Occasional Review

Investigation and treatment of amenorrhoea resulting in normal fertility

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Summary and conclusions

A simple scheme of investigation and treatment to restore fertility in amenorrhoeic women is described. Fifty-nine patients with amenorrhoea not due to primary ovarian failure were treated variously as appropriate, mainly with clomiphene (25), bromocriptine (15), or human menopausal gonadotrophins (12), and six by diet to increase their weight. All ovulated, and by the end of the study 55 (93%) had conceived, 42 (71%) had delivered at least one surviving child, and five others (8%) were pregnant and awaiting delivery. Conception rates were 49% within two cycles of treatment and 66% within three cycles; using the life-table method to standardise the cumulative conception rates by correcting for patients who did not continue as long as others in the study, the expected conception rate was 79% in six cycles, 94% in 12 cycles, and 98% after 16 cycles. The multiple pregnancy rate was 13% and abortion rate 22%. Delivery rates (for a viable baby) were 48% within 11 months of starting treatment and 53% within one year; expected rates were 76% in 18 months and 97% in two years.

The results show that a relatively simple scheme of classifying amenorrhoeic disorders endocrinologically followed by treatment directed at inducing ovulation allows amenorrhoeic women without primary ovarian failure to achieve conception and delivery rates equal to those in normal women.

Introduction

Advances in our understanding of the physiology of ovulation, together with the ready availability of direct measurements of circulating hormone concentrations and effective methods to induce ovulation, have revolutionised the prognosis for fertility in anovulatory patients. Until recently treatment was largely empirical and resulted in disappointing conception rates, but a diagnosis with accurate therapeutic implications can now be reached in most patients.¹ We report on the results of treatment of anovulatory infertility associated with amenorrhoea in 59

patients. Choice of treatment in each case was based on our treatment-orientated diagnostic classification of amenorrhoea.² The results are presented as cumulative rates of conception and delivery of a live baby to allow comparison with rates of fecundity in the normal population.

Patients and methods

Secondary amenorrhoea was diagnosed when the time that had elapsed since the last menstrual period equalled or exceeded six months. Primary amenorrhoea was diagnosed when menstrual bleeding had not occurred by the age of 16. In these cases the age of 16 was used as the reference point to calculate the duration of amenorrhoea.

In all patients a careful history was taken, with emphasis on psychological factors, weight fluctuations, use of prolactinergic drugs, and symptoms of thyroid disorder and a general and pelvic examination was performed. A blood sample was taken for measurement of serum follicle-stimulating hormone (FSH) and prolactin concentrations and radiography of the skull was performed. Patients were then given medroxyprogesterone acetate (Provera) 5 mg/day for five days followed one week later by clomiphene (Clomid) 50-100 mg/day for five days. Patients who menstruated normally after the progestogen challenge took clomiphene 50 mg/day for five days, and those who did not menstruate or who bled scantily (usually for only one to two days, but this was decided by the patient) took 100 mg/day. Twelve days after finishing the course of clomiphene (that is, four weeks after tests had begun) a blood sample was taken for measurement of serum progesterone concentration. If pregnancy did not occur a serum progesterone concentration of at least 30 nmol/l (10 µg/l) in the midluteal phase was used as the criterion for ovulation (after clomiphene or any other later treatment).

Management of patients who did not become pregnant after the first (diagnostic) course of clomiphene was based on the results of the above-mentioned tests. In patients with raised concentrations of serum FSH (usually with oestrogen deficiency, as shown by failure to bleed after progestogen challenge) primary ovarian failure was diagnosed. This was usually confirmed by laparoscopy or, when obvious dysgenesis was absent, by biopsy of an ovarian specimen taken at laparotomy. Patients with primary ovarian failure were told of the diagnosis, and induction of ovulation was not attempted. Patients with hyperprolactinaemia were managed as we have described elsewhere.³ A radiologically demonstrable tumour was usually treated by irradiation or surgery. Bromocriptine (Parlodel), given to reduce prolactin concentrations to normal, was withdrawn as soon as pregnancy was confirmed.

