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CONTENTS

Thai Journal of Obstetrics and Gynaecology

It has been recognized that publication is the last chain of event of scientific research. Although the research works can be communicated among researchers by various means but the scientific journal continues to be the most important mechanism of communication process among the scientists. The Executive Boards of the Royal Thai College of Obstetricians and Gynaecologists were well aware of this matter thereby it was decided to publish the Thai Journal of Obstetrics and Gynaecology in 1989 to help disseminate the research articles of its members.

Everyone knows that writing the scientific paper means the ability to write clearly, unequivocally, concisely and pleasantly but it is not easy to do so. To meet this objective it is the editorial policy to help attain the consistency and to set the standard of quality of manuscript submitted for publication. Since the first issue of this journal appeared, subsequently one may see a steadily improvement in various aspects of quality of the journal until it was indexed in the PASCAL database of INIST of France since 1992. The foreign circulations of the journal are also increasing every year.

Not only publishing the articles of Thai researchers but several articles of foreign researchers are being published in the journal also. Due to more and more manuscripts are waiting to be published the 2-issue published yearly is going to be the quarter-yearly one from 1996 onward.

It is my distinct pleasure to invite Obstetricians and Gynaecologists worldwide to join with us in disseminating the scientific knowledge in the field of Obstetrics and Gynaecology and related fields to submit the manuscript to be published in the Thai Journal of Obstetrics and Gynaecology. Not only the original works are welcome but reviews and the interesting case reports are also welcome.

Professor Thaviponk Suvonnakote
President, RTCOG

Letter from the editorial staffs

Dear members,

The Thai Journal of Obstetrics and Gynaecology is published on behalf of the Royal Thai College of Obstetricians and Gynaecologists and is now entering its 8th year. To commemorate the cerebration of the 50th year of ascend to the throne of His Majesty King Bhumiphol Adulyadej the emblem will appear on the front page of every issue in 1996. During the next two years we would endeavour to improve the quality of the journal. Though at present it is indexed in the PASCAL data base of Institut de l'Information Scientifique et Technique (INIST), France, we like it to be more internationally recognized. In order to achieve the international standard several changes have been made. The size of the journal is a little bigger with the title, volume number and dates printed on the spine. The format of the manuscripts remains adherent to the uniform requirements for manuscripts submitted to biomedical journals except for a slight alteration of the abstract which the authors are now advised to write in structured form. The contents are classified into sections to help readers find the articles in which they have a particular interest. The journal will be published quarterly. We will try to enhance the speed and efficiency of processing manuscripts for publications.

Needless to say, the success of the journal cannot be accomplished without the cooperation from our members. The editorial staffs would like to invite all members of the Royal Thai College of Obstetricians and Gynaecologists to submit articles for publication and welcome any comments and suggestions which will improve the quality of the journal.

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OBSTETRICS

Postoperative Pain Following Various Methods of Postpartum Tubal Sterilization

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ABSTRACT

Objective To compare the level of postoperative pain among patients using Filshie clip and Modified Pomeroy method for postpartum tubal sterilization.

Design Prospective, randomized study.

Setting Department of Obstetrics and Gynaecology, Faculty of Medicine, Siriraj Hospital.

Subjects One hundred and ten postpartum patients with spontaneous vaginal delivery, requesting tubal sterilization, were randomly assigned to one of the two study groups. The techniques of tubal sterilization carried out under local anaesthesia were not known by the patients, ward staff and the interviewer.

Main outcome measures The patients' characteristics, obstetric history, self-assessment pain intensity scale (visual analogue scales), analgesia requested by the patients and resumption of normal activity were measured.

Results The characteristics of both study groups were comparable. There were no significant differences in level of pain among the two groups before, immediately after the operation, and at 6, 12, 24 and 48 hours after the operation ($P > 0.05$). The Filshie clip group had shorter operation time and had a smaller number of patients necessitating analgesia 24 hours and over after the operation with earlier resumption of normal activity.

Conclusion For the selection of appropriate tubal sterilization technique, this study provides evidence that pain does not vary substantially between options, thereby, other parameters should also be considered in deciding upon the preferred technique.

Key words : Filshie clip, Modified Pomeroy, pain, postpartum tubal sterilization

The majority of the literature dealing with female sterilization has been devoted to establishing rates of safety and effectiveness of various approaches and techniques. Only a few have been directed towards patient discomfort or pain which could lead to decreased satisfaction with and acceptability of the specific procedure or of the overall sterilization programme.[1]

It was suggested that increased abdominal pain accompanying mechanical occlusive procedures was secondary to strangulation, ischemia and necrosis of the ligated portion of the tube which continued to synthesize and release prostaglandins.[2,3] Although the Pomeroy or Modified Pomeroy technique is still a standard procedure for laparotomy sterilization, other mechanical tubal occlusion techniques such as Filshie clip and Hulka clip are being increasingly used especially because of their claimed higher potential for reversibility.[4-7]

Since there is no comparative study of postoperative pain experienced by the patients after postpartum tubal sterilization using different procedures, it is the purpose of this clinical study to compare the pain experienced by the patients after postpartum tubal sterilization employing the Filshie clip and the Modified Pomeroy technique.

Materials and Methods

The studied patients were recruited from those who had uncomplicated term vaginal delivery requesting tubal sterilization. They were randomly allocated to two groups. The type of tubal sterilization used either Filshie clip or Modified Pomeroy was unknown to the patients, ward staff and the interviewer. The self-assessment of pain intensity scales (visual analogue scales) and the consent form for surgery were explained to them.

