

May 1996, BioClin B.V. Delft, The Netherlands

## **A Pilot Study to Evaluate the Efficacy of Multi-Gyn in the Treatment of non-specific Vulvitis and Vaginitis.**

*G. Beyer, Rode Kruis Ziekenhuis, The Hague; W. F. Beelaarts van Blokland, Deventer; R. M. Gaaymans, Made; M. C. Dersjant, Academic Hospital LUMC, Leyden; M. Csanky, The Hague; M. E. Boon, Leiden Cytology and Pathology Laboratory, Leyden; D. Goedhart, Arnhem; A. Goedbloed, BioClin, Delft*

---

**Summary:** In this open pilot study the data of 50 women with nonspecific vulvitis and vaginitis could be collected. Before and after treatment with Multi-Gyn the vaginal smears of the women were examined. The investigators and the patients evaluated the efficacy of the treatment, Only 7 women had abnormal cytology before treatment. After treatment a normal lactobacilli flora could be observed in all smears. 64% of all patients experienced a complete disappearance or strong relieve of complaints.

*Key words: vulvitis, vaginitis, vaginal smears, Multi-Gyn gel*

### **Introduction**

Evidently there are only 2 solutions for problems in the vaginal area:

- a medical solution such as treatment with antibiotics, corticosteroids etc. for serious problems
- a hygienic solution such as a vaginal rinse.

The greater percentage of problems in this area is however, on the one hand not serious enough for medical treatment, but on the other hand will not react to a mere hygienic measure.

Multi-Gyn gel was developed because the Case Reports of Multi-Skin cream and gel also reported treatment of complaints in the vaginal area such as itch, pain, dryness and inflammation. The Multi-Skin products are designed for application on the skin and the composition is not optimal for application on mucous tissues. Therefore it needed to be adapted, resulting in the product Multi-Gyn.

This pilot study was set up to obtain a better understanding of the indications for application of Multi-Gyn in the treatment of complaints of the vagina and vulva and the results for each individual indication.

We have also made an effort to support the indications and the results with the evaluation of a vaginal smear before and after treatment.

In this pilot study this was optional, because some investigators did not want to expose their patients more than necessary before positive treatment results with Multi-Gyn were obtained.

## **Materials**

The investigators received 75 ml tubes of Multi-Gyn, product information leaflets and patient diaries to hand out to the patients who wanted to participate in this pilot study.

The investigators were also provided with all materials for the optional vaginal Papanicolaou smears to be taken before and after treatment. Slides, brushes, fixation spray, tempex boxes for each individual slide and a large pre-stamped envelope were provided for expedition to the Cytologisch en Pathologisch Laboratorium Leiden.

The investigator binder contained the "instructions for the investigator", the "patient list", the patient CRF's for the registration of the data before and after treatment and pockets for the collection of the patient diaries.

## **Methods**

The patient was selected during a regular visit to her physician or gynaecologist when she mentioned to be 'annoyed' by complaints such as dryness, excessive discharge, itch, dryness and soreness, pain e.g. during intercourse etc..

The patient was then asked to participate in this pilot study with Multi-Gyn gel and received an information leaflet of the product. The investigator proceeded with the completion of the CRF of this pilot study. The evaluation of the seriousness of the complaints by the Visual Vagina/Vulva Score was performed by the investigator as well as the (optional) vaginal smear. The Vagina/Vulva Score was made up from the sum of the number given by the investigator for discharge, smell of the discharge, colour of the discharge, redness of the vagina and vulva and the swelling of this area. Normal was 0, a little abnormal 1, rather abnormal 2 and very abnormal 3.

The investigator had to explain the use of the Visual Analysing Scale (VAS score) on which the seriousness of the complaint had to be indicated by the patient with a point on a scale of 10 cm. The patient also had to give a score number (Hinder score) to the trouble she perceived from the complaint: 0 = no trouble, 10 very much trouble.