Patients who ovulated in response to clomiphene were given this drug as definitive treatment (50-100 mg/day, days two to six of menstruation). Patients who failed to ovulate with clomiphene, and in whom serum FSH and prolactin concentrations were not raised, were managed according to their oestrogen state (that is, their response to progestogen challenge).⁴ Those who menstruated normally after progestogen challenge were tested with clomiphene 100 mg/day for three cycles. If response to clomiphene was partial (that is, menstruation occurred but progesterone concentration was below 30 nmol/l in the putative luteal phase) human chorionic gonadotrophin (HCG; Pregnyl), 10 000 IU/day on day 13 of the cycle, was added to replace or supplement the presumed defective oestrogen-mediated release of

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lutinising hormone. If the patient still failed to ovulate treatment was changed to human menopausal gonadotrophin (HMG; Pergonal). Some of these patients, however, had the polycystic ovary syndrome; if they repeatedly failed to ovulate in response to clomiphene and if polycystic ovary disease was shown by laparoscopy dexamethasone was given to suppress hyperandrogenism before treatment with HMG was considered.

Patients with oestrogen deficiency who did not respond to clomiphene and who did not have raised serum FSH or prolactin concentrations were treated either with HMG and HCG or, if weight loss was thought to be important, by encouragement to increase their weight⁵ (in several such patients this entailed psychiatric treatment). HMG was given daily in doses determined by 24-hour urinary oestrogen excretion. Ovulation was induced with HCG (10 000 IU as a single injection) when oestrogen excretion had risen to 250-400 nmol/day (about 70-115 µg/day). The same protocol of investigation and treatment was used in patients with primary and secondary amenorrhoea.

Serum hormone concentrations were determined by specific radioimmunoassay. A serum FSH concentration greater than 170 µg/l or 40 U/l (MRC 68/39) was the criterion for primary ovarian failure⁶ and a serum prolactin concentration greater than 16 µg/l (VLS No 1) was the criterion for hyperprolactinaemia.⁷ The rates of conception and of ultimate delivery of a baby after treatment were calculated by the life-table method.⁸ Comparisons of multiple pregnancy rates were made using the binomial test.

Results

Thirty-three of the 92 consecutive patients with infertility associated with amenorrhoea were excluded from the analysis of results of treatment for the reasons shown in table I. The 16 patients with primary ovarian failure (only three of whom had primary amenorrhoea) had a median age of 30 years (range 21-38) and a median duration of amenorrhoea of four years (range six months to 14 years). Four of the eight patients who defaulted from treatment did so just before or as treatment was started, in each case because of marital problems. The

TABLE I—Reasons why 33 patients were either not treated or excluded from analysis of results of treatment

Pregnant at time of referral	2
Primary ovarian failure	16
Asherman's syndrome	2
Husband's azoospermia	1
Severe oligospermia*	1
Awaiting treatment after pituitary surgery†	3
Defaulted from treatment	8

*Sperm density $1-3 \times 10^6/l$ and repeatedly absent sperms after coitus in oestrogen-stimulated cervical mucus.

†Since this study was prepared all three of these patients conceived, two having required bromocriptine.

TABLE II—Distribution of disorders and definitive treatments to induce ovulation in 59 patients, together with ages and duration of amenorrhoea

Diagnosis	No of patients	Median age in years (range)	Median duration of amenorrhoea in months (range)	Treatment	No of patients
Discrete endocrine disorders:					
Primary hypothalamic/pituitary failure	3	30 (27-35)	168 (132-254)	HMG and HCG	3
Hyperprolactinaemia	17	29 (27-41)	42 (11-300)	Bromocriptine	15*
				Clomiphene	1
				HMG and HCG	1*
				Adenectomy (alone)	1
Polycystic ovary disease	4	25 (22-30)	32 (6-82)	Clomiphene	2
				Clomiphene and HCG	1
				Dexamethasone	1
Hypothalamic disorders:					
Related to weight loss (often with psychological disorder)	13	30 (19-34)	13 (9-228)	Diet	4
				Diet and clomiphene	2
				Clomiphene	3
Related to psychological disorder without weight loss	2	24, 26	6, 42	HMG and HCG	4
				Clomiphene	1
Without weight loss or psychological disorder†	20	27 (22-36)	9 (6-60)	HMG and HCG	15
				Clomiphene	2
				Clomiphene and HCG	3
				HMG and HCG	3
Total	59	28 (19-41)	24 (6-300)		59

HMG = Human menopausal gonadotrophin. HCG = Human chorionic gonadotrophin.

