

# INVESTIGATION AND TREATMENT OF THE INFERTILE COUPLE IN IRELAND

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## SUMMARY

Data are reported from 349 and 139 couples respectively attending the infertility clinics at the Rotunda and St. James's Hospitals Dublin. The time interval concerned at the Rotunda is 41 months and at St. James's 26 months prior to 31st December 1979. The mean age is between 28.3 and 28.9. Between 72% and 75% were primary infertile with an average of 3.7 years infertility. Between 23% and 47% had been investigated previously and 76-78% lived in Dublin.

The overall pregnancy rate at the Rotunda was 31.5% and at St. James's 25.2%. 50-58% of couples had full fertility profiles completed. Ovulation problems were most common (34-36%) but in St. James's 31% had male factor against 27% at the Rotunda. By a combination of hysterosalpingography and laparoscopy between 19% and 24% had a utero-tubal problem diagnosed. In between 17% and 19% no cause for the infertility could be found, whereas in 10-16% more than one problem was uncovered.

Where pregnancy was achieved, no therapy had been in use in 46-48% of cases and ovulation stimulation especially with clomiphene citrate succeeded in 29-43%. Ovulation stimulation was also the commonest method of therapy in those who did not get pregnant (61-65%).

Between 83 and 89% of pregnancies achieved continued successfully. The majority of couples who have not yet conceived are still on the clinic books (73-75%).

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## INTRODUCTION

In 1976 a clinic was re-established at the Rotunda Hospital, Dublin to cater for infertile couples. In 1977 the same medical team joined andrological services at St. James's Hospital, Dublin, to provide an additional weekly session. Although the majority of patients inevitably come from the Dublin area, the paucity of such clinics overall means that in the clinic population all areas of Ireland are represented.

In both clinics, there is an active approach to investigations and treatment. Wherever possible a basic fertility profile is established (<sup>1</sup>). Semen analysis, post-coital test and hysterosalpingography are performed and sympto-thermic data recorded. When a particular region appears at fault, more specific indepth investigations are then carried out. This may include laparoscopy which is also performed where all tests are negative. Recognised forms of therapy, including where necessary specific referral, are instituted tailored to cause.

The onset of a new decade has given the stimulus to examine these current practices which is essential if patients and staff are to benefit by our adopting only the optimal forms of investigation and treatment. This is made possible by the assiduous collection of data since clinics began but the report concentrates in greater detail on the female partner as many of the men have been previously studied and reported elsewhere (<sup>2</sup>).

## MATERIAL AND METHODS

The data concern 349 couples seen at the Rotunda Hospital, Dublin between the 1st August 1976 and 31st December 1979, and 139 who attended St. James's Hospital, Dublin between 18th November, 1977 and 31st December 1979.

All data were collected prospectively but of necessity contain a percentage of patients who were incompletely investigated on the 31st December 1979.

Table 1. — *General clinic data.*

(a)	Total No.	Average age	% gravid	Mean years infertile
R T	349	28.9(19-45)	71.7	3.7(1-14)
P	110(31.5%)	29.0(20-39)	70.0	3.5(1-12)
NP	239(68.5%)	28.8(19-45)	69.5	3.8(1-14)
J T	139	28.3(21-41)	74.8	3.7( <sup>6</sup> /12-11)
P	35(25.2%)	28.1(21-39)	77.0	3.0( <sup>6</sup> /12-11)
NP	104(74.8%)	28.3(21-41)	74.0	3.9( <sup>6</sup> /12-11)

## RESULTS

The data are analysed and shown, except where stated, as total figures which are then sub-divided into those who achieved pregnancy and those who did not in each hospital respectively. For brevity, in the tables the Rotunda Hospital is depicted as R, St. James's as J. T is the total number of patients, P those who achieved pregnancy and NP those who did not. Again for clarity and brevity the majority of results are expressed as percentages. This is validated by inclusion of initial total numbers where necessary.

1. *General Data*

The above table 1 shows that in all categories the mean average age at the clinics was between 28 and 29 years, the youngest patient being 19 and the oldest 45 (female). At least 72% had never achieved pregnancy. There was a mean average length of infertility of at least three years duration, a minimum reported six months and a maximum 14 years.

