

associated initially with loss of unilateral vision and subsequently substantial loss of field in the unaffected eye, relieved by the administration of systemic corticosteroids: the hallucinations were a very temporary effect of cortical ischaemia relieved by prednisolone. In Case 2 the hallucinations occurred after an interval of two months, following severe bilateral loss of visual acuity, with no relief from corticosteroid therapy; in this particular case it must be assumed that the occlusive process has been permanent. The time of onset of this symptom after ocular involvement is of interest since it corroborates previous descriptions in that the generalized effect of cranial arteritis may follow ocular involvement by an interval of one to six months.

The rarity of visual hallucinations in the blind has been noted by Freeman and Williams (1953) and it should be stressed at this stage that the formed hallucinations experienced by these two patients in no way resemble the psychic disturbances of postoperative cataract patients in which the imagery promptly disappears on uncovering the eyes. Walsh (1957) is of the opinion that formed visual hallucinations are due to involvement of the temporal lobe, and cites both experimental and clinical evidence to substantiate this point. A differing view is held by Weinberger and Grant (1940), who believe that no such strict localization exists within the cerebral hemispheres, such hallucinations representing psychological phenomena involving the total integrative activity of the mind, the formed imagery depending on constitutional factors, not on cortical psychic organization. In his summary, Walsh prefers to accept the localization of such phenomena to the temporal lobe, founded on the available experimental and clinical evidence. Both

patients whose cases have been described show marked complacency to their respective visual symptoms, and it is postulated that this euphoria may also be connected with the intracranial occlusive episodes of cranial arteritis.

Summary

Two cases of cranial arteritis, both manifesting formed visual hallucinations as a disturbing symptom, are described. The mode of presentation differed; in one case this symptom preceded the onset of unilateral loss of visual acuity and subsequently gave warning of impending visual loss in the other eye, whereas in the second case this symptom followed the occurrence of bilateral loss of vision. The subject of visual hallucinations and their possible relation to the known intracranial vascular pathology of this disorder are discussed.

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Effect of an Oral Contraceptive Immediately Post Partum on Initiation of Lactation

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Oestrogens are known to suppress lactation, and are often used for this purpose. The oral contraceptives currently available contain oestrogens and progestogens in varying doses. In some the progestin component itself has oestrogenic qualities (Paulsen, 1965), and treatment with this group might be expected to impair lactation to a marked extent. Rice-Wray (1964) reported that in about half of the lactating mothers she studied the milk yield was diminished by oral contraceptives. This seems to be a dose-dependent effect, for Pincus (1965, p. 262) noted that the percentage inhibited decreased from 77 to 15 as the norethynodrel dose was reduced from 20 to 2.5 mg./day. Satterthwaite (1964) thought that a 2.5-mg. dose of norethynodrel did not significantly affect lactation, but in her study there were no controls and the small number of patients makes generalization difficult.

Of oral contraceptive preparations currently available Norinyl-1 (norethisterone 1 mg. and mestranol 0.05 mg.) has the lowest total steroid content. Furthermore, norethisterone is antioestrogenic in some of its effects. In view of Rice-Wray's findings and Pincus's suggestion of a dose-dependent effect it seemed important to test the action of Norinyl-1.

The immediate post-partum period is the most convenient time to advise on contraception, and if the agent can be prescribed at this time follow-up problems are considerably reduced. This aspect is of prime importance in the developing

countries, where the immediate post-partum period may be the only opportunity for contraceptive treatment, and where breast milk may be the infants' only source of protein.

Most studies of the effects of oral contraceptives on lactation have not been controlled, and since many factors influence lactation this reduces their value.

Methods

All mothers delivered in the obstetrics unit of St. Joseph's Hospital, Copenhagen, during the period July-September 1966 entered the trial, with the exception of (1) mothers who it was decided, before or immediately after delivery, should not attempt to breast-feed, and (2) mothers who gave birth to infants weighing less than 2,000 g.

A total of 451 women took part in the trial. Tablets were supplied by Syntex Pharmaceuticals Limited, England, in small containers marked only with a code number and containing 21 tablets. The code was not disclosed in Denmark until the trial had been completed, but it was known that some of the tablets were Norinyl-1 and others were inert placebo tablets. Each woman included in the trial received one tablet daily from the day after the birth of her child until discharge from hospital on the eighth day.

The relevant details of each case were recorded on a form which included the mother's previous history of breast-feeding, the code number of the tablets taken, and the baby's birth

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weight. A trained nurse accurately recorded on a decimal balance in the lying-in ward the weight of the babies on the second, fifth, and eighth days. The nursing staff were asked to assess the influence of the tablets on the onset of lactation. They recorded observations on the ease and adequacy of lactation, the state of the breast and nipples, and whether the patient was fully breast-feeding, complementary feeding, or completely artificially feeding.

Ten patients from each group were asked to continue their pills at home for a further two weeks and on completion to return to the hospital a questionnaire concerning the progress of lactation.