All study patients received premedication with atropine 0.3 mg and morphine hydrochloride 10 mg given intramuscularly 30-40 minutes prior to surgery which was performed under local

Table 1. Patients profiles, comparison of study group

		Filshie clip	Modified Pomeroy	P value
Mean age (year)		27.9 ± 5.0	27.0 ± 4.9	NS*
Mean weight (kg)		52.4 ± 8.0	59.2 ± 7.3	NS*
Mean height (cm)		153.3 ± 5.5	154.3 ± 5.5	NS*
Education (year)	: 1-6	43	45	NS**
	≥ 7	12	10	
Occupation	: trader	8	11	NS**
	labourer	18	19	
	housewife	29	25	
Parity	: 1	30	31	NS**
	2	18	18	
	≥ 3	7	6	
Mean duration of labour (hr)		5.6 ± 2.8	6.5 ± 4.3	NS*
Degree of perineal tear :	first	0	1	NS***
	second	55	54	
Mean child weight (g)		3090.0 ± 366.7	3116.4 ± 371.7	NS*
Mean time after delivery to sterilization (hr)		16.4 ± 9.0	18.9 ± 9.8	NS*

* Unpaired t-test
** Chi-square test
*** Fisher exact test

anaesthesia. For those who experienced pain necessitating analgesia, Paracetamol 1,000 mg was given orally by ward staff at 6 hourly intervals. The self-assessment pain intensity level (visual analogue scales) was recorded by the patients regarding preoperatively, immediately postoperatively and 6, 12, 24 and 48 hours postoperatively as to whether the levels of pain were within the area of the procedure or both fallopian tubes. After the operation, other measures of discomfort such as analgesic medications needed by the patient and resumption of normal activity were also recorded by the interviewer.

Results

A total of 110 patients participated in the study. The patients' characteristics, obstetric history and clinical details before having tubal sterilization were comparable in the two groups (Table 1).

The median (mean ± S.D.) operative time in the Filshie clip and the Modified Pomeroy group was 9 (9.7 ± 1.8) and 11 (11.3 ± 1.9) minutes respectively which was significantly different ($P < 0.05$, Mann-Whitney U - Wilcoxon Rank Sum W test). All of the patients had normal operative findings. There was no surgical difficulty or operative complications necessitating additional anaesthetics.

Table 2. Self-assessment of pain by visual analogue scales, comparison of study group

	Filshie clip median (mean ± S.D.)	Modified Pomeroy median (mean ± S.D.)	P value*
Before operation	1.5 (2.1 ± 1.9)	1.9 (2.4 ± 1.4)	NS
Immediately after operation	4.6 (4.6 ± 2.5)	4.7 (4.6 ± 2.3)	NS
6 hour postoperation	2.1 (2.7 ± 2.0)	2.8 (2.8 ± 1.7)	NS
12 hour postoperation	1.9 (2.9 ± 2.4)	2.8 (3.2 ± 2.0)	NS
24 hour postoperation	2.0 (2.8 ± 2.3)	2.4 (2.9 ± 2.2)	NS
48 hour postoperation	1.0 (1.5 ± 1.6)	1.2 (1.7 ± 1.5)	NS

* Mann-Whitney U - Wilcoxon Rank Sum W test

Table 3. Analgesic medications needed by the patient for pain, comparison of the study groups

	Filshie clip	Modified Pomeroy	P value
Postoperation - 6 hours			
no drug	54	52	NS*
1 time	1	3	
6 - 12 hours			
no drug	19	18	NS**
1 time	36	37	
12 - 24 hours			
no drug	23	20	NS**
1 time	32	35	
24 - 48 hours			
no drug	37	28	0.03**
1 time	15	15	
2 times	3	12	

* Fisher exact test
** Chi-square test

Table 4. Analgesia needed by the patients for pain at various intervals postoperatively, comparison of study groups

	Filshie clip	Modified Pomeroy	P value
18 - 24 hours : no drug	34	31	NS*
1 time	21	24	
24 - 48 hours : no drug	53	50	NS**
1 time	2	5	

* Chi-square test
** Fisher exact test

Table 5. Summary of clinical details of subjects during 7 days after the operation, comparison of study groups

	Filshie clip	Modified Pomeroy	P value
Breast feeding			
no	0	1	NS*
yes	55	54	
Lower abdominal pain during breast feeding			
no	50	50	NS*
yes	5	4	
Days before ability to resume normal activity (day) : 3	52	45	0.03**
≥ 4	3	10	

* Fisher exact test
** Chi-square test

Table 2 shows the results of self-assessment of pain without significant differences between the two groups at various time intervals ($P > 0.05$).

As shown in Table 3 the patients in the Filshie clip group required less analgesics than those in the Modified Pomeroy group significantly at the interval 24-48 hrs.

Table 4 shows the number of patients who needed analgesic postoperatively with no statistical difference in both groups.

As shown in Table 5, all patients returned for a follow-up visit on the 7th day after the operation and experienced no signs and symptoms of wound or pelvic infection. The patients in the Filshie clip group were able to resume normal activity sooner than the Modified Pomeroy group.

Discussion

Pain is a subjective complaint and its measurement is difficult to standardize. Thus, susceptibility to and reporting of pain may differ among patients with different characteristics and culture. However, in this study, the recorded pain rates for patients having had tubal sterilization by the two comparative tubal occlusion techniques is comparable because of the random allocation of patients and the "blind" outcome assessment made by the patients and the interviewer.

Because of the method of study, patients assigned to each technique were similar in terms

of patients' characteristics, obstetric history and clinical details of subjects before surgery. Therefore potential confounders that might interfere with the report of pain such as age, education level, duration of labour, degree of perineal tear and the interval between delivery to sterilization were equally distributed in the two groups. Furthermore, the reports of surgical difficulties, complications and complaint rates other than pain in each comparative group were also similar.

Although the operative time of the two groups was statistically significant different, clinically this difference plays no influence in the report of pain. This difference was due to the different techniques of each procedure. The Filshie clip group had shorter operative time than the Modified Pomeroy group because it was very easy to fill the clip in the clip applicator and place the clip on the tube.[4,8] With the other method, the operator spent more time crushing the tube, ligating a knuckle and removing a segment of the tube in the Modified Pomeroy techniques.

After the operation, all of the patients were offered additional analgesia on request using a standard regimen, which is not only mandated by ethical considerations but is also consistent with prevailing clinical practice. The resulting measurements of pain intensity were therefore "contaminated" by the additional analgesic medication. On one hand, a more painful procedure will lead to a greater use of analgesia, while on the other extra analgesia may reduce the report of pain. Because of this, it is necessary to compare the number of patients who requested and had some more drugs 6 hours before the assessment of pain each time between the two groups and the result of the study showed no significant difference (Table 4). So the self-assessment of pain at each different time of the two groups in the study is comparable.