110 out of 349 couples attending the Rotunda Hospital achieved pregnancy whereas at St. James's 35 of 139 couplee became pregnant.

Apart from those who achieved pregnancy at St. James's (7.9 months) all other groups had attended the clinics for between 18-21 months. A few had just started and a few had attended throughout the 41 months possible maximum at

the Rotunda. Between 75.9% and 78.4% of couples lived within the environs of Dublin and twice as many (46.8%) of those at St. James's compared with the Rotunda (23.2%) had had previous investigations elsewhere. Approximately one-quarter of these were specific referrals from other clinics.

2. *Fertility Profile*

Four basic investigations were employed to establish the couple's fertility profile. During the time data were collected at the Rotunda Hospital 57.9% of couples and at St. James's 50.4% of couples had undergone all four tests. Semen analysis had been performed at the Rotunda Hospital in 83.7% and at St. James's 86.3% of all men who had been on the books during that time. Post-coital tests were performed in 85.9% and 88.5% of cases respectively and hysterosalpingography in 65% and 61.2% of women in the two hospitals. At the Rotunda 68.5% successfully completed sympto-thermic charts whereas in St. James's Hospital this was only achieved in 52.5% of cases.

In those who achieved pregnancy, 60% of the Rotunda patients had been fully investigated whereas in St. James's this was only achieved in 34.3% of cases. There were also incidence differences associated with semen analysis (83.6% compared with 65.7%) and sympto-thermic charts (81.8% compared with 66.9%).

Table 2. — *General clinic data.*

(b)	Mths. at clinic	Domicile Dublin	Attended elsewhere
R T	21.0 (0-41)	265 (75.9%)	81 (23.2%)
P	21.5 (0-38)	80 (72.7%)	27 (24.5%)
NP	20.9 (0-41)	185 (77.7%)	54 (22.6%)
J T	18.2 (0-26)	109 (78.4%)	65 (46.8%)
P	7.9 (0-16)	28 (80.0%)	17 (48.5%)
NP	19.5 (0-26)	81 (77.9%)	48 (46.0%)

Table 3. — Percentage number of tests performed in fertility profile.

		Total No.	Semen analysis %	Post-coital test %	HSG %	Symptotermic %	All tests %
R	T	349	83.7	85.9	65.0	68.5	57.9
	P	110	83.6	86.4	63.6	81.8	60.0
	NP	239	83.7	85.8	65.7	62.3	56.9
J	T	139	86.3	88.5	61.2	52.5	50.4
	P	35	65.7	77.1	62.9	66.9	34.3
	NP	104	93.3	92.3	60.6	49.0	55.8

### 3. Specific Tests

#### (a) The Male

Many men had more than one semen analysis performed. This table is concerned with the best results only. The majority of patients (67.1%) at the Rotunda Hospital had normal semen analysis whereas at St. James's in 58.3% the parameters were abnormal<sup>(3)</sup>. 69% of those at the Rotunda who achieved pregnancy and 43.4% of those at St. James's had normal readings. However only 30.4% of the pregnancies at the Rotunda had abnormal semen analysis whereas at St. James's the figure was 56.5%.

#### (b) Cervical Region

Only valid post-coital tests were considered for analysis, i.e. performed with normal sperm count in the presence of good quality mucus. The best test obtained in each case only was considered.

In each hospital 67% of couples had normal valid post-coital tests. However, in each establishment 25% of couples achieving pregnancy had persistently negative cervical tests. Further testing for the cervical factor was considered necessary in a number of cases. At the Rotunda 70% of these were abnormal showing a cervical factor incidence of 2.3%. At St. James's 21.4% of these further tests were negative, a total incidence of 2.4%.

#### (c) Utero-tubal Region

Hysterosalpingography performed under direct image intensification monitor without anaesthetic proved normal in 79.7% of patients attending the Rotunda and 63.5% of those attending St. James's. 88.6% of those who achieved pregnancy at the Rotunda had normal hysterosalpingographic findings as did 77.2% of St. James's patients.