During the latter part of the trial observations were made with respect to the quantity of uterine haemorrhage, the type of lochia, after-pains, and the rate of involution of the uterus. These were not quantitated, however, and their assessment was purely clinical.

Results

Breast-feeding was discontinued in 33 infants. The reasons are given in Table I, from which it can be seen that the incidence of illness in infants of both groups is almost equal.

Of the 33 infants discharged from hospital on complementary feeds, 26 were from the remaining 212 women receiving the active Norinyl-1 tablets and seven were from the 218 women who were receiving the placebo tablets (Table II).

TABLE I.—*Infants Removed From the Trial and Sent Home on Artificial Feeding*

	233 Taking Norinyl-1		218 Taking Placebo	
	Primips	Multips	Primips	Multips
Illness in mother ..	0	1	0	1
Previous absence of lactation ..	0	2	0	0
" breast operation ..	1	0	0	0
Inverted nipples ..	0	1	1	0
Illness in infant ..	8	5	6	4
Twins ..	3	0	0	0
	12	9	7	5

TABLE II.—*Incidence of Complementary Feeding by Parity and Tablet Received*

	Norinyl-1 (212)		Placebo (206)	
	Primips	Multips	Primips	Multips
Fully breast-feeding ..	83	103	103	96
Complementary feeding ..	12	14	5	2
	95	117	108	98

Of the 117 multiparous women who received Norinyl-1 tablets 14 needed to use complementary feeds, and of the 98 who received placebo tablets only two required complementary feeds. This difference was found to be significant at the 1% level ($\chi^2=7.6185$ on 1 degree of freedom). Of the 95 primiparae receiving active Norinyl-1 tablets 12 had to use a complement, while of the 108 who received the placebo only five had to give a complement. The difference is found to be significant at the 5% level, but not at the 1% level ($\chi^2=4.2020$ on 1 degree of freedom). The overall effect when the primiparae and multiparae are grouped together is that Norinyl-1 appears to diminish significantly the quantity of milk produced, as measured by the number of times complementary feeding was found necessary ($\chi^2=11.9114$ on 2 degrees of freedom). Lactation was not inhibited in these patients by Norinyl-1 or placebo tablets, and it was not necessary to resort to full artificial feeding.

The weights of the infants in the two groups have been compared. For this purpose birth weight has not been used, as this was estimated on a spring-balance in the labour room; the difference between the second-day and eighth-day weights has been taken as an estimate of weight change during the first

week of life. If we exclude the infants receiving part or total artificial feeding and group together those of primiparous and multiparous mothers, then 186 infants from the Norinyl-1 group and 199 from the placebo group were breast-fed. In the Norinyl-1 group there was an average loss of weight during the first week of 6 g., while in the placebo-treated group there was an average gain of 15 g. The standard error of the difference of these two means is 12 g. Thus the infants who were wholly breast-fed showed no significant change in weight over the first week whether their mothers received Norinyl-1 or placebo tablets ($0.10 > P > 0.05$). From this trial it was not possible to assess whether a significant weight difference would appear at a later date.

Febrile breast engorgement was not significantly different in the two groups: Norinyl-1, 2 out of 233 cases; and placebo, 5 out of 218 cases. Feeding difficulties (psychological and mechanical) were encountered in approximately equal numbers in both groups, which amounted to 7%.

Discussion

This trial was concerned only with the effect of Norinyl-1 on the initiation of lactation and was confined to observations made in the first week post partum. In no case was the initiation of lactation suppressed by the drug.

A larger number of women in the Norinyl-1 group had to give their babies supplementary feeds than was observed in the placebo group, and this difference was statistically significant: there was a measurable diminution in the quantity of milk. The number of cases of febrile engorgement of the breasts in the Norinyl-1 group tended to be lower than that in the placebo group. Most of the women (88%) could feed their babies without any artificial complement after taking Norinyl-1 from the first day after birth. The woman who is anxious to breast-feed her baby would be best advised not to use Norinyl-1 until her baby is weaned, or at least until lactation is well established.

The follow-up of the 20 patients who continued treatment at home for three weeks was unsatisfactory, as only eight taking Norinyl-1 and eight taking placebo returned their questionnaires. Four of the mothers on Norinyl-1 reported that they were still fully breast-feeding and four were having to give complementary feeds. The eight women who were on the placebo were still fully breast-feeding.

As previously mentioned, observations were made on the state of uterine involution in the latter half of the trial. The impressions of the observers were that there was no difference between the women on Norinyl-1 and those on the placebo.

Summary

A total of 451 women were given either Norinyl-1 (norethisterone 1 mg. and mestranol 0.05 mg.) or an inert placebo once daily from the day after birth under double-blind conditions.

In no case was lactation inhibited by the drug. Complementary feeds were given by 12% of the women taking the active tablet and by only 3.5% of those receiving placebo.

There was no significant difference in the change in weight of the infants in the two groups during the first week, though there was a tendency for the treated ones to gain less.

The incidence of febrile breast engorgement appeared to be slightly lower in the group receiving the active drug.

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