rifampicin and clindamycin and those treated by other treatments

	Combination rifampicin and clindamycin (n = 116)	Other treatments (n = 257)	p
Age at examination, years	33 ± 10	32 ± 9	0.88
Men	31 (27)	57 (22)	0.34
Weight, kg	77 ± 18	71 ± 17	<0.001
BMI	27 ± 6	25 ± 6	0.01
Current smokers	92 (79)	192 (75)	0.30
Cigarettes per day	15 (8)	15 (8)	0.92
Active acne	14 (12)	31 (12)	1.00
History of acne	29 (25)	67 (26)	0.83
Length of disease, years	11 ± 9	11 ± 8	0.40
Sartorius score median	28 [14.5]	14 [10]	<0.0001
Hurley's classification			
I	51 (44.0)	187 (81.6)	
II	57 (49.1)	37 (16.2)	<0.001
III	8 (6.9)	5 (2.2)	
Max. pain/10 med.	7 [3]	4 [6]	0.0001
Max. suppuration/10 med.	7 [3]	3 [6]	0.0001
Number of days per month with pain			
None	3 (2.6)	7 (3.1)	
<15	35 (30.4)	154 (68.8)	<0.001
≥15	27 (23.5)	37 (16.5)	
Permanent	50 (43.5)	26 (11.6)	
Number of days per month with suppuration			
None	5 (4.4)	81 (31.9)	
<15	30 (26.0)	115 (45.1)	<0.001
≥15	23 (20.0)	23 (9.0)	
Permanent	57 (49.6)	36 (14.0)	

Continuous data are expressed as means ± SD except when otherwise indicated; categorical data are expressed as numbers, with percentages in parentheses; figures in square brackets indicate IQR. p values were determined by the  $\chi^2$  or Fisher exact test for categorical variables, by the Student t test for normally distributed continuous variables (BMI) and by the Wilcoxon-Mann-Whitney U test for non-normally distributed continuous variables (age, Sartorius score).

The 257 patients who did not receive the combination therapy had similar demographic characteristics, but had a lower BMI and were less severely affected than the 116 who received the combination of antibiotics (table 3).

### Therapeutic Results

When considering the 70 patients whose W0 and W10 data were available (table 4), the main outcome measure (the severity of the disease assessed by the Sartorius score) dramatically and significantly decreased at the end of the

treatment (median = 29, IQR = 14.5, vs. median = 14.5, IQR = 11;  $p < 0.001$ ). A significant decrease in the Sartorius score (median = 28, IQR = 14.5, at W0 and median = 19.3, IQR = 15.5, at W10;  $p < 0.001$ ) was also observed when assuming that the 46 patients whose W10 data were not available had no improvement of the Sartorius score (i.e. 'worst-case hypothesis').

Eight patients (11%) had complete remission (Sartorius score = 0). One patient demonstrated no improvement, and the severity of HS increased in 2 patients.

Similarly, a higher proportion of patients were classified before treatment into the severest Hurley grades, i.e. II and III, as compared to after treatment (53.5% at W0 and 34.5% at W10;  $p = 0.018$ ). The median of the maximum pain score was 7 (IQR = 3) before treatment versus 3 (IQR = 5) after treatment ( $p < 0.001$ ), and the median of the maximum suppuration score was 6 (IQR = 4) versus 2 (IQR = 6;  $p < 0.001$ ).

Among the 70 patients, 46 (66%) considered the result of treatment as very good, 19 (27%) as good, 4 (6%) as stable, and 1 patient complained of a worsening of the disease.

Twenty-nine patients filled in the skin-disease-specific quality of life questionnaire (Skindex-France). The score of each dimension (emotion, symptoms and function) was significantly improved after treatment (table 4).

### Adverse Events

Ten out of the 70 patients (14%) complained of side effects, mostly nausea, diarrhoea and abdominal pain. Eight had to stop the antibiotic treatment (11.4%), 6 of whom because of digestive symptoms; all recovered without any specific treatment after stopping the antibiotic combination. One patient stopped because of a skin eruption 21 days after the beginning of the treatment and 1 because of absence of improvement after 7 weeks of treatment. Six of these 8 patients recorded the results of the antibiotic combination treatment as good or very good.

Among the 46 patients whose W10 data were not available, 10 came more than 10 days before or after the planned visit at W10. Their medical records were reviewed. Seven patients felt that they had improved, i.e. 4 with very good and 3 with good results.

### Discussion

After 10 weeks of treatment with the antibiotic combination of clindamycin and rifampicin in severely affected patients with HS, we observed a dramatic improve-

**Table 4.** Changes in the Sartorius score, Hurley's classification, intensity and duration of pain and suppuration, and skin-disease-specific quality of life score (Skindex-France) before and after treatment with clindamycin and rifampicin

		W0	W10	p
Sartorius score median	(n = 70)	29 [14.5]	14.5 [11]	<0.001
Hurley's classification	(n = 58)			
I		27 (46.6)	38 (65.5)	
II		27 (46.6)	18 (31.0)	0.018
III		4 (6.9)	2 (3.5)	
Maximal pain/10 median	(n = 69)	7 [3]	3 [5]	<0.001
Maximal suppuration/10 median	(n = 70)	6 [4]	2 [6]	<0.001
Number of days per month with pain	(n = 59)			
None		2 (3.4)	6 (10.2)	
<15		17 (28.8)	43 (72.9)	
≥15		13 (22.0)	3 (5.0)	<0.001
Permanent		27 (45.8)	7 (11.9)	
Number of days per month with suppuration	(n = 59)			
None		1 (1.7)	17 (28.8)	
<15		10 (17.0)	22 (37.3)	
≥15		13 (22.0)	5 (8.5)	<0.001
Permanent		35 (59.3)	15 (25.4)	
Skindex-France factors				
Emotion/100	(n = 29)	71 ± 7	49 ± 9	<0.001
Symptoms/100	(n = 29)	58 ± 14	34 ± 8	<0.001
Function/100	(n = 29)	57 ± 10	33 ± 11	<0.001