Laparoscopy, carried out because of salpingographic abnormalities or if all investigations proved normal, was performed on both groups of patients at the Rotunda Hospital. Findings were normal in 80% who attended the Rotunda but only 32% of those who attended St. James's. Where pregnancy ensued however the percentage normal laparoscopies at the Rotunda was 92.4% and in St. James's 83.3%.

Results of hysterosalpingography and laparoscopy were compared with chief regard to tubal function. At the Rotunda 66.6% of cases correlated and findings in the St. James's patients were identical in 72%. However, 10.1% of Rotunda patients and 8% of St. James's patients had falsely abnormal hysterosalpingograms and 23.3% and 20% respectively of women from the two clinics had normal salpingography results refuted by abnormal laparoscopic findings.

#### (d) Ovulation and Menstrual Cycle Control

Analysis of basal body temperature charts in those who were able to complete

Table 4. — Results of best semen analysis.

		No. tested	Normal %	Abnormal %
R	T	292	67.1	32.9
	P	92	69.6	30.4
	NP	200	66.0	34.0
J	T	120	41.7	58.3
	P	23	43.4	56.5
	NP	97	41.2	58.8

Table 5. — *Valid post-coital, slide invasion and SCMC tests.*

				Post-coital test		Slide invasion + SCMC		
				Normal %	Abnormal %		Normal %	Abnormal %
R	T	300	247	67.6	32.4	10	30.0	70.0
	P	95	80	75.0	25.0	2	—	100
	NP	205	167	64.1	35.9	8	37.5	62.5
J	T	123	86	67.4	32.6	14	78.6	21.4
	P	27	28	75.0	25.0	2	50.0	50.0
	NP	96	58	63.8	36.2	12	83.3	16.6

them showed an apparently normal biphasic pattern in 51.9% of women at the Rotunda Hospital and 67.1% at St. James's Hospital. Of those who achieved pregnancy, 47.8% at the Rotunda Hospital and 36.4% at St. James's had atypical patterns.

#### (e) *Other Investigations*

Where necessary, i.e. general disease, or where the basic regional profile test showed up as abnormal, further indepth investigations were carried out including relevant hormone assays and immunological tests. Lack of space precludes these being reported specifically in this paper.

#### 4. *Diagnosis of Cause*

This section concerns only couples who had at least completed the basic fertility profile.

In 10.3% of couples at the Rotunda and 15.7% of those attending St. James's more than one factor was found to be abnormal in the basic fertility profile, whereas in 18.8% of patients at the Rotunda and 17.1% of patients at St. James's all profile tests were normal. Ovulation problems were present in 36.1% of couples at the Rotunda and 34.2% at St. James's, and the male was indicted in 27.2% of patients at the Rotunda and 31.4% at St.

James's. An utero-tubo-peritoneal factor, diagnosed by a combination of hysterosalpingography and laparoscopy was found to be present in 19.3% of Rotunda patients and 24.2% of St. James's patients.

In those couples who achieved pregnancy at the two hospitals the figures are not dissimilar excepting where a male factor was identified at St. James's only 16.7% achieved pregnancy and where a tubal factor was present at the Rotunda only 5.7% of these achieved pregnancy and at St. James's only 8.3%. However, where an ovulation factor was present at the Rotunda 47.1% of these achieved pregnancy and in St. James's Hospital 66.7%. (That is 45.2% and 30.3% respectively of all those with an ovulation problem).

#### 5. *Therapy*

##### (i) *General*

##### (a) *Patients achieving pregnancy*

Only therapy actually used in the cycle of conception is ascribed as the cause for success. In males and the utero-tubal region a time limit of two years following operation was given. As these figures refer to all pregnancies and include some not fully investigated, these are not comparable with other parts of the paper.

In both clinics 11% of couples were having combined therapy at the time of conception whereas at the Rotunda Hospital 46.3% and at St. James's 48.5% of cases were later found to have had no

Table 6. — *Results of hysterosalpingography.*

		No. tested	Normal %	Abnormal %
R	T	227	79.7	20.3
	P	70	88.6	11.4
	NP	157	75.8	24.2
J	T	85	63.5	36.5
	P	22	77.2	22.7
	NP	63	58.7	41.3

Table 7. — Results of laparoscopy and correlation with hysterosalpingography.