Careful explanation of the "visual analogue scales" to each patient was provided by the interviewer. This scale is a simple, sensitive and reproducible instrument that enables a patient to express the severity of her pain in such a way that it can be given a numerical value.[9] The results of the study indicated that there was no difference in the pain experienced by the patient after postpartum tubal sterilization between the two groups. However, during 24-48 hours after the operation, even though the results of the study showed no significant difference in the report of self-assessment pain intensity between the two groups, we found that during this time, the Filshie clip group had lower incidence of analgesic remedication. Furthermore, the Filshie clip group was able to resume normal activity sooner than the Modified Pomeroy group. However, the two techniques are equally efficient in preventing future pregnancy[5] but may present different opportunities for reconstructive surgery if needed. The Filshie clip technique is possibly the best potential for reversal at present.[4,10] This study supports the Filshie clip technique as easy and safe to perform as reported previously[4,7,8,11] and also accountable as the least painful technique. It can then be the most suitable method for postpartum tubal sterilization, especially in younger patients and lower parity of family planning acceptors.

This study indicates that postpartum tubal sterilization employing these two techniques is easy and safe under local anaesthesia plus analgesia. Pain experienced by the patients after postpartum tubal sterilization by using Filshie clip is less severe than the Modified Pomeroy technique which is acceptable as the standard procedure. Then, in selecting a tubal occlusion technique, this study provides evidence that pain does not vary substantially between options and hence factors such as the relative effectiveness,

safety, equipment costs, ease of application and potential for reversibility are more important variables to be considered.

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The authors wish to thank patients, medical and nursing staff in the postpartum ward, Siriraj Hospital for their co-operation in this study. We also wish to thank Professor Sommai Toongsuwan and Professor Thaviponk Suvonnakote whose reflection and comments on this work are much appreciated.

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OBSTETRICS

Induction of Labour by Prostaglandin E_2 Intracervical Gel or Vaginal Suppository

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ABSTRACT

Objective To compare the effectiveness in induction of labour between prostaglandin E_2 intracervical gel and vaginal suppository.

Design Prospective, randomized study.

Setting Department of Obstetrics and Gynaecology, Faculty of Medicine, Chulalongkorn University Hospital.

Subjects Nineteen pregnant women with unfavourable cervix (Bishop score ≤ 5) were randomized to receive either prostaglandin E_2 intracervical gel (0.5 mg) or vaginal suppository (3 mg) for induction of labour.

Main outcome measures Mode of delivery, time from initial application of PGE_2 unitil delivery, and adverse effect, Apgar score and immediate newborn status.

Results Caesarean section was performed in 5 out of 9 cases in intracervical gel group, comparing to 1 out of 10 cases in vaginal suppository group. The mean time of application of prostaglandins to labour (A-L) and application to delivery (A-D) in cases of successful vaginal delivery were significantly shorter in the intracervical gel than in the vaginal suppository group (A-L : 1 ± 0.71 hr vs 11.21 ± 9.29 hr ; A-D : 13.75 ± 3.63 hr vs 20.48 ± 6.74 hr, $P < 0.05$). The mean time from rupture of membranes to delivery was of no difference between the two groups (4.48 ± 2.46 hr vs 4.80 ± 2.88 hr respectively, $P = 0.85$) Neither uterine hyperstimulation nor other adverse effects both to the baby and mother was detected during the labour period.

Conclusion Prostaglandin E_2 vaginal suppository seemed to be simple and successful for induction of labour and delivery, though it required longer period of induction to delivery when compared to prostaglandin E_2 intracervical gel.

Key words : induction of labour, prostaglandin E_2, intracervical gel, vaginal suppository

Prostaglandins play a central role in the cervical ripening and, indeed, in initiating and maintaining labour. The role of prostaglandins in the natural process of cervical ripening provides the basic rationale for their use when cervical ripening is warranted.[1] Prostaglandins have been available for clinicians to assist in the cervical ripening process for more than two decades, however, the route of delivery has been changed from systemic to local. These changes have lowered the dose required for cervical ripening, and consequently, fewer side effects occurred.

Concerning prostaglandin E_2 (PGE_2) vaginal suppository, at present, the minimal dose available and commonly used is 3 mg. Many studies showed that this agent had better efficacy and safety when compared with oxytocin or placebo.[2-5] PGE_2 0.5 mg in the form of intracervical gel (2.5 ml) was first introduced in Thailand in 1992. Some suggested that this gel is used for induction of labour in pregnant women with low Bishop score when labour inducing is indicated. However, we have never had any experience in using this new route of PGE_2. To induce labour, therefore, we conduct this study to compare the effectiveness in induction of labour between this intracervical-application prostaglandin and the more commonly used intravaginal tablet. This will help us to obtain more information concerning the new pharmaceutical agents and have more alternatives in induction of labour.

Materials and Methods

This prospective randomized study was carried out at the Department of Obstetrics and Gynaecology, Faculty of Medicine, Chulalongkorn University Hospital from March 1993 to January 1995. Following the approval by our Institutional Review Board, nineteen women admitted for induction of labour, received either 0.5 mg of PGE_2 intracervical gel (Prepidil gel, Upjohn) or 3 mg of PGE_2 vaginal suppository (Prostin E_2, Upjohn). Inclusion criterias before informed consent and randomization were singleton pregnancy, vertex presentation, intact membranes, and cervical Bishop score of 5 or less. Patients with abnormal lie or presentation, premature rupture of membranes, oligohydramnios, previous uterine scars, history of allergy to prostaglandins or severe medical diseases such as asthma or heart diseases were excluded from the study. The gestational age was estimated with certainty by last menstrual period, early antenatal care or by ultrasonic findings that were compatible with the patients' own menstrual dates.

All procedures were performed in the labour room. Each patient was checked for cervical score and monitored over a period of 30 minutes to ensure that the fetal heart rate (FHR) were normal and few or no uterine contractions (fewer than three in 30 minutes). After an evaluation period, 0.5 mg of PGE_2 in a translucent, thixotropic sterile gel (2.5 ml) was administered into the cervical canal via a prefilled syringe with an accompanying introducer in the first group. Caution was taken not to push the gel above the level of the internal os.