Continuous data are expressed as means ± SD except when otherwise indicated; categorical data are expressed as numbers, with percentages in parentheses; figures in square brackets indicate IQR. p values were determined by the Wilcoxon matched-pair signed-rank test or test of marginal homogeneity (Stuart-Maxwell) for paired data.

ment of the disease activity as assessed by the Sartorius score, but also by other measurements (Hurley's classification, frequency and intensity of pain and suppuration). Furthermore, all dimensions of quality of life improved significantly. The results of a study on the same topic published in this issue of *Dermatology* are in agreement with ours: out of 34 HS patients treated by the combination of clindamycin and rifampicin, the majority (82%) had an improvement of their clinical features [15]. Conversely the proportion of side effects was substantially higher in the other study than in ours (38.2 vs. 14%).

Our study has several limitations. It is an observational study and not a clinical trial. The decision to treat these 116 patients with the antibiotic combination had been taken by the principal investigator on clinical grounds, without any prior definition of 'inclusion criteria'. Analysis of their data, however, shows that as a group they were significantly more severely affected than the 257 who received another treatment. A limited number of before and after quality of life scores were filled out.

Moreover, the clinical endpoints of 40% (n = 46) of patients out of 116 could not be analysed after the treatment, leading to the possibility of a selection bias:

- 34 did not return at the end of treatment, because they were followed up by their referring physician and no data on the results were available; however, the initial characteristics of these 34 patients did not differ from the 70 who were analysed;
- 12 patients came for review before or after the planned 10 weeks, and they were not included in the analysis, even though the results of treatment seem to have been the same as for the 70 patients analysed.

No data about long-term follow-up and recurrences are given. In fact as this treatment was aimed at being suspensive only, a maintenance treatment with tetracyclines or zinc gluconate was prescribed at the end of the 10-week regimen. The results of such maintenance treatment are not available at this time.

The Sartorius score, which we used to assess the efficacy of treatment, is not formally validated. However, our



study shows a parallel between the evolution of the Sartorius score, the degree of intensity and duration of pain and suppuration, and the quality of life scores. Therefore, it seems relevant to use the Sartorius score to measure both the severity and the evolution of HS. Furthermore, the Sartorius score has been shown to correlate closely with the intensity and duration of pain and suppuration and with the Hurley classification in a series of 302 HS patients [16].

The strengths of the study are that a large number of consecutive patients were included, the diagnosis of HS was assessed using stringent clinical criteria, and all patients were examined by the same investigator. A standardized form was used for the prospective collection of data.

The disease has a psychological impact, especially upon quality of life and mental health [3, 17, 18]. The skin-disease-specific quality of life questionnaire was significantly improved after the treatment.

Rifampicin is a broad-spectrum antibacterial agent that inhibits the growth of the majority of Gram-positive bacteria as well as of many Gram-negative microorganisms [19]. It is highly active against both *S. aureus* and coagulase-negative staphylococci. When the drug was used alone, rapid emergence of resistance limited its use, except in association with another antistaphylococcal drug [20]. Clindamycin is a lincosamide antibiotic active against Gram-positive cocci and most anaerobic bacteria [21]. One trial found topical clindamycin superior to its vehicle [22], while another showed no difference between topical clindamycin and systemic tetracycline [23]. Clindamycin helps to prevent bacterial resistance against rifampicin and covers a broad antibacterial spectrum. The combination of systemic clindamycin (600 mg

daily) and rifampicin (600 mg daily) was given for 10 weeks, with success, to 14 patients with long-lasting HS [11]; 10 patients achieved remission. As in our study, diarrhoea was the most frequent side effect: minocycline was substituted for clindamycin in 2 patients, and the treatment was stopped in 4 cases. Both antibiotics were used at a relatively low dose in the same way as they had been used by Mendonça and Griffiths [11]. This way of using rifampicin and clindamycin is different from the way it is used in acute infectious diseases where higher daily doses are used during shorter periods: here it is a long-term treatment, i.e. 10 weeks for a disease which is not primarily infectious. Clindamycin and rifampicin have both antibacterial and anti-inflammatory effects [24–28]. Our data cannot elucidate the exact mechanism of the beneficial effect of clindamycin and rifampicin; nonetheless, we can hypothesize that their efficacy in HS, which is an inflammatory disease with bacterial superinfection, could be due to both antibacterial and anti-inflammatory properties.

Recently, several studies concerning anti-tumour-necrosis-factor treatment with infliximab [29–34], etanercept [35, 36] or adalimumab [37, 38] have reported a dramatic response in HS. A prospective trial comparing the efficacy of the combination clindamycin-rifampicin to anti-tumour-necrosis-factor biologicals in HS would help to assess the respective role of these therapeutic approaches.

In conclusion, these results suggest that the antibiotic combination of clindamycin and rifampicin significantly improves the clinical features and the quality of life of patients with severe HS. Prospective randomized controlled trials are needed to confirm these results.

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