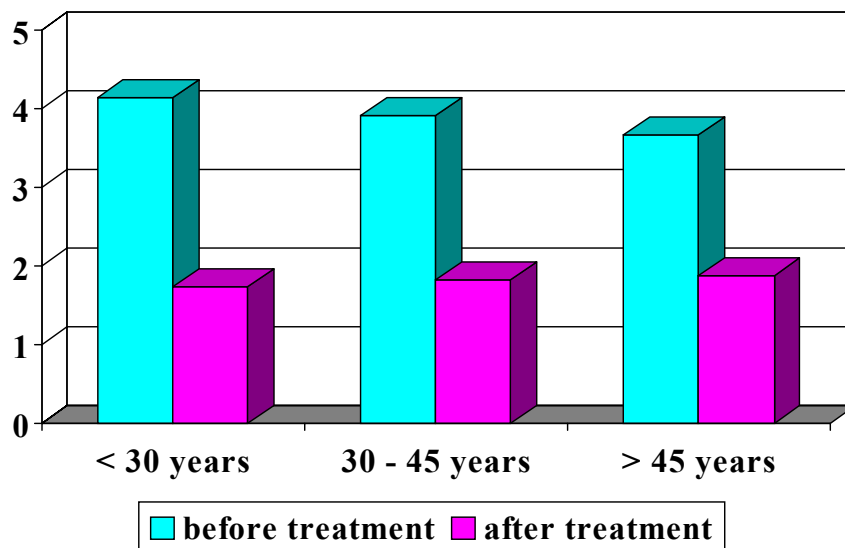
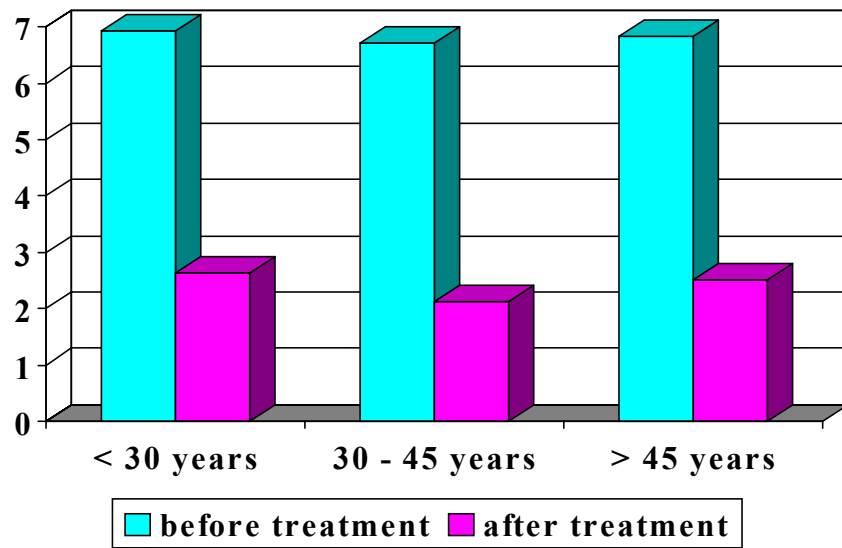
The patient was asked to apply the product vaginally during one week and to return in 2 weeks for a control visit. The patient was to report daily in the patient diary on the seriousness of the complaint with the use of the Visual Analysing Score and the Score number and to comment on the treatment. See Appendix 'Patient Diary'. The rationale of the one-week treatment and one-week no treatment was that one of the investigators wanted to collect information on the recurrence of the complaint after treatment with Multi-Gyn was stopped.

The smears were evaluated by Dr. Boon of the Cytologisch en Pathologisch Laboratorium Leiden.

All data from the CRF's have been entered into the database that was prepared by the statistician. Since the smears were optional, these results have not been evaluated by the statistician. They will be discussed separately.

## **Results**

The parameters for the efficacy of the treatment with Multi-Gyn gel were the Visual Vagina/Vulva Score, the VAS score and the Hinder-Score before and after treatment. The mean VAS Scores before and after treatment with Multi-Gyn can be seen in figure 1. Figure 2 shows the mean Vagina/Vulva scores, which were noted by the investigators.



The average efficacy of the treatment with Multi-Gyn gel of the complaints was 64 %.  
In total  $29 + 12 + 9 = 50$  patients participated. The distribution in age groups was: 29 patients age < 30 years, 12 patients age > 30 - < 45 years and 9 patients > 45 years.  
In the age group < 30 years the efficacy was 62 %, in the one of > 30 - < 45 years 68 % and in the one > 45 years 63 %.

The complaints that have been indicated in this study for possible treatment with Multi-Gyn gel were: itch - 34 patients; dryness, soreness - 16 patients; burning feeling - 15 patients; pain - 14 patients; discharge - 8 patients; coitus problem - 4 patients. ;

The complaint disappeared completely and without reoccurrence in 16 of the 50 patients. From the available patient diaries it was noted that the complaint had also disappeared completely in 3 patients during the one-week treatment but reoccurred during the week without treatment. In another 3 patients the complaint improved considerably, but worsened again during the one week without treatment.

