Discussion

Growth, behaviour, and educational achievement are influenced by many factors, and, although we found that the AA and AS children were alike in some of these, we cannot be certain that they were alike in all. Every child, however, had lived since early childhood in a small community in which living standards, child rearing practices, and educational opportunities varied within narrow ranges, and there were unlikely to be major differences in the backgrounds of the two groups.

The absence of differences in growth and achievement between children with the two genotypes conflicts with some of the results of the study in the USA,[1] in which significantly lower weights and poorer performances in psychological-intellectual tests were found in 19 AS compared with 241 AA children aged 10-16 years. No evidence was presented in that report, however, to show that the two groups were matched for socioeconomic or other factors that might have influenced the measurements. Furthermore, the selection of patients from twin studies may complicate assessment of the results. Perinatal hypoxia is more likely to occur in twins, and, although levels of Hb S are low in the sickle-cell trait at birth, the possible role of severe hypoxia precipitating sickling cannot be entirely excluded.

Both studies were limited by small numbers, and carefully controlled investigations of larger groups of children are needed. Meanwhile, the available evidence does not warrant the conclusion that the sickle-cell trait affects physical and mental development.

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Comparison of intra-amniotic prostaglandin $F_2\alpha$ and hypertonic saline for induction of second-trimester abortion

International multicentre study by the Task Force on the Use of Prostaglandins for the Regulation of Fertility of the World Health Organisation's Expanded Programme on Research, Development, and Research Training in Human Reproduction

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Summary

The efficacy and safety of intra-amniotic prostaglandin (PG) $F_{2\alpha}$ (25 mg repeated in six hours) and hypertonic saline (200 ml 20% NaCl) were compared in an international multicentre randomised study organised by the World Health Organisation's prostaglandin task force.

Both hypertonic saline and $PGF_{2\alpha}$ were found to be effective in terminating second-trimester pregnancy. The main advantage of $PGF_{2\alpha}$, however, was its greater efficacy, with significantly higher success rates in the first 48 hours. Out of 717 women given $PGF_{2\alpha}$ 614 (85·6%) aborted within 48 hours; by 24 hours 439 (61·2%) had aborted, and by 36 hours 574 (80·1%) had aborted. Out of 796 women given hypertonic saline 641 (80·5%) aborted within 48 hours; however, by 24 and 36 hours, respectively, only 161 (20·2%) and 462 (58%) had aborted.

Although $PGF_{2\alpha}$ was associated with a somewhat higher frequency of minor side effects than hypertonic saline, notably vomiting and diarrhoea, these were within acceptable limits. Only 59 women (8·2%) in the prostaglandin group had more than four episodes of vomiting and 11 (1·5%) more than four episodes of diarrhoea. Other side effects occurred only occasionally. No difference was found between the two groups in the frequency of incomplete abortion or excessive bleeding.

Clinical co-ordinators of the study were: M Bygdeman (Karolinska Hospital, Stockholm, RTC*); M P Embrey (John Radcliffe Hospital, Oxford); P Gillett (Montreal General Hospital, Montreal, CRC†); R Wilson (Human Reproduction Unit, World Health Organisation, 1211 Geneva); and N Wiqvist (Karolinska Hospital, Stockholm, RTC).

Participating centres were: Edmonton University Hospital, Edmonton, Canada, CRC (Dr D Reid); Halifax University Hospital, Halifax, Canada, CRC (Dr C Tupper); Notre Dame Hospital, Montreal, CRC (Dr L Fortier); Jewish General Hospital, Montreal, CRC (Dr M M Gelfand); Montreal General Hospital, Montreal, CRC (Dr P Gillett); Saskatoon University Hospital, Saskatoon, CRC (Dr T B MacLachlan); Toronto General Hospital, Toronto, CRC (Dr J Gare); Toronto Western Hospital, Toronto, CRC (Dr W Paul); Vancouver General Hospital, Vancouver, CRC (Dr N Lee); Winnipeg General Hospital, Winnipeg, CRC (Dr A T Coopland); Institute for Research in Reproductive Biology, KEM Hospital, Bombay, CRC (Professor Purandare); Post Graduate Institute of Medical Education and Research, Chandigarh, India, CRC (Professor Devi); All India Institute of Medical Sciences, New Delhi, RTC (Professor Hingorani); Women's Hospital University of Southern California, Los Angeles, CRC (Dr Ballard); All Union Institute of Obstetrics and Gynaecology, Moscow, RTC (Professor Persianinov); Ginekolosko-Akuserska Klinika, Belgrade (Professor Husar); and Ginekolosko-Akuserska Bolnica, Belgrade (Dr Rajkavoc).

