

Belara[®] – proven benefits in daily practice

J. Bitzer

Department of Gynaecological Public Health and Psychosomatics, Universitäts-Frauenklinik, Basel, Switzerland

ABSTRACT Today, a contraceptive method is available to suit nearly every type of woman, every age and all preferences and expectations. All that seems to remain for users is to look for the right product to satisfy their personal requirements. The physician takes on the role of the adviser, responsible mainly for errors of judgement and undesirable effects. The choice of the suitable contraceptive depends on three factors: the patient profile, the profile of the method used and the user's life situation. In selecting the method of contraception, statistical measures such as the Pearl Index, rate of adverse events, risks and health benefits as well as the pharmacological profile, resulting intake modality and potential interactions should be considered. The patient profile includes both subjective wishes and standards of value relevant for world view, family planning and psychological well-being, as well as objective parameters such as age, BMI, medical history and the woman's sexual behaviour. Evaluation of these parameters by the physician is a major component of successful contraceptive counselling. Belara[®] is a new oral contraceptive on the European market based on a monophasic combination of 2 mg chlormadinone acetate and 0.03 mg ethinylestradiol. As well as high contraceptive efficacy and a low rate of side effects, Belara[®] features an outstanding safety profile due to its almost complete absence of mineralocorticoid and glucocorticoid action and its absent impact on hepatic metabolism. In daily practice, Belara[®] exhibits mild antiandrogenic activity which also makes it suitable for users with antiandrogen-induced seborrhoea and moderate acne. Symptoms of PMS or unspecific dysmenorrhoea and menstrual irregularities can also be alleviated or completely eliminated by taking Belara[®]. Belara[®] use has not been associated with any significant weight gain. In daily practice, Belara[®] is suitable for every woman of every age without specific risk factors requiring safe contraception. Belara[®] also has considerable additional health benefits that should also be considered when choosing a suitable contraceptive.

KEY WORDS Oral contraceptive, Ethinylestradiol/chlormadinone acetate, Antiandrogenic activity, Daily practice, Patient profiles

INTRODUCTION

We live in an age of increased choice and this is particularly the case with regard to contraception. It seems that there is currently a product for every type

of woman, every age group and for all preferences and expectations. The products available vary from barrier methods and natural family planning methods to

Correspondence: Prof. Johannes Bitzer, Department of Gynaecological Public Health and Psychosomatics, Universitäts-Frauenklinik, Schanzenstrasse 46, CH-4031 Basel, Switzerland

hormonal contraceptives with different formulations and combinations, different methods of application and differing dosages. Sterilisation and postcoital contraception further add to the range of possibilities.

Women frequently seek advice from their doctor in finding the right product to satisfy their individual requirements and may hold him or her responsible for errors of judgement or undesirable effects. The choice of a suitable contraceptive depends on three factors: the method profile, the patient profile and the user's life situation.

METHOD PROFILE

The method profile is defined by two properties: the pharmaco-chemical characteristics and the statistical data (Figure 1). The pharmaco-chemical characteristics include pharmacokinetics, pharmacodynamics, the mode of application and potential interactions. Statistical data include measures such as the Pearl Index, rate of adverse events, risks and health benefits. These statistical measures may change and thus need to be continuously evaluated.

In the case of the oral contraceptive Belara[®], bioavailability is high, $t_{1/2}$ is 34–36 h and a steady state in blood plasma level is reached after 7 days¹. The chlormadinone acetate (CMA) component of Belara[®] has high affinity for the progesterone receptor, while exhibiting negligible binding to estrogen, androgen and mineralocorticoid receptors and very weak

binding to the glucocorticoid receptor². The anti-androgenic effects of Belara[®] are a result of the competition of CMA with androgens in the target tissues and also the effect of ethinyl estradiol in increasing sex hormone binding globulin levels in the plasma thus reducing free testosterone levels³.

In terms of statistical data, Belara[®] has an excellent contraceptive efficacy with an adjusted Pearl Index of 0.04. Clinical trials and post marketing surveillance studies have shown that Belara[®] is well tolerated^{4,5}. Adverse effects were those commonly reported with oral contraceptives; the occurrence of these was diminished after continuing treatment. Importantly, Belara[®] has shown a number of health benefits including good cycle control, reduction of dysmenorrhoea, alleviation of PMS and improved quality of skin and hair condition^{3,6}.