7 patients did not benefit from treatment with Multi-Gyn. One of these was a 2 year old child of which the physician concluded at last that it had probably pushed something in the vagina: it was then given antibiotics.

However all the other 6 patients of this group noted that they benefited from a soothing and itch stopping effect. 3 patients of this group were > 45 years and 2 patients > 30 < 45 years.

### **Vaginal smears**

The vaginal smears in this pilot study were optional and have been performed on 27 patients before and after treatment.

Only in 7 patients the cytology before treatment was abnormal. In 5 cases either an abnormal coccoïd flora was noted, a high number of granulocytes or both. In 2 cases Trichomonads were detected in the pre-treatment smear. In all these cases the improvement after treatment could be seen macroscopically as well as microscopically in the smears in which a normal lactobacilli was observed. In the cases with Trichomonads in the pre-treatment smear, the post-treatment smear was clean with a physiological = lactobacilli flora devoid of Trichomonads. In the cases with a coccoïd overgrowth in the pre-treatment smear, the post treatment smear showed a Döderlein flora.

All other smears were judged 'normal' while the patient was indicating to be seriously annoyed by a complaint!

With these observations it becomes apparent that in many cases there is hardly a relationship between the seriousness of complaints such as itch and soreness and the cytology of the smear.

Therefore the cytological diagnosis can not be solely used as an instrument for the evaluation of the source nor the seriousness of this group of complaints. Other methods should be applied and these should probably be found in biochemical analyses of intercellular processes of the tissues.

## Discussion

This pilot study showed a high efficacy of the treatment with Multi-Gyn gel in the relief of complaints of the vagina and vulva, which are usually not serious enough to be medically treated with e.g. antibiotics or corticosteroid creams and which are persistent with extended hygienic measures such as vaginal rinses.

The patients which were included in this study could not be diagnosed but for 'atypical' vulvitis and -vaginitis. No medication was withheld on patients and patients with a diagnosis such as candida or chlamydia which would be routinely treated were not to be included.

The vaginal smears however showed in 5 cases the presence of coccoïd overgrowth - a Gardnerella pattern - and in 2 cases the presence of trichomonads before treatment. In all cases the smear pattern returned to normal after treatment.

Not all patient diaries were retrieved and 12 diaries have been lost during the move of the department to another hospital location of one of the investigators. 27 diaries could be checked for the course of the study period and comments.

In 6 patients the diaries indicated that the complaint had disappeared or improved considerably during the one-week treatment but reappeared afterwards. These last scores have been evaluated in the study results.

Looking at the one-week treatment results including this group of 6 patients the efficacy would be considerably higher.

The seriousness of the complaint as indicated by the VAS score and the Hinder score was similar: patients could visualise as well as estimate the number for the amount of annoyance they experienced from their complaint to the same degree.

All indications previewn in the CRF for the use of Multi-Gyn in this pilot study have been stated. The only new indication was the problem with pain during or after coitus which was specifically indicated by some patients. In view of the results obtained in the indications pain and dryness, soreness it is not surprising that Multi-Gyn is applied for this problem.

Itch is apparently the most frequent and most "annoying" problem -34 patients-, followed by dryness, soreness -16 patients-, burning - 15 patients, pain 14 patients- discharge -8 patients and coitus problem -4 patients. Treatment with Multi-Gyn showed a great relief in all these problems.

The larger group of patients was of the age group < 30 years (29 patients), followed by the one of > 30 - < 45 years (12 patients) and > 45 years (9 patients).

The treatment results as evaluated from the Vagina/Vulva score could give rise to the suggestion that other underlying processes such as atrophic post menopausal vaginal tissue are giving reason to the complaints of older women. However the number of this older patient group is not substantial enough for conclusions.

The results as evaluated by the VAS score and the Hinder score did not show large differences between the age groups.

## **Conclusion**

From the results of this pilot study on the efficacy of one week treatment with Multi-Gyn and the evaluation of the lasting results after one week no treatment of atypical vulvitis and - vaginitis it can be concluded that Multi-Gyn is a great relief for the complaints (64%) and often a complete cure.

Multi-Gyn could take position between medication and hygienic measures for the treatment of frequent 'intimate' complaints.

It greatly improves 'the quality of life' by a strong itch stopping and soothing effect.

From the available number of the (optional) vaginal smears we have come to the preliminary conclusion that these don't offer a trustworthy tool for the diagnosis of the source of this group of complaints. In the small number of cases with an unphysiological flora and/or inflammatory pattern and/or trichomonads, we saw that after treatment the cytology had returned to normal.