Laparoscopy					Correlation with hysterosalpingography			
					No. tested	Same %	False (+ %)	False (- %)
R	T	221	80.0	20.0	198	66.6	10.1	23.3
	P	66	92.4	7.5	60	55.0	15.0	30.0
	NP	155	74.8	25.1	138	71.7	8.0	20.3
J	T	25	32.0	68.0	25	72.0	8.0	20.0
	P	6	83.3	16.7	6	100	-	-
	NP	19	15.8	84.2	19	63.2	10.5	26.3

therapy given during the cycle of conception. 42.7% of patient at the Rotunda and 28.6% of patients at St. James's pregnancies occurred during ovulation stimulation and 14.5% and 17.1% respectively of husbands were on therapy at that time. Only 2.7% pregnancies at the Rotunda and 5.7% of pregnancies at St. James's had had tubal sugery within the last 2 years.

Although psycho-sexual factors were thought to be the main contributory factor in 3.6% of patients at the Rotunda and 5.7% at St. James's, as the total number in the clinic with these problems was small, this shows how successful such treatment can be.

(b) Non-Pregnant Patients

At the cut-off point for data analysis in those couples who had been fully investigated, 17.5% at the Rotunda and 38.6% at St. James's had had multiple therapy, whereas 7.4% at the Rotunda and 15.9% at St. James's had received no treatment. 64.8% of patients at the Rotunda and 61.4% at St. James's were using drugs to stimulate ovulation as yet without success and 11.1% of patients at the Rotunda and 20.5% of patients at St. James's' had husbands on male therapy. Tubal surgery had been attempted in

23.1% of Rotunda patients and 36.4% of St. James's patients.

(ii) Ovulation induction

This section examines the specifics of ovulation stimulation. It includes a number of patients involved in drug trials apparently ovulating with a diagnosis of idiopathic infertility (<sup>4, 5</sup>), both were placebo controlled studies and may have distorted the results somewhat.

70.2% of those who achieved pregnancy at the Rotunda Hospital on ovulation therapy were given clomiphene citrate, 19.1 % parlodel, 8.5 % tamoxifen and 2.1% were given HMG therapy. At St. James's Hospital 80% of pregnancies achieved on ovulation stimulation were on clomid and 20% on parlodel.

Of those couples who were fully investigated and yet did not achieve pregnancy clomiphene citrate was used in 80% of Rotunda patients and 92.6% of St. James's patients.

(iii) Pregnant without therapy

In both hospitals a significant number of patients achieved pregnancy in the cycle when no therapy was given. This amounted to 46.3% of all pregnancies achieved at the Rotunda and 48.5% of all pregnancies achieved at St. James's. At the Rotunda 9.9% and at St. James's 17.1% of women were found to be pregnant at first visit. 4.5 % and 11.4 % respectively followed post-coital tests and

Table 8. — Results of basal body temperature and sympto-thermic charts.

		No. tested	Normal %	Abnormal %
R	T	239	51.9	48.1
	P	90	52.2	47.8
	NP	149	51.7	48.3
J	T	73	67.1	32.9
	P	22	63.6	36.4
	NP	51	68.6	31.4

Table 9. — *Cause of infertility identified in those couples fully investigated.*

	Total No.	Male %	Cer. %	U.T. tubal peri. %	Ovul. %	Psy. sex. %	Nil %	More than 1 %
R T	202	27.2	3.5	19.3	36.1	5.0	18.8	10.3
P	70	27.1	2.8	5.7	47.1	6.0	22.7	10.0
NP	132	27.2	3.7	26.5	30.3	4.5	17.4	10.6
J T	70	31.4	4.3	24.2	34.2	4.3	17.1	15.7
P	12	16.7	8.3	8.3	66.7	8.3	8.3	16.7
NP	58	34.5	3.4	27.6	27.6	3.4	19.0	15.5

2.7% and 5.7% the cycle following perturbation. As previously referred to in section (ii) as part of drug trials at the Rotunda Hospital, some achieved pregnancy on placebo (4.5%). In the majority of cases however (Rotunda 24.5% and St. James's 14.3%) no cause whatsoever could be ascribed to the conception success.