THE PATIENT PROFILE

The patient profile includes both subjective wishes and standards of value relevant for family planning and psychological well-being, as well as objective parameters such as age, body mass index (BMI), medical history and the woman's sexual behaviour (Figure 2). Evaluation of these parameters by the physician is a major component of successful contraceptive counselling^{7,8}.

The subjective part of the patient profile is often not well evaluated and should be approached with open

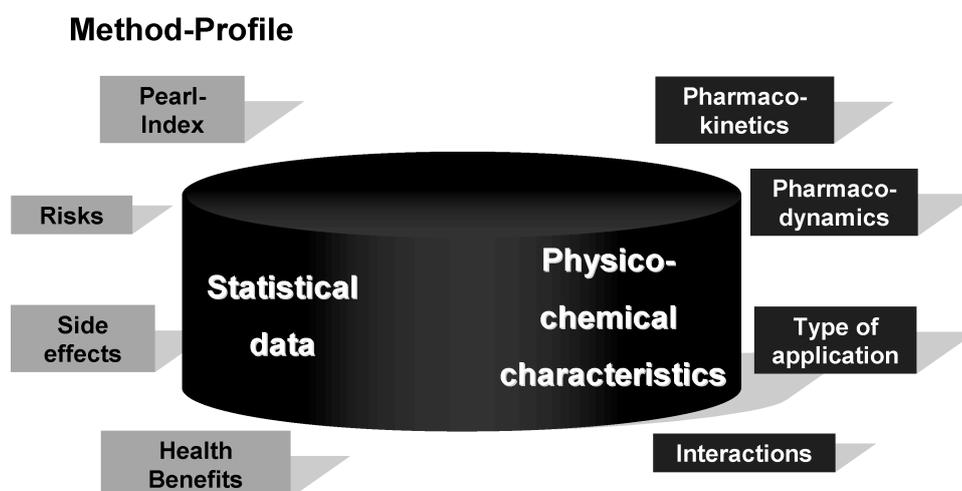


Figure 1 Methods profile for Belara[®]

questions to determine motives for wanting contraception, future family planning and attitude to different contraceptive methods. It is important to discuss the practical impact of the various available methods and whether the partner should be involved⁸.

Part of the objective side of the profile is straightforward medical history, family risks, lifestyle, and so on, which can be compiled in response to goal-directed closed questions. A psychosocial risk profile should be compiled to assess educational and socio-

economic status, stress at home and at place of work, type and quality of relationship, and risk behaviour, including impulsive sexual behaviour, drug abuse, protection against sexually transmitted disease, and so on. It is also important to determine behavioural and personality characteristics of the patient as these can influence the woman's compliance in contraceptive use, provoking unwanted pregnancies.

Active questions about physical and psychological symptoms, their individual importance and contra-