In the other group, 3 mg of PGE_2 as a vaginal suppository was placed in the posterior fornix. Then, all the patients were asked to remain in flat position for at least 1 hour. In the first 2 hours, the patients were closely monitored for abnormal FHR and uterine hyperstimulation.

The Bishop score was assessed by the same obstetrician until delivery. After the first 2 hours, the routine labour care was carried out. Amniotomy was performed when cervical dilatation reached 3-4 cm unless membranes rupture spontaneously. Augmentation with oxytocin was done as indicated by arithmetic progression method. Route

and method of delivery was performed under obstetric indication.

We used the following indices to compare the outcome : time from initial application of PGE_2 until delivery, mode of delivery, incidence of uterine hyperstimulation, or other adverse effects, Apgar score and immediate newborn status.

The data were reported as mean and standard deviation and compared by unpaired t-test. $P < 0.05$ was considered significant.

Results

Nineteen cases with unfavourable cervix (Bishop score ≤ 5) were randomized to receive either PGE_2 intracervical gel or vaginal suppository. The patients' characteristics, shown in Table 1, were similar between the two groups.

Table 2 reveals the indications for induction of labour in both groups. Selected pregnancy outcome parameters are listed in Table 3. There were 2 cases of chorioamnionitis and 1 case of

Table 1. Patients' characteristics

	Gel (N = 9)	Suppository (N = 10)	P-value
Mother			
- Age (y)	25.33 ± 5.20	27.80 ± 5.35	0.32
- Parity	0.33 ± 0.71	0.70 ± 0.95	0.35
- Gestational age (wk)	39.44 ± 3.68	40.70 ± 1.57	0.36
- Initial Bishop score	3.33 ± 1.12	4.00 ± 0.94	0.18
Newborn			
- Birthweight (g)	3,022 ± 347	3,025 ± 308	0.99

Gel = Prostaglandin E_2 intracervical gel (Prepidil gel) 0.5 mg
Suppository = Prostaglandin E_2 vaginal suppository (Prostin E_2) 3 mg
y = year, wk = week, g = gram

Table 2. Indications for induction of labour

	Gel (N =9)	Suppository (N = 10)
1. Postterm	2	5
2. Fetal anomalies* or FDU	2	1
3. Poor weight gain	2	1
4. Mild preeclampsia	1	1
5. Others**	2	2

FDU = Fetal death in utero

* Fetal anomalies : Dandy-Walker syndrome, Hydrocephalus

** Decreased fetal movement, Thalassemia, Haemoglobinopathy, Systemic lupus erythematosus (SLE)

Table 3. Pregnancy outcome

	Gel (N=9)	Suppository (N=10)
Mother		
1. Route of delivery		
- Abdominal	5#	1@
- Vaginal	4	9
2. Augmentation with oxytocin	3	4
3. Analgesics given	8	7
4. Postpartum complication*	3	0
Newborn		
1. Sex (Male : Female)	4 : 5	6 : 4
2. Birthweight (g)	3,022 ± 347	3,025 ± 308
3. Apgar score (at 1 min < 7)	1	1
4. Neonatal jaundice	1	1

Reasons for caesarean section

Chorioamnionitis with fetal distress (1), Dandy Walker syndrome with chorioamnionitis (1), Fetal death in utero with cephalopelvic disproportion (1)-later developed endometritis, Failure to progress (2). The time of induction to delivery of the former 3 cases was 3 days.

@ Failure to progress (1)

* Chorioamnionitis (2), Endometritis (1)

Table 4. Mean time from application of PGE_2 to delivery in cases of successful vaginal delivery*

	Gel (N = 4)	Suppository (N = 8)	P-value
1. Application to labour (hr)	1 ± 0.71	11.21 ± 9.29	0.017
2. Application to delivery (hr)	13.75 ± 3.63	20.48 ± 6.74	0.049
3. Rupture of membranes to delivery (hr)	4.48 ± 2.46	4.80 ± 2.88	0.85

* Not included a case of hydrocephalus in the vaginal suppository group

postpartum endometritis in the gel group. In these cases, it took 3 days from induction of labour with PGE_2 until delivery. Birthweights were 2,990, 2,320 and 3,500 g respectively. The last two fetuses were Dandy Walker syndrome and fetal death in utero. In the other cases, delivery took place within 24 hours.

There was no uterine hyperstimulation found in both groups. Concerning the time-interval from labour to delivery, when considered only cases of successful vaginal delivery which also had similar patients' characteristics, the mean time interval of application to labour and application to delivery of the intracervical gel were significantly shorter than in the vaginal suppository group. However, the mean time of rupture of membranes to delivery had no statistical difference between the two groups (Table 4).

Discussion

The use of locally applied prostaglandin E_2 (PGE_2) has become a common intervention in the management of the unriped cervix in term pregnancy. Many studies have shown that induction of labour with prostaglandin E_2 vaginal suppositories was proved to be simple, safe and highly acceptable to patients and obstetricians alike in all cases in which a simple amniotomy would not suffice.[2,6-8] Nevertheless, in 1983 Stewart et al[9] found that extraamniotic prostaglandin E_2 produced a more reliable cervical ripening effect and rapid onset of labour in the cases of unriped cervix than vaginal prostaglandin E_2 group.The former route is relatively invasive when compared to vaginal application. When considering intracervical prostaglandin E_2 gel which is less invasive than the extraamniotic route, some studies have revealed that it is a safe and effective method of cervical ripening in parturients with highly unfavourable cervix.[10,11]

In this study, we compared pregnancy outcome between the two groups using intracervical prostaglandin gel or vaginal suppositories. It was found that the intracervical gel group had more caesarean section rate, partly due to chorioamnionitis, which is different from the studies of Legarthe et al[12] and Hales et al[13] which revealed no significant difference in the routes of delivery and reported no infection both intrapartum or postpartum. This might be due to the prolonged duration of the time interval from induction to delivery in 3 cases of the gel group which took 3 days. Moreover, the indication for induction of labour in this group were fetal death in utero in one case and Dandy Walker syndrome in another.