## 6. The Final Outcome

### (a) Patients Who Achieved Pregnancy

89% of patients at the Rotunda and 82.8% of patients at St. James's pregnancies continued successfully. Although 10% of patients at the Rotunda and 14.3% at St. James's aborted, all but one of these patients have since conceived again. The ectopic pregnancies reported occurred in patients with previous tubal surgery.

### (b) Patients Who Did Not Achieve Pregnancy

74.5-73% of non-pregnant patients were still on the two clinic books and many are still undergoing investigation. Only 3% had asked for help elsewhere. However, at the Rotunda 15.5% and at St. James's 9.6% of couples only attended the clinic once and in both centres 2% had signified a desire to stop altogether.

## DISCUSSION

In this study 488 couples with fertility problems were considered. Unlike recent reports from the Department on specific forms of therapy<sup>(4, 5)</sup> there was no significant difference in either clinic in age, length of infertility or any of the general data parameters (tables 1 and 2) between those who achieved pregnancy and those who did not except at St. James's. The majority of patients came from the Dublin area, although 21-24% of all couples travelled long distances from various parts of Ireland to attend the clinic, giving rise to specific problems involving the timing of some tests and the supervision of treatment which could have been better overcome by a more adequate infrastructure. It is however debatable whether this study can be considered typical of the infertility problem in Ireland for the large number of patients who had already had unsuccessful investigations elsewhere may distort the incidence of certain problems. This may in fact be a prime factor not only in the calculation of the apparently low pregnancy rate of 31.5% at the Rotunda Hospital, identical to a previous report from the author elsewhere<sup>(6)</sup> but more especially in the even lower calculated pregnancy rate at St. James's of 25.2% where 47% had previously been investigated elsewhere.

Specific test analysis (table 3) shows that a full fertility profile was established in 50-58% of cases. The post-coital test was the most frequently performed investigation, followed closely by semen

Table 10. — *Therapy in use at time of conception.*

	Total No.	Male %	Cer. %	U.T. tubal %	Ovul. stim. %	Psy. sex. %	Nil %	More than 1 %
R	110	14.5	1.8	2.7	42.7	3.6	46.3	11.8
J	35	17.1	5.7	5.7	28.6	5.7	48.5	11.4

Table 11. — *Therapy used in non-pregnant patients fully investigated.*

	Total No.	Male %	Cer. %	U.T. tubal %	Ovul. stim. %	Psy. sex. %	Nil %	More than 1 %
R	108	11.1	3.7	23.1	64.8	5.0	7.4	17.5
J	44	20.5	2.2	36.4	61.4	2.2	15.9	38.6

analysis. Specific test analysis (tables 4-8) showed the majority of all investigations to be normal and in higher percentage in those who managed to conceive. The necessity for a cervical factor to be diagnosed by multiple tests<sup>(7)</sup> is shown in table 5 as is the complimentary nature of hysterosalpingography and laparoscopy (tables 6 and 7), although in a procedure that is not without hazard<sup>(8)</sup>, the large number of normals at the Rotunda Hospital (80%) who underwent laparoscopy suggests a degree of overkill. But a pick-up rate of 20-23% of hidden pathology is gratifying. This was associated with endometriotic lesions which would interfere with the ovum pick-up mechanism in all except two cases where small ovarian cysts were noted.

The value of basal body temperatures as a method of diagnosis and monitoring ovulation problems and therapy has recently been cast into doubt<sup>(9)</sup> and in fact in only between 52 and 67% of our patients were such recordings actually successfully completed. However, in combination with cervical mucus changes, sympto-thermic chart records are still the most cost-effective screening procedure for presumptive ovulation allowing proper selection of patients who need further hormone assay.

Ovulation abnormalities and problems in the male were the chief causes of infertility in those patients fully investigated (table 9). However, a significant number of patients (17-18.8%), greater than the 10% usually quoted<sup>(10)</sup> and similar to the incidence of unexplained infertility re-

ported by Cox (1975)<sup>(11)</sup> were found to have all basic tests normal. In contrast, a combination of factors, usually between the male and ovulation, were present between 10.3% and 15.7% of couples. The poor results associated with treatment of utero-tubal factors, which can only be diagnosed by a combination of hysterosalpingography and laparoscopy are particularly illustrated in this study by the significant differences in incidence between those who attained pregnancy and those who did not (5.7% and 26.5% at the Rotunda and 8.3% and 27.6% at St. James's). At St. James's Hospital the high incidence of male factor reflects the presence of the established andrological clinic. A large number of these men specifically attend this hospital where tests show no therapy is possible and this is reflected in the figures where non-pregnant patients are double those who achieve pregnancy (34.5%-16.7%).