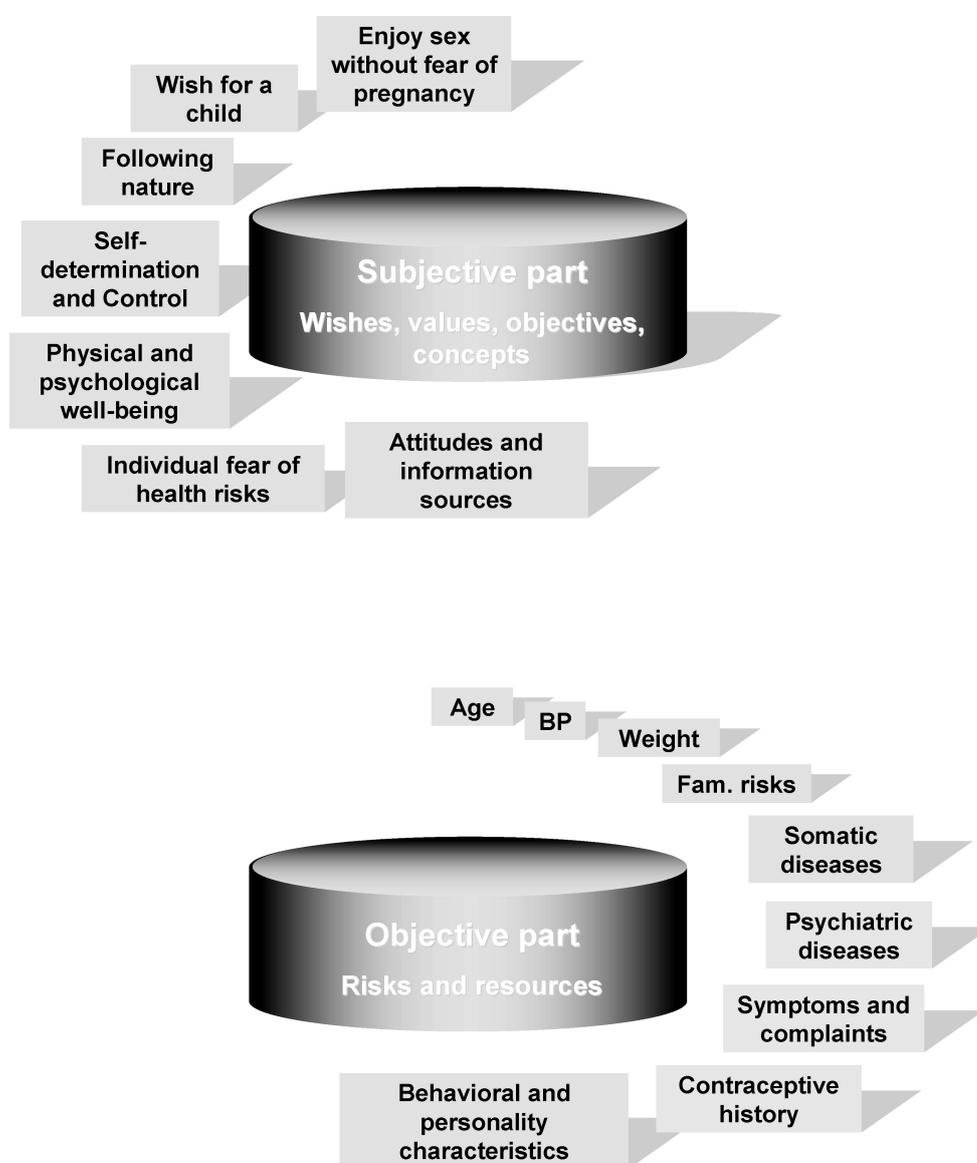


Figure 2 The patient profile

ceptive history of the woman complete the profile. Menstrual problems, anxieties, mood and dissatisfaction with body appearance can have a diminishing effect on perceived quality of life. It is therefore important when asking for physical and psychological symptoms to allow the woman to rate her subjective importance to reported symptoms, although this will not necessarily correspond directly with the objective intensity of the problem. The use of standardized questionnaires may be helpful in this situation⁹.

PATIENT PROFILES

Belara[®] has now been on the market in Switzerland for four years and some of our experience of patient profiles is illustrated here.

Patient 1 (Figure 3)

This young woman has no stable relationship and her priority is to enjoy sexual experiences without fear of pregnancy. In this case efficacy is of prime importance and ease of use is also an important consideration. Medical risk includes a father who has had a mild cardiac infarction, and this should be taken into consideration when choosing an hormonal contraceptive. The young lady plays tennis regularly and has an active lifestyle. When asked about symptoms and complaints she rates them highly, but after questioning only mentioned pre-menstrual syndrome (PMS), so

that the subjective importance is quite low. Her satisfaction with her physical appearance is not very high and could be improved by diminishing her seborrhoea and PMS problems. She has previously used condoms and now wishes to switch to a safer contraceptive method. Belara[®] is a suitable product to guarantee safe and effective contraception, improvement of body self image, PMS related symptoms and health related quality of life.

Patient 2 (Figure 4)

This patient is in a stable relationship and rates attractiveness as important. As with many patients she rates her skin problem highly although evidence of acne was not pronounced. She has had previous spotting, dysmenorrhoea and she smokes. She was taking a combination oral contraceptive, but suffered from weight gain, bloating and lack of libido, which led to discontinuation. She would be a good candidate for Belara[®] since she would benefit from the good cycle control, stable weight control, and beneficial effect on the skin without loss of libido.