*One patient with a previously irradiated pituitary tumour remained hyperprolactinaemic despite treatment with bromocriptine and required HMG and HCG instead. Her responses to the two treatments are therefore given separately here and in table III and fig 2, but total duration of treatment was used in overall calculations of conception and delivery rates.

†This group included a few with clinical features of polycystic ovary syndrome without direct confirmation of polycystic ovary disease.

TABLE III—Results related to type of treatment. Six patients whose first pregnancy aborted or was terminated successfully delivered in a subsequent pregnancy and are included in the final column, and two others (not shown) were still pregnant. Figures are numbers of patients

Treatment		Con- ceived	Outcome of first pregnancy			Eventu- ally delivered
			Aborted	Ter- minated	Con- tinuing	
Clomiphene	25*	23	3	2		18
Bromocriptine	15†	14	4			12
HMG and HCG	12†	11	1	1	2	7
Diet	6‡	5	2	1		5
Dexamethasone	1	1	1			1
Pituitary adenectomy (alone)	1	1			1	
Total	59	55	11	4	3	43

HMG = Human menopausal gonadotrophin. HCG = Human chorionic gonadotrophin.

*Three patients also received HCG.

†One patient received HMG and HCG after bromocriptine failed (see footnote to table II).

‡Two patients later received clomiphene.

other four patients who defaulted went abroad before treatment could begin and were lost to follow-up.

Table II shows the distribution of diagnoses in the remaining 59 patients and the definitive treatment they received. Only three patients had primary amenorrhoea. This was due to hyperprolactinaemia in one patient aged 41 years and hypogonadotrophic hypogonadism associated with hyposmia in two. These two patients and one who had panhypopituitarism after surgery for a pituitary tumour were the only patients in whom the causes of hypogonadotrophic hypogonadism were organic. The median serum prolactin concentration in the patients with hyperprolactinaemia was 34 µg/l (range 17-130 µg/l). In four of them pituitary tumours were detected radiologically: two received external irradiation before treatment with bromocriptine; transethmoidal adenectomy alone was completely successful in another; and the fourth was given bromocriptine as primary treatment. Six patients with hypothalamic amenorrhoea (who would otherwise have required HMG) were treated by dietary measures to increase their weight. Two later required clomiphene to correct luteal deficiency when menstruation had resumed.

Table III shows the results related to the type of treatment. All 59 patients ovulated and 55 (93%) had conceived when this report was prepared. Of those who failed to conceive, one received clomiphene for four cycles, one HMG for five cycles, one clomiphene and HCG for six cycles, and the fourth received dietary treatment and later clomiphene for 16 months. Figure 1 shows the overall cumulative conception rates, both actual and computed (calculated by the life-table method). The cumulative conception rate was 49% within two cycles of treatment and 66% in three cycles; and the computed conception rate was 79% in six cycles, 94% in 12 cycles, and 98% after 16 cycles, which was the maximum duration of treatment. For the individual forms of treatment (fig 2) the median times to conception

FIG 1—Cumulative conception rates in 59 amenorrhoeic patients who received various types of treatment. Computed rate is calculated on the assumption that patients who have not yet conceived but have not yet continued to the end of the period shown (16 months) will behave similarly to those who have continued further. Treatment cycles (or response cycles) were roughly monthly in most cases, whether treatment was cyclical (clomiphene and human menopausal gonadotrophin) or continuous (bromocriptine and diet). When continuous treatments resulted in delayed response time elapsed in months was substituted for cycles in computation.