Where conceptions occurred between 46.3% and 48.5% of patients had not had any therapy in the cycle of conception (table 10). The placebo effect that investigations and treatment have in the infertile couple is well known<sup>(12)</sup> as are the chances of spontaneous pregnancy<sup>(13)</sup>. This level, however, appears extremely high but is boosted by pregnancies achieved on placebo as has been previously reported elsewhere<sup>(4, 5)</sup>. Further analysis shows (table 13) 9.9-17.1% of these patients to be pregnant at first visit and although a number followed post-coital tests or tests for tubal factors, in the majority no therapeutic cause could be attributed to the pregnancy.

Table 12. — *Drugs used in ovulation stimulation.*

	Total No.	Clomid %	Parlodel %	Tamoxifen %	HMG %
R P	47	70.2	19.1	8.5	2.1
NP	70	80.0	18.6	—	1.4
J P	10	80.0	20.0	—	—
NP	27	92.6	3.7	3.7	—

Table 13. — *Infertile patients with no treatment yet pregnant.*

	Total preg.	First visit %	Post-PCT %	Post-tubal %	Post- placebo %	Unknown %	Total %
R	110	9.9	4.5	2.7	4.5	24.5	46.3
J	35	17.1	11.4	5.7	—	14.3	48.5

As reported elsewhere<sup>(14)</sup> (table 12) the majority of therapeutic successes followed ovulation stimulation with clomid; the major drug of therapy. However both clomid and parlodel were used in therapeutic trials in patients apparently ovulating normally<sup>(4, 5)</sup> which may distort the figures in both the pregnant and the non-pregnant (tables 10 and 11). In this latter group again ovulation stimulation was the most common form of therapy.

A continuation rate of between 82.8% and 89% (table 14) for those who achieved pregnancy is satisfactory in what may be considered a particularly at risk group of patients<sup>(15)</sup> and it is gratifying to note that of those who aborted all but one achieved a second pregnancy. The majority of patients (table 15) who did not achieve pregnancy are still on the clinic books. Although there is a policy of active investigation and treatment to allow patients to find out quickly what their problem is and to make an educated choice as to when they should stop their quest for "fulfillment", patients are seldom dis-

Table 14. — *Outcome of patients who achieved pregnancy.*

	Total No.	Continued %	Aborted %	Ectopic %
R	110	89.0	10.0 (Preg. again) 91%	0.9
J	35	82.8	14.3 (Preg. again) 100%	2.9

Table 15. — *Patients who did not achieve pregnancy.*

	Total No.	On books %	Adop- tion %	Else- where %	Stop- ped %	Only one attendance %
R	239	74.5	4.6	3.3	2.1	15.5
J	104	73.0	11.5	3.8	1.9	9.6

charged from the clinic. This is to avoid the usually futile exercise, known to all fertility clinic workers of couples moving to another clinic immediately on discharge from a previous centre, a practice judging by the figures of those in this study who had previously attended elsewhere to be as common in Ireland as in any other country. A relatively high percentage of patients (15.5%) who attended once only at the Rotunda may be a reflection of the facilities that we offer a couple in what is traditionally an all female maternity hospital and may be contrasted with the 9.6% at St. James's where specific nursing and secretarial staff are delegated for infertility work.

Critical analysis of infertility data is probably the only way of evaluating the efficacy of current practice. As illustrated in this study however, absolute identification of cause and evaluation of therapy in what is often a multi-factorial situation is difficult. Pregnancies may arise at unsuspected moments and at the particular chosen point of time a number of patients will still be undergoing investigations and treatment. Inter-clinic variabilities in methodology and a differing population makes comparison with other clinics difficult and many of the conclusions drawn may be valid only in the local context. Nevertheless, such audit, however difficult, is essential and results are of consequence to all who work in the infertility field.

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