Regarding the mean time of application of prostaglandins to delivery, in cases of successful vaginal delivery, this study revealed that the intracervical gel had significant shorter time-interval of application to labour and application to delivery than the vaginal suppository group eventhough the mean time of rupture of membranes to delivery was not different. The results in this study are reversed to the study of Legarth et al[12] which found that in the suppository group the delivery time was significantly shorter than the cervical gel group, eventhough the study of Hales et al,[13] found no statistically significant difference. This might be due to the difference in form and dose of PGE_2 used in each study and also the frequency of repeated administration. Besides this, the instillation procedure of the intracervical gel is another key factor due to difference in depth of catheter insertion and amount of the gel spillage from the endocervical canal. This is only the first limited experience in our institute and further large scale studies are needed to clarify the appropriateness in using this new route in our population.

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GYNAECOLOGY

Laparoscopic Removal of Ovarian Cysts Using Home-made Endopouch

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ABSTRACT

Objective To assess the use of home-made endopouch, made from surgical glove, to remove ovarian cyst by laparoscopic approach.

Design A retrospective analysis study.

Setting A teaching hospital serving a regional population in Southern Thailand.

Subjects Twenty-one women who had undergone laparoscopic removal of ovarian cysts between March 1993 and March 1994.

Main outcome measures Operative time, intra-operative and post-operative complications.

Results The mean operative time was 102 ± 16 min, all patients were discharged within 72 hours with minimal pain and there were no intra-operative and post-operative complications.

Conclusion This technique is cost-effective and permits little or no risk of intraperitoneal spillage without the need to extend the wound. We believe that its use is appropriate in developing country.

Key words : endopouch, ovarian cyst, laparoscopic surgery

Laparoscopic removal of ovarian cysts is a controversial issue. The advantages of laparoscopic surgery over laparotomy are reduced pain, morbidity, duration of hospital stay and the convalescent period.[1] However, the major problem of such an approach is how to remove the tumour without spillage of its contents. Laparoscopic removal of an apparently benign ovarian cyst of which pathologic analysis shows to be malignant or borderline may be problematic if the cyst ruptures and peritoneal seeding occurs.[2,3] Using only transabdominal or transvaginal ultrasonography cannot absolutely rule out malignant cysts.[4] The serum CA 125 level may be used to rule out malignant cysts but the accuracy is high in only postmenopausal patients[5,6] and is not always

available in Thailand.

We describe the use of a home-made endopouch, made from a surgical glove, which avoids the problem of cyst content spillage in laparoscopic removal of ovarian cysts.

Materials and Methods

A total of 21 cases of benign ovarian cyst which were removed laparoscopically at Songklanagarind Hospital from 1 March 1993 to 1 March 1994 were retrospectively evaluated. Indications for surgery included pelvic pain, persistent ovarian cyst after hormonal suppression, and ovarian cyst in the postmenopausal period. All had no ultrasonographic finding suggestive of malignancy. Measurement of serum CA 125 level was not available during the study period.

The surgery was performed under general anaesthesia with endotracheal intubation and the patient in the lithotomy position. After Foley catheter was retained, a uterine manipulator was inserted into the uterine cavity. Pneumoperitoneum was established with Verres needle and electronic CO_2 insufflator. Laparoscopy was performed using a 10-mm O-degree telescope inserted subumbilically and visualized on a screen monitor. 10-mm and 5-mm disposal cannulae were inserted laterally in the left and right iliac fossae respectively, avoiding the inferior epigastric vessels after identifying them by transillumination of the abdominal wall.

The pelvis and abdominal cavity were evaluated thoroughly. The ovaries were inspected carefully for evidence of malignancy and to assess the possibility of cystectomy. Oophorectomy or salpingo-oophorectomy was performed by sequential bipolar electrodissection and division of the infundibulopelvic ligament, uterine tube and utero-ovarian ligament, taking care not to rupture the cyst. The salpingo-oophorectomy was performed unless preservation of fertility was required as this accelerated the surgical procedure.

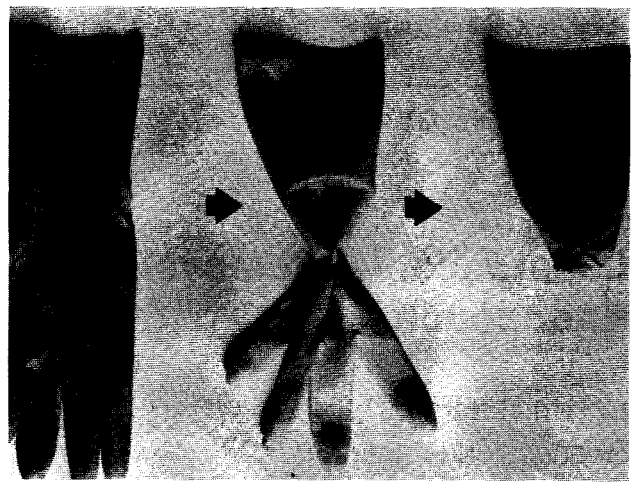

Fig. 1. Step for making home-made endopouch.

Endopouch preparation

The home-made endopouch was made from a #8 sterile surgical glove. The surgical glove were tied tightly with #1-0 black silk at the level just above all the finger projections and then the finger portion of the glove was excised to make a bag-like device. Leakage at the stump of the pouch was tested by closing the pouch-opening with air inside the pouch, then submerging the stump in sterile irrigation solution to see whether there is any leakage of air bubbles or not. The preparation procedure is illustrated in Fig.1.

