

## Norplant in South Africa — the first 100 patients

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High maternal mortality rates coupled with poor socio-economic conditions in developing countries indicate the need for those truly dedicated to improvement of maternal well-being to investigate advances in methods of pregnancy regulation and to implement those found to be effective and acceptable.

In a trial involving 100 patients at Tygerberg Hospital that commenced in December 1993, Norplant was found to be highly acceptable and easy to use.

It is strongly recommended that the acceptability of Norplant to the general South African population be evaluated further and then, hopefully, made available to all our people without undue delay.

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The harsh realities of an unacceptably high maternal mortality rate — 630 - 1 000/100 000 women in parts of Africa' due, in part, to repeated or unplanned pregnancies and unsafe abortion — and ever-increasing economic hardship must surely indicate the very real need for planned parenthood and effective long-term female fertility regulation.

This can be provided, *inter alia*, by Norplant (levonorgestrel (LNG) in silastic tubes),<sup>2</sup> which has already had extensive clinical testing worldwide and is widely recognised as safe, effective and acceptable to patients. A progestogen-only method, Norplant is implanted subdermally<sup>3</sup> in the early proliferative phase of the cycle or 6 weeks postpartum and affords at least 5 years' effective and compliance-free contraception. It is effective within 24 hours of insertion<sup>4</sup> and no plasma LNG is detectable more than 96 hours after removal. Resumption of ovulation is swift — 100% within 7 weeks.<sup>5,6</sup>

Norplant causes a pronounced increase in cervical mucus viscosity,<sup>7</sup> suppresses ovulation<sup>8</sup> and renders the endometrium unreceptive to implantation.<sup>3</sup> No clinically important side-effects have been noted in respect of carbohydrate and lipid metabolism, liver functions,<sup>9-11</sup> blood coagulation<sup>12</sup> and hormone levels, except in the case of oestradiol levels, which may fluctuate.<sup>13</sup>

Although contraindicated in pregnancy and in patients with undiagnosed genital bleeding, breast dysplasia, benign or malignant liver tumours, acute liver disease and acute thrombophlebitis or thrombo-embolic disease, Norplant

appears to be eminently suitable for those needing long-term fertility regulation, especially if oestrogen or an intra-uterine contraceptive device is contraindicated. It is also an excellent contraceptive for sexually active adolescents.<sup>13</sup>

The first year of the Tygerberg trial of this drug, aimed at determining its acceptability as well as its side-effects in our local population, is now complete. Experience to date is reported here.

### Aim of study

To determine whether Norplant (LNG subdermal implants) would be an acceptable alternative method of fertility control for the patients cared for by the family planning service of Tygerberg Hospital.

### Sample population

Patients were recruited from those attending the family planning clinics served by Tygerberg Hospital for the first time; all were informed about Norplant and out of those who showed interest and gave written consent, 100 consecutive patients were entered into the study. Twenty-five white, 70 coloured and 5 black patients were included. This distribution is representative of the current demographic trends at the hospital.

### Material and methods

A descriptive study was undertaken on a pre-registration trial basis at the Department of Obstetrics and Gynaecology, Tygerberg Hospital. Biochemical and haematological parameters were not investigated as the extensive world literature available had already covered this aspect adequately.<sup>9-11,13,14</sup>

The insertions and removals were performed according to standard procedure<sup>13</sup> under local anaesthesia by medical staff in the clinic setting. Ten insertions were done under specialist supervision by registered nurses qualified in family planning. Four lactating mothers received Norplant.

Follow-up was undertaken at the clinic at 3-monthly intervals and patients were questioned about acceptability, pain on insertion, bleeding and other disorders, infection at the implantation site and effect on lactation where applicable.

In an attempt to obviate bias, data capture was by independent and otherwise uninvolved nursing personnel. Data were subsequently entered onto standardised questionnaires.

### Results (Table I)

Ninety-four patients are currently continuing on Norplant. Of the 6 removals, 2 have been for pain at the insertion site, 1 for severe mood changes, 1 to have another pregnancy, 1 because of a perceived shift in her fat distribution, and 1 because her husband simply did not like the method. All removals were easily accomplished and uncomplicated.

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gain on insertion was noted by 4 patients. In 3 cases, wound infection was suspected clinically but no removals were required after antibiotic therapy. No adverse effect on lactation has been noted to date. Occasional cases of headache, bloatedness, dizziness and weight gain have been recorded, while 4 patients experienced appreciable hair loss.

**Table 1. Results of a 1-year trial of Norplant at Tygerberg Hospital (N = 100)**

	Yes	No	%
Removals	6	94	6
Pain on insertion	4	96	4
Implant site 'infection'	3	97	3
Lactation affected	0	4	0
Bleeding disorders	52	48	52
Treatment required	13	39	25

\*Other disorders: mastalgia 2, hair loss 4, weight gain 3.

As expected, breakthrough bleeding has been the most common side-effect, occurring in 52% of patients, 13 (25%) of whom required treatment with cyclic ethinyl oestradiol at a dosage of 0.05 mg per day for 21 days and repeated for 3 months. While it may as yet be too early to evaluate this result, all patients have responded excellently to treatment and subsequent amenorrhoea has been the rule. Reassurance sufficed for the remainder and all are continuing on Norplant.

## Conclusion

From the above it appears that Norplant has performed very well in this group of patients, a finding comparable with world experience.

Undoubtedly acceptability of Norplant will need to be assessed in the general South African population and more and larger trials should be undertaken, including trials to evaluate immediate postpartum insertion. Paramedical staff should also be trained in its use. Norplant is easy to use,<sup>13</sup> effective and highly acceptable to our patients and should be made available to South African women as an alternative fertility regulation method without undue delay.

Some caution is, however, advocated with regard to the introduction of Norplant in South Africa and its public health services. It will, for instance, be necessary to ensure adequate training of care providers, so as to avoid the negative experiences of some parts of the world, notably Indonesia. These have apparently been ascribed to insensitive launch handling as well as to lack of provider empathy.<sup>15,16</sup> Adequate service facilities must also be made available.

It must be noted that Norplant is not recommended for patients on phenytoin, carbamazepine or rifampicin (all commonly used in southern Africa) because of hepatic microsomal enzyme induction and consequent decreased efficacy of Norplant.<sup>17</sup>

## Cost

As Norplant is not yet available in South Africa speculation

about its possible cost appears premature. It has been said, however, that costs in the USA are in the vicinity of \$350 and \$50 for private and state patients respectively. This apparent high cost must, of course, eventually be offset against that of unplanned (unwanted?) pregnancies.

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