FIG 2—Cumulative conception rates for each main type of treatment (see table III). Computation and code as in fig 1. HMG=Human menopausal gonadotrophin (Pergonal).

were two cycles for clomiphene and HMG, two to three cycles for bromocriptine, and eight months for dietary treatment. Seven of the 55 patients who conceived (13%) had multiple pregnancies: three triplet and one quadruplet pregnancy after HMG, and two twin and one triplet pregnancy after clomiphene.

Four of the 55 pregnancies were terminated (table III) for the following reasons: immunisation against rubella during an unsuspected pregnancy that occurred shortly after the patient had begun dietary treatment; rubella in a patient whose susceptibility had been unfortunately overlooked; exacerbation of depression and quadruplet pregnancy resulting from treatment with HMG; and one patient with prolonged amenorrhoea confidently expected the treatment (with clomiphene) not to work and conceived in her husband's absence. The

first two patients received further treatment to induce ovulation (one began treatment recently and the other has already had a baby).

Eleven of the remaining 51 pregnancies (22%) resulted in abortion, though this was not related to any particular treatment (table III). One patient aborted three times and another twice after treatment with clomiphene. A 41-year-old woman with primary amenorrhoea aborted twice after treatment with bromocriptine for hyperprolactinaemia. Nevertheless, six patients who aborted subsequently had a baby after receiving the same treatment and two others were pregnant when this report was prepared. No pregnancy resulted in stillbirth, but seven neonatal deaths occurred in four pregnancies: one set of twins and one set of triplets born at 28 and 29 weeks' gestation, and one from each of two sets of triplets born at 33 and 34 weeks. Of the surviving babies, one has a short-limb defect and another Down's syndrome. This baby was born to a 31-year-old patient who subsequently delivered a normal child.

Calculation of the rates of delivery (that is, the birth of any baby of at least 28 weeks' gestation) was based on results in all 59 patients, including those who discontinued treatment after termination of pregnancy. At the time of the study 43 patients (73%) had been delivered and 42 (71%) had a surviving child; the unsuccessful one did not try to conceive again after losing premature twins. In addition five patients (8%) were pregnant and awaiting delivery, including the two mentioned above, who were in their second pregnancies (not shown in table III), their first having ended in abortion. Since four of these pregnancies were beyond the first trimester when the results were analysed, we assumed when computing the delivery rates in figure 3 that they would have delivered, and allowed for the expected delay until term. We balanced any bias caused by this assumption by making the opposite assumption for patients who had not yet had a baby as a result of treatment and were not pregnant—that is, they were assumed not to have delivered for a further nine months after the study ended. Figure 3 shows that the delivery rate was 48% within 11 months of starting treatment (that is, conception in the third cycle of treatment) and 53% within one year; the computed rate was 76% in 18 months and 97% in two years.

FIG 3—Cumulative delivery rates (for a viable baby) in 59 amenorrhoeic patients, computed as in fig 1.

Discussion

Apart from the high multiple pregnancy rate conception and delivery rates in our study were the same as those in the normal population (figs 4 and 5). Cumulative conception and delivery rates were calculated by the life-table method,⁸ and although this computation may seem to improve the results artificially, it is the only way to compare them^{9 10} with the normal populations represented in figures 4 and 5. To avoid confusion we have given both the actual and computed rates in figs 1-3, which show that the actual results already achieved are better than those previously reported.

In reported series of amenorrhoeic women treated with clomiphene the conception rate was only 42%, even among those who apparently ovulated,¹¹ although the low conception rates previously reported might be due to misdiagnosis of ovulation.¹² Lamb *et al*⁸ claimed "virtually" normal conception rates, but in their study only 65% of patients conceived in six to seven cycles. Lunenfeld and Insler,¹³ reporting on their wide experience with gonadotrophin treatment, achieved a pregnancy rate of 51% in three months and 60% in six months in their

FIG 4—Cumulative conception rates in patients in present study compared with highest available rates similarly computed from results of various studies on normal North American women (Tietze, 1956,²² 1968⁸).