*RTC = Collaborative centre for research and training in human reproduction.

†CRC = Collaborative centre for clinical research on human reproduction.

Introduction

Early studies of the intra-amniotic administration of prostaglandin (PG) $F_{2\alpha}$ showed that doses of 5-25 mg often needed to be repeated to induce therapeutic abortion.[1-8] When an initial dose of 25 mg was repeated in 24 hours (if abortion was not imminent) a success rate of about 95% was achieved within 48 hours with an induction-abortion interval of about 30 hours.[4 9-11] When the second injection was given after six hours the success rate was as high or higher and the induction-abortion interval fell to about 20 hours.[10 11]

Since the half life of $PGF_{2\alpha}$ (25-40 mg injected) in amniotic fluid is 13-18 hours,[11-13] its concentration may fall too low for

efficient stimulation of the uterus if the interval between injections is too long—say, 24 hours.

On the basis of these data the steering committee of the prostaglandin task force of the World Health Organisation's Expanded Programme on Research, Development, and Research Training in Human Reproduction planned and organised a randomised study to compare the efficacy and safety of intra-amniotic administration of $PGF_{2\alpha}$ and hypertonic saline. Centres in Canada, India, the USA, the USSR, and Yugoslavia took part, the final evaluation of the results being undertaken at the World Health Organisation's collaborating centre for research and training in human reproduction in Stockholm.

Patients and methods

Patients suitable for intra-amniotic administration of saline or $PGF_{2\alpha}$ were selected for the study and were mainly in the 15th-20th weeks of gestation. A few in the 13th and 14th weeks as well as in the 21st and 22nd weeks were also included.

Criteria for exclusion from the trial were previous heart disease, hypertension, respiratory disease, ulcerative colitis, diabetes mellitus, disorders of blood coagulation, kidney disease, liver disease, sickle-cell anaemia, severe hypersens tivity, and serious systemic disease. Patients with a contraindication to transperitoneal uterine puncture were also excluded from the study. Contraindications were previous abdominal surgery or surgery on the body of the uterus, large uterine myomata or other pelvic tumours, major congenital abnormalities of the uterus, rupture of the membranes, or earlier failed saline induction.

Patients who fulfilled the criteria for the study were allocated to treatment with either hypertonic saline or $PGF_{2\alpha}$ according to a computer-generated randomisation table. The identity of the compound chosen was marked on the protocol and kept from the investigator in a sealed envelope until the patient was accepted for the study.

The total number of patients was 1525. Twelve, however, were excluded because of failure to adhere to the protocol. In one of these, after 50 ml of saline had been given the injection was interrupted because of intensive uterine and abdominal pain and abortion was induced by other means. Another patient received 25 mg $PGF_{2\alpha}$ initially. One to two minutes later, however, strong uterine contractions were associated with severe abdominal pain, the systolic blood pressure fell to about 60 mm Hg, and bronchospasm was experienced. The condition was corrected within one hour but the second injection was not given. Of the remaining 1513 patients 717 were given $PGF_{2\alpha}$ and 796 hypertonic saline.