Patient 3 (Figure 5)

This 23 year old woman is in a stable relationship and has no personal health risks. Her mother suffers from hypertension and her father from diabetes. She suffers from PMDD and has menstrual headaches and

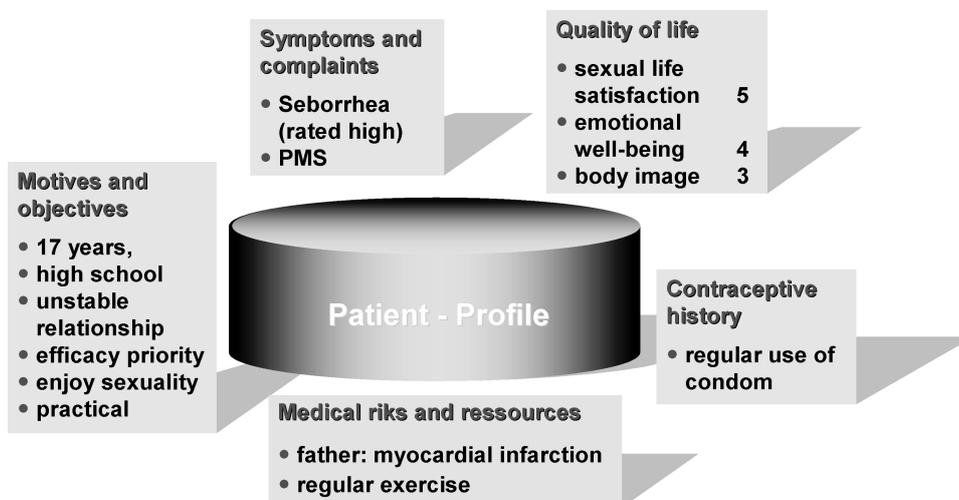


Figure 3 Patient 1 profile

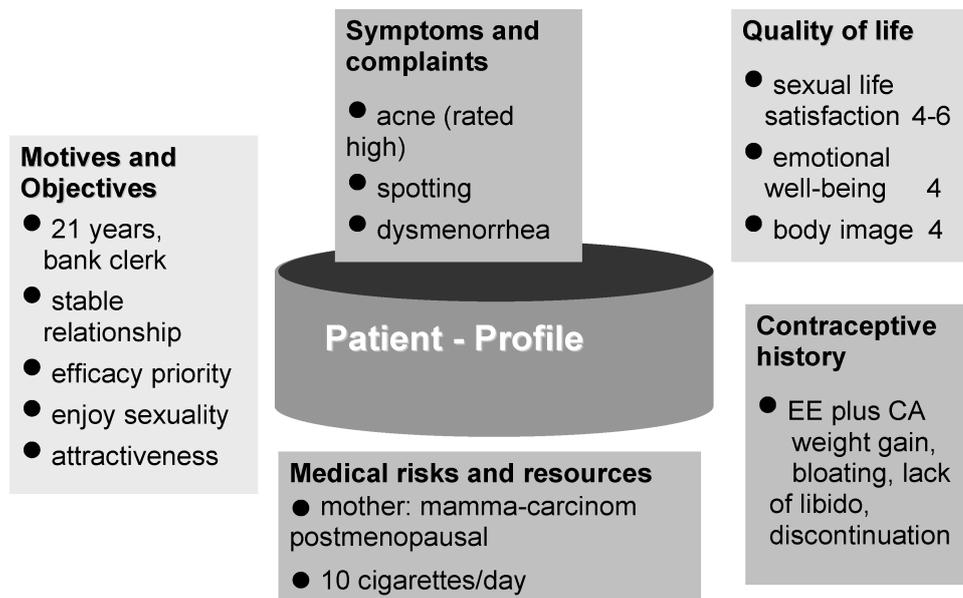


Figure 4 Patient 2 profile

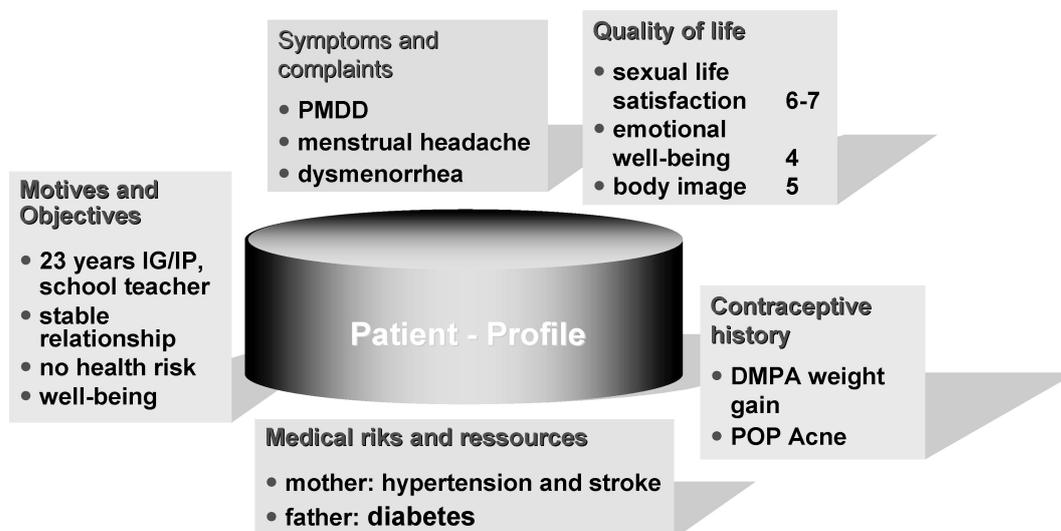


Figure 5 Patient 3 profile

dysmenorrhoea. In the past she has used a continuous progesterone-only pill but had suffered from weight gain and acne. In view of its potential reduction of dysmenorrhoea symptoms and acne, its good profile regarding adverse drug reactions such as weight gain and headache, and its metabolic neutrality Belara® would be a good choice for this patient.

Patient 4 (Figure 6)

This 22 year old nurse is not in a stable relationship and although she has used condoms in the past she is currently not using contraception. She has cycle problems, considers herself overweight (although her BMI is normal) and has problems with excessive

hair on her upper lip and breast. As a consequence she gives a low value to her body image and a non-existent sexual life. Nevertheless her emotional well-being is good and the current consequences for her health-related quality of life are moderate and could

be improved. It needs to be ascertained whether the hyperandrogenic symptoms are related to a polycystic ovarian syndrome. Diabetes diagnostics should be performed, especially when taking into account that her mother shows this as a risk factor in