FIG 5—Cumulative delivery rates in patients in present study compared with slowest and fastest rates similarly computed in normal British women who had discontinued contraception (data of Vessey *et al*²³). The initially faster rate in the present study probably reflects an excess of premature multiple births. The apparent increased rate after 20 months is probably due to successful second pregnancies, the spontaneous abortion rate in first pregnancies possibly having been excessive.

amenorrhoeic patients who did not have primary ovarian failure. Nevertheless, these figures concern their more favourable group—namely, those with oestrogen deficiency (diagnosed, as in our patients, with the progestogen challenge test). Unfortunately, in Lunenfeld and Insler's report, those without oestrogen deficiency were not separated from menstruating and oligomenorrhoeic patients, of whom only 21% conceived. The highest conception rate reported for gonadotrophin treatment in women receiving prolonged treatment is 89%.¹⁴

In treating hyperprolactinaemia with bromocriptine we have reported that, in the absence of a large pituitary tumour, all our patients ovulated³ and similar results have been reported by Pepperell *et al*.¹⁵ Using various treatments (as appropriate) in patients without primary ovarian failure Evans and Townsend¹⁶ claimed that all patients ovulated, although only 61% became pregnant. In our patients, considering all treatments together, about half (49%) conceived within two cycles, 66% within three cycles, and 93% within 16 cycles, and the expected rate should approach 98% when all patients have tried this long (fig 1).

Delivery rates are rarely mentioned in reports of ovulation-induction treatment. In Lunenfeld and Insler's series¹³ 52% of patients in their more favourable amenorrhoeic group who were treated with gonadotrophins delivered a surviving infant. In our series 71% (42 out of 59) already had at least one surviving baby and another 8% (five patients) were shortly expecting to deliver. The delivery rate was 53% within one year of starting treatment, and we expect 76% to have succeeded within 18 months and 97% within two years (fig 3). The multiple pregnancy rate (13%) is accounted for entirely by treatment with gonadotrophins (33% of those so treated) and clomiphene (12%). These rates are not significantly different from those generally reported for gonadotrophin treatment (28%; $P=0.44$; Lunenfeld and Insler¹³) and for clomiphene (7.5%; $P=0.28$; Merrell¹¹). The spontaneous

abortion rate of 22% is similar to that generally reported in pregnancies resulting from treatment with gonadotrophins (14–31%¹³) or with clomiphene (20%¹¹).

We have emphasised the importance of recognising weight loss as a cause of amenorrhoea because restoration of weight alone through dietary measures can result in spontaneous ovulation⁵ and thus avoids the need for treatment with HMG and its attendant risks (clomiphene is seldom effective in these patients). Many of these patients are psychologically disturbed, and of the 13 in this series, six had the typical psychopathy of chronic anorexia nervosa.¹⁷ Collaborative treatment with psychiatrists may be necessary but many patients resist it. These patients often present the clinician with a difficult problem when requesting induction of ovulation because of concern for the psychological welfare of the offspring.¹⁸ Persuasion to, even insistence on, dietary restoration of weight may be preferable to yielding to the request for gonadotrophin treatment: it is both physically and psychologically beneficial, aiming as it does at the underlying problem as well as restoring reproductive function.

In two of our patients with hyperprolactinaemia prolactin concentrations were only slightly higher than normal. One patient, whose serum prolactin concentration was 18 $\mu\text{g/l}$, conceived in her first (test) cycle with clomiphene, the only patient with hyperprolactinaemia treated by us who has ovulated in response to clomiphene. After her pregnancy, however, her prolactin concentration was 23 $\mu\text{g/l}$ and intravenous injection of thyrotrophin-releasing hormone failed to elicit a response, which is typical of patients with pathological hyperprolactinaemia.¹⁹ The second patient, whose prolactin concentration was 17 $\mu\text{g/l}$, had galactorrhoea as well as amenorrhoea and failed to ovulate in response to clomiphene, but she conceived in her third month of treatment with bromocriptine. Subsequently she conceived again spontaneously. Although this might suggest that her condition had been misdiagnosed, this course of events has also been reported in patients with documented prolactin-secreting pituitary tumours.²⁰

