A SAFE AND EFFECTIVE METHOD OF TERMINATION OF MID-TRIMESTER PREGNANCY

by

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Introduction

Liberalisation of the abortion laws and the need of family planning have led to increased demand for termination of pregnancy throughout the whole world. While termination upto 10th week of pregnancy by suction-evacuation or dilatation and curettage is easy and safe, it is not so when the pregnancy reaches mid-trimester.

Different methods and different abortifacients are being used for termination of mid-trimester pregnancy such as use of hypertonic saline, prostaglandins, hypertonic urea and glucose, mannitol and rivanol but none of them are ideal and safe. As such with a view to find out a safe, effective and easy method of termination of mid-trimester pregnancy the present work was undertaken.

Materials and Methods

Two hundred and twenty-five cases of pregnancy between 12 and 20th week were chosen at random from those admitted in the N.R.S. Medical College Hospital, Calcutta for medical Termination of pregnancy. Full history was taken and thorough clinical examination was performed with particular attention to cardiovascular, respiratory and renal conditions.

The patients were divided into two groups. First 125 cases constituted Group I. 150-200 ml. of 20% urea in 2% saline and half million units of crystalline penicillin were introduced by a Foley's catheter extra-aminotically.

Second 100 cases formed Group II. In these patients 150-200 ml. of 30% urea in 2% saline was introduced in the same manner extra-amniotically. Penicillin was not given in these cases. Instead when there was need of reinstillation after 48 hours oxytetracyclin 250 mg. was given 6 hourly orally for 3-4 days.

The solution was prepared locally by dissolving required amount of urea and sodium chloride in ordinary tap water and then it was autoclaved.

Antiseptic dressings were applied and light diet was given in the morning. An intramuscular injection of Trifluopromazine (Siquil) 20 mg. was given half an hour before instillation. In the lithotomy position, after cleansing vulva and vagina with 2% cetrimide in aqueous solution. Sim's speculum was introduced, cervix was caught by Allis' forceps and a Foley catheter No. 14-16 size was introduced through the cervix for about 2 inches. The bulb was distended with 20 ml. sterile water and pulled down so as to fit in snugly over the cervical canal. Through the catheter 150-200 ml. of sterile urea saline solution was introduced extra-amniotically slowly by means of a 50 ml. syringe. 150 ml. was introduced in pregnancies upto 14 weeks, otherwise 200 ml. was instilled. The bottle of urea-saline was shaken repeatedly during instillation.

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Penicillin was introduced through the same catheter in the Group I cases only. The catheter was then tied with thread and strapped to one of the thighs. Sterile pad was applied and the patient was sent back to the ward, had normal diet and free movement. The catheter was taken out after 8 hours.

Syntocinon 5 units was injected subcutaneously in Group I cases and intramuscularly in Group II cases every 4 hours starting soon after instillation till abortion. If the placenta did not come out within half an hour or there was delay in the process of abortion by more than 4 hours Syntocinon drip (10 units in a bottle of 540 ml. of 5% dextrose) was started intravenously with 40 drops per minute. After complete expulsion of conceptus ergometrine 0.5 mg. was given intramuscularly.

Reinstillation of 150 ml. of the same solution was given in the same manner if the process of abortion did not start in 48 hours.

The patients were discharged within 24 hours of abortion unless there was any complication.

The follow up was done after 6 weeks and 3 months or earlier if there was any complication.

Results

TABLE I
Induction Aborton Time (Groupwise)

Group	No. of cases	Range (hours)	Mean (hours)
I	125	16—78	30.5
II	100	13—75	30

Age Distribution

Out of 225 cases, 102, 45% were below 20 years of age and 14.6% were below 16 years. All the girls below 16 years and 80% of those within 20 years were carrying illegal pregnancies.

Parity

One hundred and four, 46% of the cases were nulliparous. Out of 121 multigravidae, only 4 had one previous induced abortion and 1 had 2 induced abortions earlier.

Marital Status

Only 41% cases were married and 38% were unmarried. The rest were widows or left by husbands.

Duration of Pregnancy

While 70% of the cases were above 14 weeks, 30% were between 12 and 14 weeks in which time the present method was quite effective too.

Induction-abortion Time

I/A time was counted from the time of instillation of the solution to the delivery of the foetus irrespective of delivery of the placenta. No relationship was found between I/A time and parity or marital status. Mean I/A time was less (28 hours) in pregnancies above 14 weeks than in those below 14 weeks (35.6 hours).

The mean I/A times of the two groups were not different (Table I) which were around 30 hours.