Technique of insertion and using the home-made endopouch

The home-made endopouch was inserted through the 10-mm port into the abdomen. The pouch was placed in the anterior part of the cul-de-sac and the pouch-opening was opened by grasping forceps. In case where the excised ovarian cyst was smaller than the pouch-opening, it was grasped by one of the grasping forceps and

gradually slipped into the pouch. But if the cyst was large, it was first placed at the anterior part of the cul-de-sac. The pouch-opening was then opened with two grasping forceps, positioned it to the cyst and pushed the cyst into the pouch against the anterior part of the cul-de-sac. After that, each rim of the pouch-opening was grasped together with grasping forceps to close the pouch. Then, the 10-mm port in the left iliac fossa was removed and the wound was sealed with the surgeon's finger, waiting for appropriate pneumo-peritoneum, then inserting the sponge holding forceps in via the 10-mm wound to grasp the pouch opening near the grasping forceps, releasing the grasping forceps and pulling the pouch-opening through the 10-mm wound above the skin. The

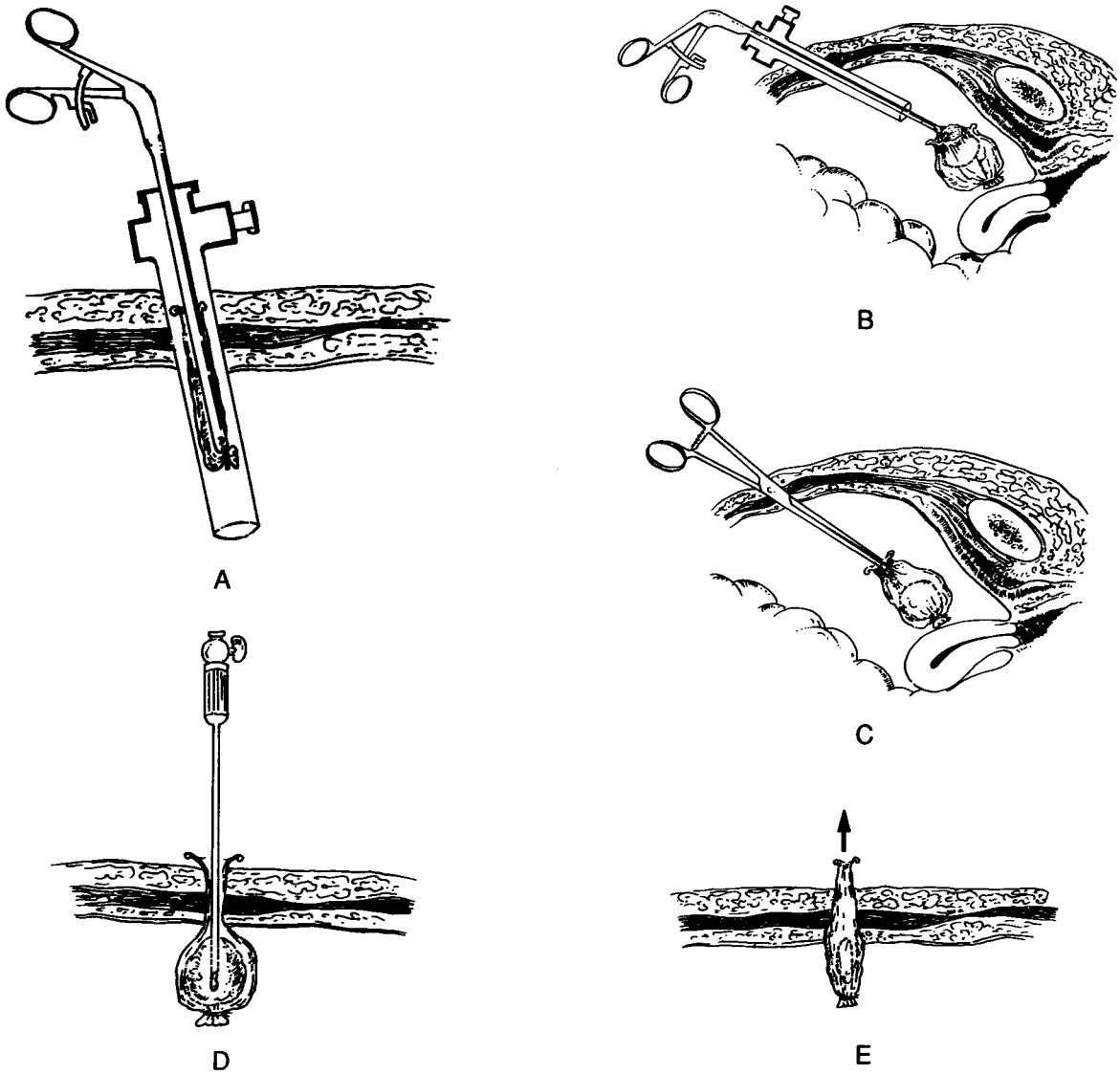

Fig. 2. Technique of insertion and using the home-made endopouch. A) The endopouch can be inserted through a 10-mm port. B) The excised cyst was slipped into the pouch. C) The pouch-opening was grasped with grasping forceps. D) The cyst contents were aspirated with Verres needle. E) The pouch and cyst wall were delivered through the abdominal wall.

pouch-opening was opened outside the abdominal cavity and the cyst contents were aspirated with Verres needle via the neck of the pouch. Visualization of the home-made endopouch during aspiration by laparoscope was very important to prevent pouch perforation by Verres needle. Finally, the pouch and its remaining contents were delivered through the abdominal wall once the cyst had been sufficiently reduced in size to pass through the incision. The technique of insertion and using the home-made endopouch is illustrated in Fig.2.

Results

The average age ± SD of the 21 patients was 34.8 ± 10.0 years (range 21-63 years). The mean diameter of the ovarian cysts was 6.4 ± 0.9 cm (range 5-8 cm). In all fifteen multipara patients, the tumour involved the whole ovary and normal ovarian tissue could not be separated from the cysts, therefore, salpingo-oophorectomy was performed. Oophorectomy was performed in only 6 patients. The pathological diagnosis of ovarian cysts were 8 dermoid cysts, 8 endometriomas, 3 serous cystadenomas, 1 mucinous cystadenomas, and 1 follicular cyst.

The mean operative time was 102 ± 16 min (range 80 - 120 min) with minimal blood loss in all cases. All operations were performed without complications. It was not necessary to extend the skin incision to deliver the tumour in any of the cases. All 21 patients required only oral analgesic after operation. Twenty patients were discharged within 48 hours, only 1 patient at 72 hours. The mean postoperative hospital stay was 30 ± 15 hours (range 6 - 72 hours). There was no postoperative peritonitis in all cases. The mean convalescent period was 5.6 ± 2.2 days (range 3 - 10 days). All of the patients were followed with pelvic examinations and ultrasonography at 12 months, and all were negative for pelvic mass.