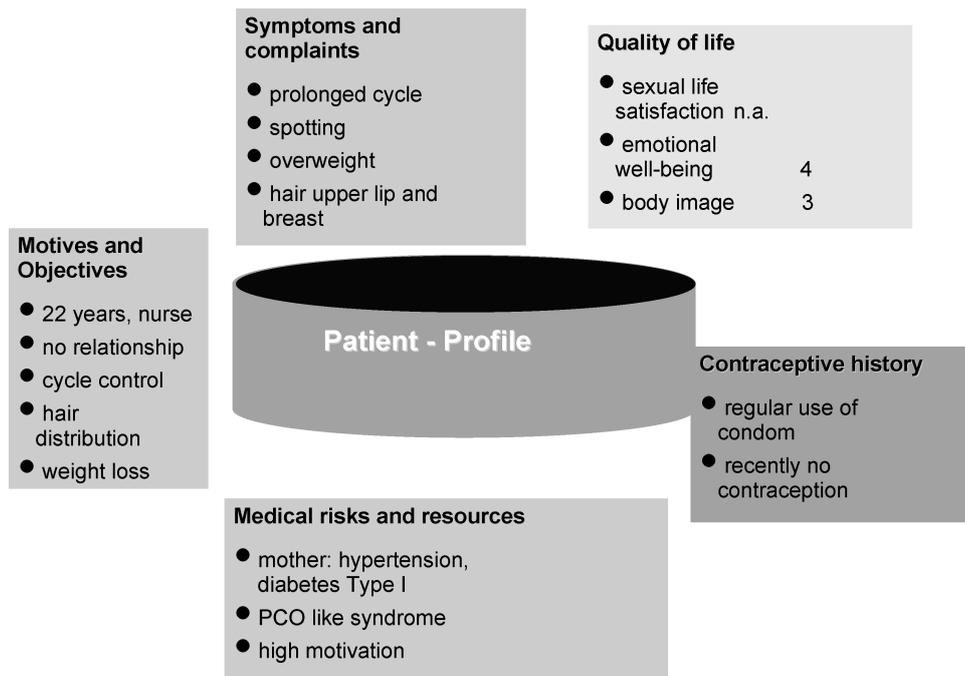


Figure 6 Patient 4 profile

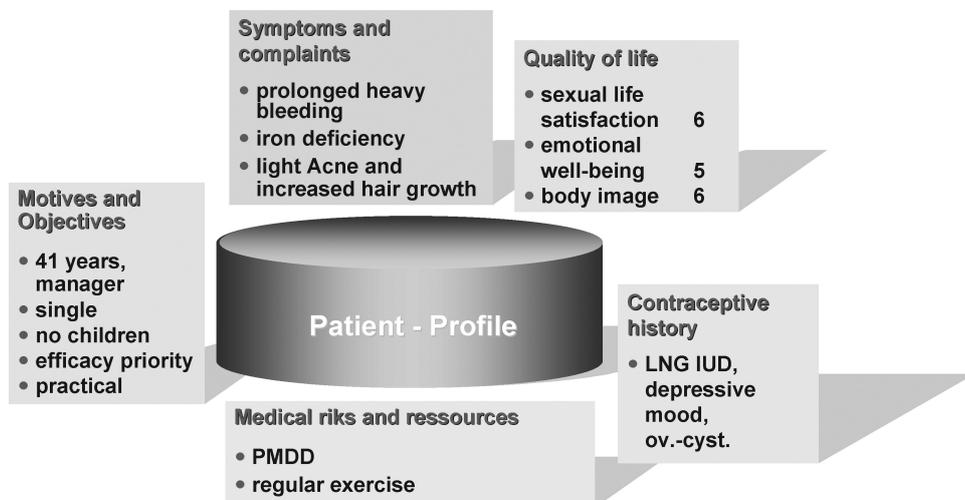


Figure 7 Patient 5 profile

combination with hypertension. Although there is not currently a need for contraception, the patient could benefit from the antiandrogenic properties of Belara[®].

Patient 5 (Figure 7)

This 41 year old manager is single, with no children, and rates efficacy as her main priority. She suffers from prolonged heavy bleeding, iron deficiency, light acne and increased hair growth. She exercises regularly. In the past she has used Mirena. She has noticed a depressed mood and also suffered an ovarian cyst that disappeared without intervention. She was also prescribed Belara[®].

CONCLUSION

From our experience, Belara[®] provides excellent contraceptive efficiency with a considerable number of health benefits. In daily practice it exhibits mild anti-androgenic activity which makes it suitable for users with androgen induced seborrhea and moderate acne. Symptoms of PMS or unspecific dysmenorrhoea and menstrual irregularities can also be alleviated or completely eliminated by taking Belara[®]. Belara[®] use has not been associated with any significant weight gain. Belara[®] is suitable for every woman in every age group without specific risk factors who wishes to select a safe method of contraception.

REFERENCES

1. Curran MP, Wagstaff AJ. Ethinylestradiol/Chlormadinone acetate. *Drugs* 2004;64:751–60.
2. Raudrant D, Rabe T. Progestogens with antiandrogenic properties. *Drugs* 2003;63: 463–92.