Success Rate

Table II shows the cumulative success rate in each group. On the whole the success rate was about 98% and no difference was found between the two groups, but success rate within 48 hours was more (88%) in Group II cases than in Group I cases (80.8%). Only 2 cases in each group went beyond 72 hours. The cumulative success rate within 72 hours was 96% in each group.

TABLE II
Cumulative Success Rate

Group	No. of cases	Within 24 hours	Within 48 hours	Within 72 hours	Total
I	125	50 (40%)	101 (80.8%)	120 (96%)	122 (97.6%)
II	100	43 (43%)	88 (88%)	96 (96%)	98 (98%)

Complications

Table III shows that there was not much difference in the complications of the two groups. The commonest complication was incomplete abortion which happened in 23% cases in Group I and in 25% cases in Group II. In these cases placenta was evacuated manually or with ovum forceps after administering pethidine 100 mg. and phenergan 50 mg. intramuscularly. There was no difficulty and the operations were performed mostly by the house staff. Pelvic infection occurred in 2 cases only in each group. One patient in each group had vasovagal attack during instillation but was revived quickly without any drug, and instillation was continued slowly in these 2 cases. One patient developed unexplained shock at the end of instillation and had to be revived after administering intravenous fluids and cortisone. She aborted completely after 26 hours without any further trouble. Three cases in Group I had necrosis ulcer due to inadvertent subcutaneous injection of 5 ml. ampoule of syntocinon containing 5 units instead of 2 ml. ampoules. Nausea with one bout of vomiting happened during instillation in 5 out of 225 cases due to possibly over distension of the uterus.

TABLE III
Complications

Complications	Group I (125 cases)	Group II (100 cases)
Incomplete abortion	29 (23%)	25 (25%)
Pelvic infection	2 (1.6%)	2 (2%)
Vasovagal attack	1 (.8%)	1 (1%)
Shock	1 (.8%)	0
Siquil sensitivity	1 (.8%)	0
Necrosis ulcer	3 (2.4%)	0
Nausea + vomiting	3 (2.4%)	2 (2%)

Follow up

Only 53 patients out of 225 ones could be followed for 6 weeks to 3 months. There was no incidence of abnormal menstrual flow in any of them. One case was admitted for retained products of conception and was cured by dilatation and curettage.

Discussion

In the present study hypertonic urea-saline has been used in 2 different strengths extra-amniotically in 225 cases chosen at random for the termination of

pregnancy between 12 and 20 weeks. No report has yet been published by any other worker of the use of the present method.

Different methods are being used in different places to procure mid-trimester abortion but each one of them has got its drawbacks. The common methods are use of hypertonic saline, prostaglandins and urea particularly the first two ones.

Intra-amniotic instillation of hypertonic saline with or without Syntocinon I.V. drip is very commonly used. The success rate is 78-80% within 48 hours and 88% within 72 hours (Datta Gupta et al, 1977 and Palanichamy, 1976). In 12-18% cases the method fails counting 72 hours or 48 hours as the deadline. The success rate is more when there is no time limit. Mean I/A time varies from 20.4 to 36 hours (Datta Gupta et al, 1977 and Tietze and Lewit, 1973). Besides its failure rate the other drawbacks are need for intra-amniotic instillation which fails in one third cases between 12-14 weeks, incomplete abortion in 16 to 45% cases, excessive bleeding often needing blood transfusion in 1.2 to 15% cases, and pyrexia with or without pelvic infection in 6 to 16% cases (Datta Gupta et al, 1977; Tietze and Lewit, 1973; Palanichamy, 1976). Serious complications like severe consumptive coagulopathy, hypernatraemia, shock and haemorrhage leading to several maternal deaths have occurred. There were 3 such deaths in 600 cases in our hospital at N.R.S. Medical College, Calcutta. Wagatsuma (1965) reported 25 such maternal deaths in Japan between 1946 and 1952. Since then hypertonic saline instillation has been almost abandoned in Japan. Schiffer *et al* (1973) reported 10 deaths out of 49,474 cases in New York and Datta Gupta *et al* (1977) had 3 deaths out of 1,447 cases of intra-amniotic hypertonic saline in Calcutta. Several other maternal deaths have been reported by other authors. However, W.H.O. Prostaglandin Task Force (1976) in a Collaborative Study while reporting on 796 cases from different parts of the world have concluded that intra-amniotic hypertonic 20% saline wthout oxytocin is safe and effective though their failure rate was 18% taking 48 hours as time limit.