From the physical characteristics the two groups of patients appeared to be closely matched for state of health, age, height, weight, height to weight ratio, gravidity, and parity. The average interval since the last delivery was slightly longer in the prostaglandin-treated group (1·9 ± SE 0·13 years) than in the saline-treated group (1·5 ± 0·10 years), and so also was the average time since the last pregnancy (prostaglandin group 1·6 ± 0·11 years, saline group 1·3 ± 0·09 years). The average stage of gestation based on uterine size was similar in the two groups (prostaglandin group 17·5 ± 0·08 weeks, saline group 17·7 ± 0·06 weeks).

After sterilising the abdominal wall and infiltrating a local anaesthetic the uterine cavity was punctured with a fine-bore needle and a small amount of amniotic fluid withdrawn to confirm the intra-amniotic position of the needle tip. When hypertonic saline was used the solution (200 ml 20% NaCl) was slowly injected through the needle, which was then withdrawn. For the administration of $PGF_{2\alpha}$ a polyethylene catheter was first introduced via the needle, which was then withdrawn. A 5 ml solution of the tromethamine salt of $PGF_{2\alpha}$ (equivalent to 25 mg $PGF_{2\alpha}$) was then slowly injected through the catheter, which was left in position. Six hours later a second injection of 25 mg $PGF_{2\alpha}$ was given, after which the catheter was withdrawn.

If abortion occurred within 48 hours after the initial treatment—that is, after the injection of saline or the first injection of $PGF_{2\alpha}$—the case was classified as successful; otherwise it was classified as a failure. If supplementary treatment was given to stimulate uterine contractility during the 48-hour period the trial was designated as "interrupted." An abortion was accepted as "complete" if the placenta was spontaneously expelled through the cervix into the vagina. If any manipulation or surgical intervention was needed for delivery of the placenta the abortion was considered "incomplete."

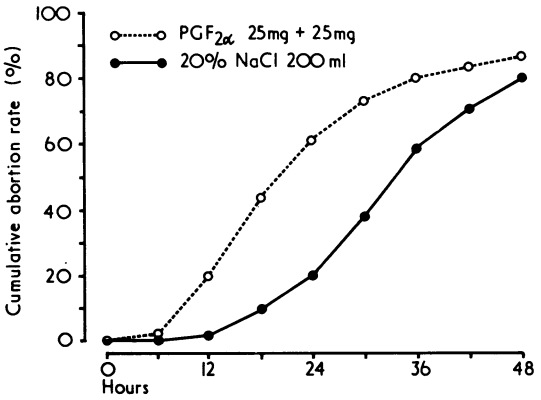
Late complications were recorded at a follow-up visit four to six weeks after the abortion. Altogether 778 patients attended for this examination, 381 in the prostaglandin group and 397 in the saline group.

Results

In the prostaglandin-treated group 614 of the 717 patients (85·6%) aborted within 48 hours after the initial injection. Altogether 439 (61·2%) of the abortions occurred within 24 hours and 574 (80·1%) within 36 hours (see table). In the saline-treated group 641 (80·5%) of the 796 patients aborted within 48 hours, while 161 (20·2%) had aborted by 24 hours and 462 (58·0%) by 36 hours (table). The differences between the two groups at 24 and 36 hours were highly significant ($P < 0·001$).

In 17 cases (10 in the prostaglandin group, 7 in the saline group) the trial was interrupted because the patients received additional treatment before the end of the 48-hour period. These patients were regarded as failures.

The mean induction-abortion interval in the prostaglandin group (19·7 hours) was significantly shorter than that in the saline group (30·4 hours) ($P < 0·001$). The cumulative abortion rates (see fig) show that abortion occurred sooner after $PGF_{2\alpha}$. The difference was most pronounced at 24 hours, when some 61% of the prostaglandin-treated patients had aborted compared with about 20% of the saline-treated patients. After 48 hours the difference was less marked, though still significant ($P < 0·05$). In the prostaglandin group multigravidae aborted on average faster than primigravidae (induction-abortion interval 17·0 ± SE 0·5 hours compared with 22·0 ± 0·5 hours). A similar but smaller difference was seen in the saline group (28·8 ± 0·6 hours compared with 31·6 ± 0·5 hours).