3. Worret I, Arp W, Zahradnik HP, *et al.* Acne resolution rates: results of a single-blind, randomized, controlled, parallel phase III trial with EE/CMA (Belara[®]) and EE/LNG (Microgynon[®]). *Dermatology* 2001;203:38–44.
4. Schramm G, Steffens D. Contraceptive efficacy and tolerability of chlormadinone acetate 2mg/ethinylestradiol 0.03mg (Belara[®]): results of a postmarketing surveillance study. *Clin Drug Invest* 2002;22:221–31.
5. Schramm G, Steffens D. A 12-month evaluation of the CMA-containing oral contraceptive Belara[®]: efficacy, tolerability and anti-androgenic properties. *Contraception* 2003;67:305–12.
6. Zahradnik HP, Goldberg J, Andreas JO. Efficacy and safety of the new anti-androgenic oral contraceptive Belara[®]. *Contraception* 1998;57:103–9.
7. Bitzer J. Contraception from the women's point of view (Part 1). *Praxis* 2000;89:1142–6.
8. Bitzer J. Contraception from the women's point of view (Part 2): Longterm pill users are convinced of the advantages of hormonal contraception. *Praxis* 2000;89: 1237–42.
9. Bitzer J, Hänggi W, Husslein P, *et al.* Longterm contraception. Recommendations of an Austrian-Swiss-Working Group. *Gynäkologisch-geburtshilfliche Rundschau* 2002;41: 253–9.

Copyright of European Journal of Contraception & Reproductive Health Care is the property of Taylor & Francis Ltd. The copyright in an individual article may be maintained by the author in certain cases. Content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.

Copyright of *European Journal of Contraception & Reproductive Health Care* is the property of Taylor & Francis Ltd and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.