We excluded patients who had absolute antifertility factors (including azoospermia and severe oligospermia; table I). Nevertheless, we accepted all others and placed no limit on age (the oldest was 41; table II). The husbands of four of our successfully treated patients had oligospermia (sperm density $7\text{--}13 \times 10^9/\text{l}$ in these cases), two being referred specifically for that reason. Only one man required treatment (ligation of a varicocele). These results are similar to those reported by Smith *et al*²¹ and indicate that causes of infertility in women should not be ignored even if the male partner has a low sperm count.

Two anovulatory patients failed to conceive because of additional problems. One was a 33-year-old woman with chronic anorexia nervosa. Menstruation resumed after she had increased her weight, but she then needed clomiphene to overcome luteal deficiency. She had not conceived after 16 months of treatment, but she had a blocked Fallopian tube (which followed salpingitis) and her husband had pyospermia and postcoital sperm survival was poor. The other patient, aged 35, had panhypopituitarism after transfrontal hypophysectomy at the age of 15 for a pituitary tumour. She failed to conceive after five cycles of treatment with HMG. The discovery, during treatment, of the absence of sperms in a postcoital sample of cervical mucus exposed a major psychosexual problem. She declined psychosexual counselling and abandoned treatment.

These results show that a simple scheme of investigation can be used to classify amenorrhoeic disorders on an endocrinological basis, with treatment primarily directed towards inducing ovulation. The validity of this approach is shown by the conception and delivery rates achieved, which show that without primary ovarian failure, women with amenorrhoea given appropriate treatment have as good a chance as normal women of delivering a living child.

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General Practice Observed

How to find a practice

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General practices vary considerably and it has been said that it is as important to find the right practice as it is to find the right wife, since you will spend more of your waking hours at work than you will at home. While most people spend a year or more sizing up a marriage partner, one often has to choose a practice on the basis of one short interview. I have recently been through the traumas of finding a practice, and to others about to embark on the same journey I offer a few thoughts.

Deciding on a practice

From the time you decided on general practice as a career you probably had a rough idea of the kind of practice you wanted—for example, where you wanted to live (or where you did not want to live) and the size of practice you wanted. Although you decided these long ago, think again. If you dream of a rural practice in the Yorkshire Dales, have you thought of doing night calls in winter with snow on the ground? If your only knowledge of the West Country is an idyllic summer spent sunbathing and surfing you may be surprised by how hard general practitioners have to work in July and August while their colleagues elsewhere are on holiday. The South coast is

also nice, but what will your work load be like if most of your patients are retired?

Think again, too, about singlehanded practice. I realise that most of you will have already dismissed the idea, but it does have the advantage that you can organise your work in a way that is impossible if you join a partnership. If you want to problem-orient the records or do some research no one can stop you. If you want to use A4 records or buy a computer you have no one to convince but your bank manager. If there are other small practices in the area you can make a rota and have as much time off as in larger practices. If the area grows you may be able to take on a partner. For singlehanded practices one applies to the family practitioner committee and is interviewed by them and the medical practices committee.

Undoubtedly the place for finding a practice is the *BMJ*, and you should start reading the advertisements at least 18 months in advance. This has several advantages. Firstly, it gives you an idea of what is available. Thus, if you are looking for a practice in a specific area or a practice with a research interest you will get an idea of how often such vacancies occur. You will also get some idea of the kind of salaries offered and time to parity, and generally you will learn to "read between the lines." A few practices may advertise vacancies a long time in advance and these you will miss if you wait till the last minute.

If you already know where you want to settle, then in addition to reading the advertisements you should put our "feelers" in the area by asking general practitioner or consultant friends to recommend you if they hear of a practice with a vacancy for a partner. If a practice can find a partner by personal contact then they may not even advertise the post. The administrator of the local family practitioner committee may also know of coming vacancies.

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