Cumulative abortion rates with intra-amniotic $PGF_{2\alpha}$ and hypertonic saline.

Although in the prostaglandin group the induction-abortion time in the early part of the second trimester (less than 16 weeks) was shorter than in patients with greater gestations (more than 16 weeks), the difference was not significant. No such trend was seen in the saline group. No correlation was found between the induction-abortion interval and the haemoglobin level or weight of the patients.

The proportions of complete and incomplete abortions in the two groups were similar, 408 (66·4%) of the abortions being complete in

Comparative success rates with intra-amniotic $PGF_{2\alpha}$ and hypertonic saline

Compound	Total No of patients	Success rate						Failures		Trial interrupted	
		24 h		36 h		48 h					
		No	%	No	%	No	%	No	%	No	%
$PGF_{2\alpha}$	717	439	61·2	574	80·1	614	85·6	93	13·0	10	1·4
NaCl	796	161	20·2	462	58·0	641	80·5	148	18·6	7	0·9

the prostaglandin group and 437 (68·2%) being complete in the saline group.

The incidence of heavy uterine bleeding (over 500 ml) was higher in the prostaglandin group (32 patients; 4·5%) than in the saline group (12 patients; 1·5%), as was the frequency of blood transfusion (22 (3·1%) compared with 6 (0·8%)) and surgical evacuation of the uterus (296 (41·3%) compared with 253 (31·8%)). The differences, however, were not significant.

SIDE EFFECTS

Minor side effects occurred in both treatment groups, vomiting and diarrhoea being the most common. Diarrhoea occurred in 109 (15·2%) of the patients given $PGF_{2\alpha}$, although only 11 (1·5%) had more than four episodes. Only 10 (1·3%) of the saline-treated patients had diarrhoea and none had more than four episodes. Vomiting was also more common in the prostaglandin group, occurring in 384 (53·6%) of the patients given $PGF_{2\alpha}$ compared with 153 (19·2%) of those given saline. More than four episodes occurred in 59 (8·2%) of the prostaglandin-treated patients and 17 (2·1%) of those given saline. The mean number of episodes of vomiting per patient was 1·5 in the prostaglandin group and 0·4 in the saline group. The corresponding figures for diarrhoea were 0·4 and nil respectively. The differences were highly significant ($P < 0·001$).

Apart from vomiting and diarrhoea side effects were found only occasionally. The incidences of episodes of dyspnoea were, in the prostaglandin group 2·6% (19 patients) and, in the saline group, 0·4% (3 patients). The corresponding incidences of flushing were 6·6% (47 patients) and 1·3% (10 patients), and of chest pain 1·0% (7 patients) and 0·1% (1 patient). Other side effects occurred in 22 patients in the prostaglandin group and 33 in the saline group. The commonest of these in the prostaglandin group was nausea (16 patients), while in the saline group nausea (six patients), headache (11), and thirst (four) predominated. There was one epileptic seizure and two cases of syncope in the saline group and none in the prostaglandin group. One case of urticaria and one of shivering occurred in the prostaglandin group. A cervicovaginal fistula was found in one patient in each group.

Attendance for follow-up examination at four to six weeks was disappointing in many centres. Only 778 patients (51%; 381 in the prostaglandin group and 397 in the saline group) were examined at least once after abortion. Among these the incidence of late complications was low.

The duration of bleeding was similar in the two groups. In most cases bleeding stopped within two weeks. Slight bleeding continued for more than four weeks in 23 patients (13 in the prostaglandin group, 10 in the saline group) and more menstrual-like bleeding in 13 (6 in the prostaglandin group, 7 in the saline group).

Readmission to hospital was necessary for 17 patients given $PGF_{2\alpha}$ and 13 given saline; the main reasons were excessive blood loss, retained products of conception, and signs of genital tract infection.

Pelvic examination at the follow-up visit showed minor abnormalities in 45 patients (5·8%); usually these were signs of vaginal or pelvic infection or delayed uterine involution.

