Implanon® the single rod contraceptive implant

R.M. Melief

Abstrak

Implanon® merupakan kontrasepsi implant satu batang dengan panjang 4 cm dan diameter 2 mm. Berisi 68 mg etonogestrel (ENG). Implanon akan melepaskan ENG ke aliran darah 60-70 µg/hari pada 5 minggu pertama, menurun menjadi 35-45 µg/hari pada akhir tahun pertama dan turun lagi menjadi 25-30 µg/hari pada akhir tahun kedua. Efek kontrasepsi utama dengan menekan ovulasi. Karena itu efektivitasnya sangat tinggi. Satu minggu setelah Implanon® dicabut tidak ditemukan lagi ENG dalam darah, sehingga kehamilan dapat terjadi setiap saat. Keunggulan lain dari Implanon® adalah pemasangan dan pencabutan mudah karena hanya terdiri dari satu batang dan menggunakan inserter sekali pakai.

Abstract

Implanon® is a single implant contraceptive method. It contains 68 mg etonogestrel. Etonogestrel (ENG) is released from Implanon® at a rate of approximately 60-70 µg/day during week 5-6, declining to approximately 35-45 µg at the end of the first year, and approximately 25-30 µg at the end of the third year. The contraceptive action mainly by ovulation inhibition. That's why until now there is not a single pregnancy observed during Implanon-use. Another advantage of Implanon® is that it is using a disposable insertion.

Keywords: *Implanon®, single implant contraceptive.*

Clinical research programme

Contraceptive efficacy and tolerability of the Implanon® rod was investigated in an extensive clinical development program. Studies were conducted in 9 European countries, North- and South America and in South East Asia. In comparative studies, an implant system consisting of 6 levonorgestrel (LNG) containing capsules (Norplant®), has been used as the reference product.

The database resulting of this development program contains the observations in about 2,300 women treated for 70,000 cycles with Implanon® and of about 800 women treated for over 25,000 cycles with Norplant®.[6]

Features of Implants

There are various differences between the Implanon® and Norplant® system. The duration of use of Implanon® is 3 years compared to 5 years for Norplant®. The type and consequently the dose of progestogen is different: Implanon® contains 68 mg of etonogestrel while Norplant® holds 216 mg of levonorgestrel. The single Implanon®-rod is supplied in a pre-filled and disposable applicator; the 6 Norplant® capsules are inserted with a trocar which is re-used after sterilisation. Consequently time needed for insertion and removal is considerably less for the single-rod system. The Implanon®-rod has a diameter of 2 mm, the 6 Norplant capsules are 2.4 mm in diameter. The length of the single Implanon®-rod is 40 mm compared to a length of 34 mm for each Norplant® capsule. The carrier of the active compounds is ethylenevinylacetate (EVA) with Implanon® and silicone with Norplant®.

Pharmacological profile

Serum levels of ENG increase rapidly in the first four days after insertion and reach a level sufficient for ovulation inhibition within the first day. This level declines in the first year of use after which a steady state is reached.[1,5,6] During the first two years the ENG serum concentration remains at ovulation inhibiting level. In the 3rd year of use ovulation recurred in less than 5% of users.[5,6] Contraceptive efficacy is maintained by the additional effect on the cervical mucus which inhibits sperm penetration[1]. In Norplant® users first ovulations have been observed in the second year.[5,6]

Medical Adviser Contraception
NV Organon, Oss, The Netherlands

Ovarian activity

Although ovulation is inhibited effectively, substantial ovarian activity may still be present. This is apparent from almost normal FSH activity and estradiol levels.[1,5,6]

More follicular activity is observed with Norplant® compared to Implanon®, especially during the first year of use indicated by the development of a larger number of pre-ovulatory follicles.[6]

Return of ovulation

Within one week after Implanon® removal ENG serum levels can no longer be detected independent of the time Implanon® has been used. This indicates the rapid return of the user's normal fertility.[1,6]

Contraceptive efficacy

The studies assessing contraceptive efficacy of Implanon® included more than 70,000 cycles. No pregnancies were observed in Implanon® users resulting in a Pearl Index of 0.[6] Documented pregnancy rates with Norplant® vary from a Pearl Index of 0.2 in the first year to 1.1 in the fifth year.[7]

Bleeding pattern

The bleeding pattern observed with Implanon® is comparable to that seen with other progestogen-only contraceptives.[6]

Tolerability

The most frequently reported side effects during the use of Implanon® were headache (13.5%) acne (10.3%) which is balanced by the observation of improvement of this condition in approximately the same percentage users, vaginitis (8.9%) and breast pain (7.6%).[6]

The increase in body weight observed with both methods may be considered only partially attributable to the treatment and is not much different from a normal weight increase over time in women who are not exposed to exogenous sex steroids.[6]

Reported incidences of side effects were higher in the studies performed in USA/Europe and lower in the trials carried out in Indonesia. The above figures represent the combined data.

No statistically significant differences in side effects were reported between Implanon® and Norplant® users. No clinically relevant effects on metabolic parameters have been observed during the use of Implanon®.[6]

Beneficial effect on dysmenorrhoea

Implanon clearly demonstrated a beneficial effect on the occurrence or severity of dysmenorrhoea.[6]

Insertion and removal

Insertion and removal of the Implanon® rod can be performed four times faster than with the Norplant system. On average Implanon® insertion takes 1.1 minutes, while removal requires 2.7 minutes.[6]

Hardly any complications with insertion were reported for either method. A ten-fold difference in removal complications was observed for Norplant® (6%) compared to Implanon® (0.6%).[6]

Women might change doctors or move to other areas while using Implanon®. Therefore Organon recommends to keep the insertion site of Implanon® consistent world-wide: 6-8 cm above the elbow at the inner side of the upper arm on the non-dominant side,in the groove between the biceps and triceps (sulcus bicipitalis medialis).

By following this procedure, users can palpate the implant as it is in situ and the removing doctor can easily locate the implant by palpation.

Conclusion

In summary, Implanon® offers a compliance independent method for three years of contraceptive protection. The hormonal exposure is low. Physicians can, after being trained, easily insert and remove the single rod. All described features of Implanon® contribute to a high acceptability of users and physicians.

References

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