Prostaglandins in different forms and in different methods have been used for mid-trimester abortion. I/A time of intra-amniotic prostaglandin F_2 is 19.7 hours (W.H.O. Report, 1976). Prostaglandins are successful in 86% cases within 48 hours (W.H.O. Report, 1976) and Brenner (1975) has got successful result in 95% cases. The greatest drawbacks are nausea, vomiting and diarrhoea which happen in 54-90% cases. Severe haemorrhage occurs in 3.1 to 9.4% cases and incomplete abortion happens in 41% cases (W.H.O. Report, 1976 and Brener, 1975). However, WHO Prostaglandin Task Force (1976) reporting on 717 cases of intra-amniotic instillation of Prostaglandin F_2 in mid-trimester abortion has found the method safe and effective.

Newer prostaglandins particularly 15(S) Methyl compounds of PGE, and PGF_2 are being tried by different routes including vaginal applications which seem to have an edge over intra-amniotic PGF_2 but results of large trials are still lacking.

Intra-amniotic instillation of hypertonic urea (30-53%) has been reported by some investigators (Burnett *et al*, 1975; Rajan and Nair, 1977). They have been found to be quite safe and no maternal deaths have been reported as yet. But the drawbacks are prolonged I/A time of 44.8 to 51.1 hours, failure rate of 4 to 8.8%, incomplete abortion of 15-20% and pelvic infection 6.6% (Rajan and Nair, 1977; Weinberg and Shepherd, 1973).

Use of mannitol, hypertonic glucose and bongie have never been found favour due to their drawbacks. Ethacridine has been used extra-amniotically by some investigators with some good promise but published details of no large series are yet available.

Abdominal hysterotomy is performed by many in patients who desire mid-trimester abortion with ligation inspite of its high morbidity rate of 38.9% (Palanichamy, 1976), particularly where facilities for laparoscopic ligation are not available.

With a view to find out a safer and more effective method of mid-trimester abortion, the author has tried extra-amniotic instillation of different strengths of urea-saline. To start with 20% urea in 5% saline was tried on 100 cases with 99% success rate with mean I/A time of

35.6 hours with complications almost similar to the present cases (Chaudhuri, 1978). In the present paper trials of 2 other strengths e.g. 20% urea in 2% saline and 30% urea in 2% saline are being pubished.

Maximum amount of urea used for one instillation was 40 gm. in the Group I cases and 60 gm. in Group II cases which are well within the therapeutic doses of urea used intravenously as osmotic diuretic. As such chance of uraemia is nil, as has been found out by practical trial in these cases. The chance of uraemia is further lessened due to use of the solution extra-amniotically from where the absorption is slower (Blake *et al*, 1976). Chances of hypernatraemia has been nullified by lowering the concentration of saline from 20% to 2%, by the use of solution extra-amniotically lowering the absorption rate (Blake *et al*, 1976) by the concommitant use of urea which causes not only excretion of water but also that of sodium chloride and lowers the level of sodium and chloride in blood (Barnett *et al*, 1975) and by the use of syntocinon by intramuscular or subcutaneous route thus reducing its anti-diuretic effect.

Instillation of hyperosmolar urea-saline in the present cases was found to produce overdistension of the uterus quickly in 2 to 3 hours time which regained its size in about 12 hours and then got shrunk. Foetuses delivered were all dead and placentae were degenerated and shrunk.

Termination of pregnancy by the present method is thought to be due to several factors namely (a) overdistension of the uterus by hyperosmolar urea-saline causing reflex contractions, (b) death of the foetus and placenta leading to inhibition of the progesterone block, (c) liberation of prostaglandin from the degenerated decidua, (d) irritation and pressure of Foley-catheter on the cervix and lower part of the body of the uterus initiating reflex contractions, and (e) Syntocinon injections. These injections were given intramuscularly in the Group II cases with a view to avoid the trouble of prolonged stay in bed and high incidences of thrombophlebitis of intravenous drip, to mimick sparting release of oxytocin as happens in initiation of labour and to reduce the anti-diuretic effect of oxytocin.

Extra-amniotic route was chosen because it is easier to use, it can be used even in 12 to 14 weeks of pregnancy, it avoids chance of cervico-vaginal fistula and absorption of urea and saline are slower.

The present method is easy to use and is very effective as judged by the overall success rate of 98%, abortion taking place in 96% cases within 72 hours and in 88% cases within 48 hours, the mean I/A time being 30 to 30.5 hours. Only 12 per cent cases in Group II had reinstillation after 48 hours. It has also been found to be very safe as the complications were within tolerable limit and there was no incidence of serious side effects like hypernatraemia, consumptive coagulopathy, severe haemorrhage and severe infection leading to any maternal loss.

In view of the safety and effectiveness and case of administration the present method deserves wider trial.

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