Discussion

Intra-amniotic administration of hypertonic saline has long been the most widely used method of terminating second-trimester pregnancy, especially after the 15th week, when the amniotic sac may be readily punctured. In recent years intra-amniotic $PGF_{2\alpha}$ has been increasingly used for the same purpose, and in several countries its routine use has been approved under drug safety regulations. While individual studies have indicated the efficacy and safety of $PGF_{2\alpha}$, a large, randomised comparative trial between the two methods has not been conducted previously.

The present trial shows that both hypertonic saline and $PGF_{2\alpha}$ are safe and effective for terminating second-trimester pregnancy when administered by intra-amniotic injection. The main advantage of $PGF_{2\alpha}$, however, lies in its greater efficacy, with significantly higher success rates during the first 48 hours and a highly significantly shorter induction-abortion interval.

Before the study there was doubt about the way in which anaemic or malnourished patients would respond to the dose of $PGF_{2\alpha}$ or hypertonic saline. It is therefore important that no correlation was found between the induction-abortion interval and either the haemoglobin level or weight of the patients. Nor was there any correlation between these criteria and the frequency of complications.

A drawback of the $PGF_{2\alpha}$ treatment was the necessity for two injections, although the inconveinence was minimised by leaving a polyethylene catheter in situ during the six hours between the injections, and there was no evidence of a higher complication rate in this group compared with the saline-treated patients. Furthermore, recent investigations indicate that a one-injection technique may be successfully employed by increasing the dose to 40 or 50 mg[14–18] or by using prostaglandin analogues with a longer duration of stimulatory action on the myometrium than the primary prostaglandins.[15 19] Both these possibilities are under investigation in multicentre clinical trials being sponsored by the World Health Organisation.

Compared with hypertonic saline, treatment with $PGF_{2\alpha}$ was associated with a somewhat higher frequency of minor side effects, notably vomiting and diarrhoea, although these symptoms were within limits acceptable to both patient and physician. No specific treatment was given to reduce these side effects, but it is known that diphenoxylate hydrochloride may reduce the frequency of diarrhoea.

No serious complications occurred at the time of the injection of either $PGF_{2\alpha}$ or saline. Probably, however, the consequences of an inadvertent leakage of the injected compound into the systemic circulation would be less hazardous with $PGF_{2\alpha}$ than hypertonic saline owing to the rapid metabolic degradation of $PGF_{2\alpha}$ compared with the slow elimination of saline.

There were no strict criteria governing treatment after delivery of the fetus, and clinical management—of importance in determining the likelihood of complete abortion—varied between the centres. Consequently to evaluate the frequency of complete abortion with different methods of termination by comparing results of one centre with another would be fallacious. It is probable, however, that individual institutions treated both prostaglandin and saline patients alike. The similar frequency of complete abortion in the two treatment groups—66·4% in the prostaglandin group and 68·2% in the saline group—therefore suggests that the likelihood of complete abortion was not influenced by the compound used.

The incidence of heavy bleeding (more than 500 ml) and frequency of blood transfusion were low in both treatment groups, no significant difference between them being found in either respect.

Statistical evaluation of the frequency of late complications for the whole series is not possible since only 778 (51%) of the patients attended for follow-up examination. Among those attending, however, no difference was observed in the frequency of complications between the two treatment groups.

Lyneham *et al*[20] described epileptic seizures in five out of 320 patients treated with intra-amniotic $PGF_{2\alpha}$. The treatment schedule used was an initial dose of 30 mg followed by a further 15 mg at 24 hours if abortion did not occur, repeated again if necessary 18 hours later. In the present study there was no instance of an epileptic convulsion in the prostaglandin group, though one patient had an epileptic seizure after treatment with hypertonic saline. Other reports[21–23] have also indicated a low incidence of convulsions after termination with prostaglandins. Hence epileptic convulsions probably do not constitute a significant complication of the use of $PGF_{9}\alpha$ to terminate pregnancy.