Discussion

A variety of techniques can be employed successfully to manage benign ovarian cysts, depending on the patient's desire for future fertility, normal ovarian tissue left, and the surgeon's skill and confidence. The laparoscopic aspiration of unilocular, smooth-walled, translucent ovarian cysts, or dermoid cysts remains controversial.[1,7] The main concern is spillage of malignancy or sebaceous material. Careful preoperative evaluation of the patient, combining transabdominal or transvaginal ultrasonography of ovarian tumours with measurement of serum CA 125 level, may improve greatly the accuracy of diagnosis of ovarian malignancy. However, malignancy is not absolutely excluded. Removing ovarian cysts with a commercial endopouch has been reported.[1,2,8] The use of an endopouch completely avoids spillage of cyst or tumour contents into the abdominal cavity or through the tract of the incision. The technique described in this paper is cost-effective and appropriate for developing countries where serum CA 125 level is not available and cost of laparoscopic surgery is high.

The use of a home-made endopouch is limited in the size of the pouch for passing through the 10-mm port, the circumference of the opening of #8 surgical glove is around 22 cm. Therefore, this technique cannot be used when the smallest diameter of the tumour is significantly larger than 7 cm. Such a large tumour can be removed intact or with minimal intraperitoneal spillage by posterior colpotomy.[1]

Considering that malignancy is very uncommon in women under the age of 40,[9] we believe that expert laparoscopic management in selected cases, with careful technique to minimize the chance of cyst content spillage, is a safe and

beneficial alternative to laparotomy. With use of the home-made endopouch demonstrated in this study, the risk of cyst content spillage can be minimized without increasing the cost. In all our patients, the duration of operation was slightly longer than that reported for laparoscopic removal of ovarian cysts using a commercial endopouch.[8] This is the most important element of laparoscopic management of ovarian cyst in developing countries, although considerable expertise with laparoscopic manipulation is required.

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Royal Thai College of Obstetricians and Gynaecologists

MEETING AND COURSES IN 1996

24-26	APRIL	REFRESHER COURSE (to be held at the Phra Mongkutklao Hospital)
13-15	MAY	RESEARCH METHODOLOGY (to be held at the Siriraj Hospital)
13-15	OCTOBER	WORKSHOP "FETUS AS A PATIENT"
		AND
16-18	OCTOBER	XI th SCIENTIFIC AND ANNUAL RTCOG MEETING (to be held at the Dusit Resort Pattaya, Pattaya City)

Further details can be obtained from :
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GYNAECOLOGY

Interval Female Sterilization : Standard Minilap vs a New Modified Minilap Technique

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ABSTRACT

Objective To introduce a new modified minilap technique for female sterilization and to compare the operative time, difficulty and complication with those of the standard minilap method.

Design A single-centre prospective randomized study.

Setting Health Promotion Centre, Region 6, Khon Kaen, Thailand.

Subjects Thirty-one multiparous women requesting interval female sterilization, were randomly assigned (16 in the standard and 15 in the modified minilap technique).

Main outcome measures Operative time, difficulty, intra-operative and post-operative complications.

Results There was no statistical difference in the operative time. With the standard procedure, there were bleeding complications at the abdominal incision and at the cervix after removal of the Hulka clamp. There were no significant problems or complications with the modified technique.

Conclusion The modified minilap technique is a safe, rapid procedure which has the same effectiveness as that of the standard minilap with less complications. Further research is needed to address the applicability of the technique in community hospitals.

Key words : interval female sterilization, uterine elevator, appropriate technology

Thailand's National Family Planning Programme is a successful one among developing countries. This achievement can be measured in terms of the contraceptive prevalence rate which was 71% in 1987. Of all the methods employed to achieve this high prevalence rate, female steriliza-

tion accounts for the largest portion of 25%, mostly postpartum sterilization. At present, there are fewer women with three or more children and most have only one or two. Consequently decisions to have postpartum sterilization are made less frequently and most prefer to wait until their last child is old enough to ensure the survival. The National Family Planning Programme must, therefore, focus its attention at this moment on strengthening the provision of interval female sterilization.[1]

There has been no increase in the number of interval sterilizations performed because interval female sterilizations are mostly carried out in community hospitals[1] and contemporary sterilization techniques such as laparoscopy and standard minilap are not readily available in community hospitals which are mostly staffed by new graduates or general practitioners.

Laparoscopy needs expensive instruments and a team of well trained personnel. In standard minilap, the incision is made just above the symphysis pubis passing between rectus and pyramidalis muscles and may cause bleeding from injury to the inferior epigastric artery. The bladder may also be traumatized because of the low incision. Uterine elevator, such as Hulka's or Ramathibodi's, makes the standard minilap easier but may perforate the uterus or injure the bladder and rectum if the operators are careless or fail to insert the clamps along the axis of the uterine cavity.[2]

The operators must therefore have a certain amount of skill and experience to avoid complications and subsequent referral of cases to provincial or regional hospitals. Rumours and adverse publicity about the operators and community hospitals may result in lower acceptance of family planning by sterilization.

To avoid these complications, the minilap technique has been modified[3-5] as follows :-

1. The incision is made at a higher level 1/3-1/2 above the symphysis pubis along the midline joining it and the umbilicus, where the rectus muscle can be separated without passing through the pyramidalis muscles, in order to reduce bleeding and to avoid bladder injury.

2. The uterus is elevated by a pair of sponge holding forceps (a standard 24 cm long), holding three pieces of doubly folded 4" x 4" gauzes, inserted and positioned in the posterior vaginal fornix pushing in the forward and upward direction on to the abdominal wall.

Materials and Methods

A comparative study of the standard minilap and the modified minilap technique was conducted.

All patients were volunteers for sterilization at the Health Promotion Centre, Region 6, Khon Kaen, Thailand during the period between February and July 1989. They were allocated to either study groups by stratified block randomization according to age and parity. All operations were performed by the same obstetrician. Indications, contraindications and operative procedures of both techniques are summarized in Table 1, 2. Following recovery from anaesthesia, the patients were admitted overnight and discharged the day after with appointments for follow up visits at 1 and 6 weeks after surgery.