There have been several reports of cervicovaginal fistulae developing after intra-amniotic administration of $PGF_{2\alpha}$.[8 24–26] In this study one case was detected in each group, but this may have been an underestimate of the true frequency since post-abortal vaginal inspection was not performed in all cases and many patients were lost to follow-up. Ballard *et al*[27] reported four cases of cervicovaginal fistulae among 6000 saline-induced abortions and three among about 300 prostaglandin-induced abortions. All were in young primigravidae. In all four treated patients supplementary oxytocin infusion had been used to

effect delivery. Similar results have been reported by others.[24-26]

It may be concluded that the occurrence of a cervicovaginal fistula is a non-specific phenomenon that may follow the use of hypertonic saline or prostaglandin, alone or in combination with oxytocin, and is predisposed to by excessive uterine stimulation in the face of a long, tightly closed cervix.

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Outpatient laparoscopic sterilisation

J H BRASH

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Summary

One-hundred consecutive laparoscopic sterilisations were carried out on an outpatient basis without serious operative complications. All patients were discharged home on the day of operation. Two patients subsequently required emergency admission to hospital. Most patients were completely satisfied with the day-case service.

Introduction

The increasing demand for female sterilisation has placed an additional burden on an already overstretched gynaecological service. Laparoscopy offers a safe and acceptable method of female sterilisation which can be adapted to an outpatient setting, as has already been done in North America over the past five years.[1-5]

Outpatient laparoscopic sterilisation was introduced in this hospital in June 1972, and by August 1974 219 outpatient sterilisations had been carried out. A prospective study of 100 consecutive patients was begun in September 1974 and completed in September 1975.

Patients and methods

Patients had to satisfy strict criteria before they were accepted for outpatient sterilisation. They had to be medically fit, thin, have had no previous abdominal surgery, and have suitable home conditions. Most were selected from those presenting at the gynaecological clinic requesting sterilisation. In 11 cases the patient's request for sterilisation had been made while attending the antenatal clinic, but laparoscopic sterilisation two to three months after delivery was preferred to immediate postpartum sterilisation. In every case the nature of the procedure was explained to the patient and she was given the option of having the operation performed as an inpatient or outpatient. Every patient in this series chose the outpatient procedure. In every case written consent for sterilisation was obtained from the patient and her husband.

The ages of the 100 women studied ranged from 24 to 45, and their parity ranged from 1 to 5. The time on the waiting list varied from one to 11 months, the average time being three months.

Routine on admission—Patients were admitted to the day bed area at 8.30 am on the morning of operation. They were instructed to fast from 9.30 pm the previous evening but were not given a bowel preparation. On admission they were seen by an anaesthetist who examined the cardiovascular and respiratory systems. The patient was also seen by the gynaecological registrar or senior registrar who was to perform the operation. Five operators were concerned in this series.

Anaesthesia and operative technique—The theatre list began at 9.15 am and ended at 10.45 am. The list contained six patients, the first two for laparoscopic sterilisation and the subsequent four for diagnostic curettage or cautery of cervix. Forty-six of the 100 patients were premedicated with either atropine alone, valium alone, or atropine and valium together. The remaining 54 patients were not premedicated. All operations were carried out under general anaesthesia induced with either Althesin or thiopentone and maintained with nitrous oxide, oxygen, and halothane by face mask. Muscle relaxants and endotracheal intubation were not used. Laparoscopy was carried out by Steptoe's method[6] and sterilisation was effected by electrocoagulation of the tube without division.[7] The skin incisions were closed with black silk sutures.

Postoperative phase and discharge—After operation the patient was returned to the ward when the anaesthetist considered her condition satisfactory. Pulse and blood pressure were recorded on arrival at the ward and again after half an hour and an hour. If satisfactory no further recordings were taken. The patient was seen by the gynaecological registrar at 2 pm. If her condition was satisfactory she was discharged home between 3 pm and 4 pm. On the evening of operation a district nurse visited the patient at home and made a return visit on the fifth day after operation to remove skin sutures. Each patient was given an appointment to return for review six weeks after operation.

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