Results

There were 31 patients studied (16 in the standard technique group and 15 in the modified minilap technique group), all having similar general characteristics (Table 3). Total operative time from skin incision to skin closure was not significantly different between the two groups, but the time taken from skin incision to peritoneal entry was shorter in the modified minilap group than in the standard minilap group. It meant that entry into the

Table 1. Indications, contraindications and procedures for female sterilization

Indication	Age 20-45 years Living children 2 or more
Contraindication	During menstruation, or during luteal phase without contraception Chronic systemic disease Pelvic inflammatory disease Previous abdominal operation Body weight > 60 kg Blood pressure > 130/90 mmHg Haemoglobin < 10 g/dl Sugar in urine
Pre-operative procedure	Pre-medication with Morphine gr 1/6, Atropine gr 1/150 intramuscular Patients in lithotomy position, scrubbed and painted with antiseptic solution, draped Pelvic examination Ketamine HCl 1 mg/kg body weight intravenously as anaesthetic agent

Table 2. Operative procedure

Standard minilap	Modified minilap
- Bivalve speculum inserted to clean the cervix and vagina, Hulka clamp applied, then speculum taken off	- Inserting sponge holding forceps with doubly folded 3 pieces of 4" x 4" gauzes into the posterior vaginal fornix without the use of speculum
- Transverse incision 3 cm, at 2 finger-breadths above symphysis pubis, through skin and rectus sheath	- Uterine elevation, sponge forceps held by an assistant nurse
- Longitudinal split of muscles and peritoneum	- Longitudinal incision 3 cm, at uterus, through skin and rectus sheath
- Uterine elevation, Hulka clamp held by an assistant nurse	- Longitudinal split of muscles and peritoneum
- Tubal ligation (Pomeroy's)	- Tubal ligation (Pomeroy's)
- Abdominal wall closure	- Abdominal wall closure
- Hulka clamp taken off	- Sponge forceps taken off
- Post-operative speculum examination	- Post-operative speculum examination

peritoneal cavity was faster in the modified minilap group.

Several factors which affected the operative time were thickness of fat in the anterior abdominal wall, uterine position, adnexal adhesions and unsatisfactory anaesthesia (Table 4).

Uterine elevation by sponge forceps holding folded gauzes was easily achieved in all cases, in 12 cases the uterus were elevated 1/2 above the symphysis pubis and in 3 cases elevation to 1/3 above the symphysis pubis was possible.

Bleeding from rectus and pyramidalis muscles requiring clamping and ligation occurred in 3 out of the 16 cases in the standard minilap group but one occurred in the modified minilap group. Bleeding from the cervix at the site of Hulka clamp's teeth occurred in 10 out of 16 cases in the standard minilap group, as revealed during

Table 3. General characteristics of the study cases

Characteristics	Standard minilap (n = 16)	Modified minilap (n = 15)	P-value
Age (yr)			
X± SD	29.5 ± 4.2	29.7 ± 4.9	NS
Range	23 - 29	22 - 38	
Parity			
X±SD	2.2 ± 0.4	2.1 ± 0.4	NS
Range	2 - 3	2 - 3	
Body weight (kg)			
X±SD	50.5 ± 4.1	53.1 ± 5.5	NS
Range	43.0 - 57.5	44.5 - 60.0	
Height (cm)			
X±SD	153.6 ± 3.7	153.8 ± 5.2	NS
Range	146.5 - 159.0	147.5 - 164.0	

Table 4. Operative time and factors that might affect the operative procedure

	Standard minilap (n = 16)	Modified minilap (n = 15)	P-value
Total operative time (skin to skin) (min)			
X ± SD	12.3 ± 3.8	12.2 ± 4.2	NS
Range	7.0 - 22.0	7.0 - 22.0	
Operative time (skin to peritoneum) (min)			
X ± SD	3.0 ± 1.3	2.1 ± 1.0	< 0.05
Range	1.0 - 5.0	1.0 - 4.0	
Abdominal fat thickness (cm)			
X ± SD	1.6 ± 0.4	1.9 ± 0.7	NS
Range	1.0 - 2.4	1.0 - 3.2	
Position of uterus			
Anterior	3/26 = 18.8%	5/15 = 33.3%	NS
Posterior	13/16 = 81.2%	10/15 = 66.7%	
Adnexal adhesions and unsatisfactory anaesthesia	0	1/15 = 6.7%	-

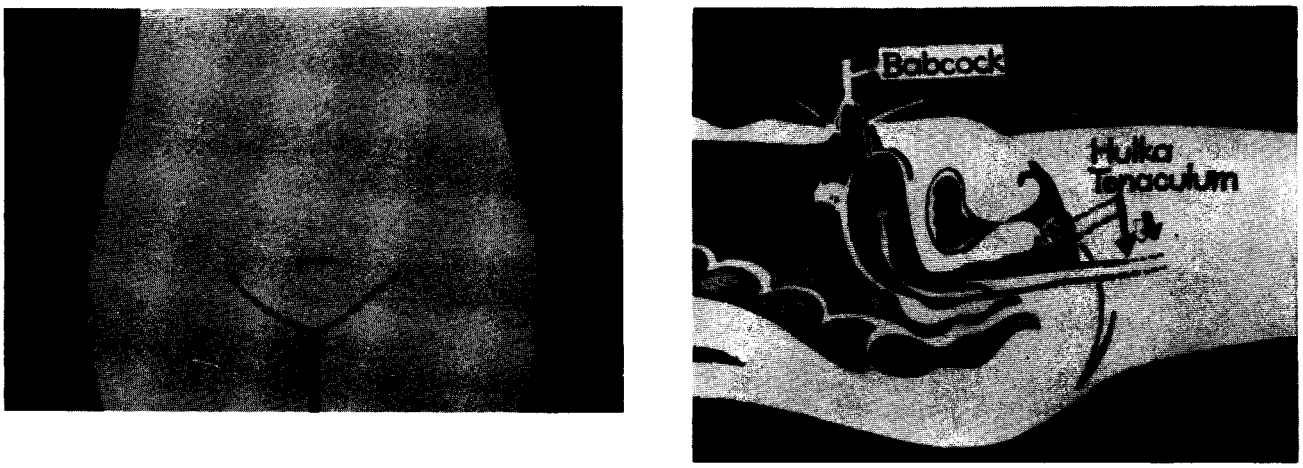

Fig. 1. The standard minilap technique.

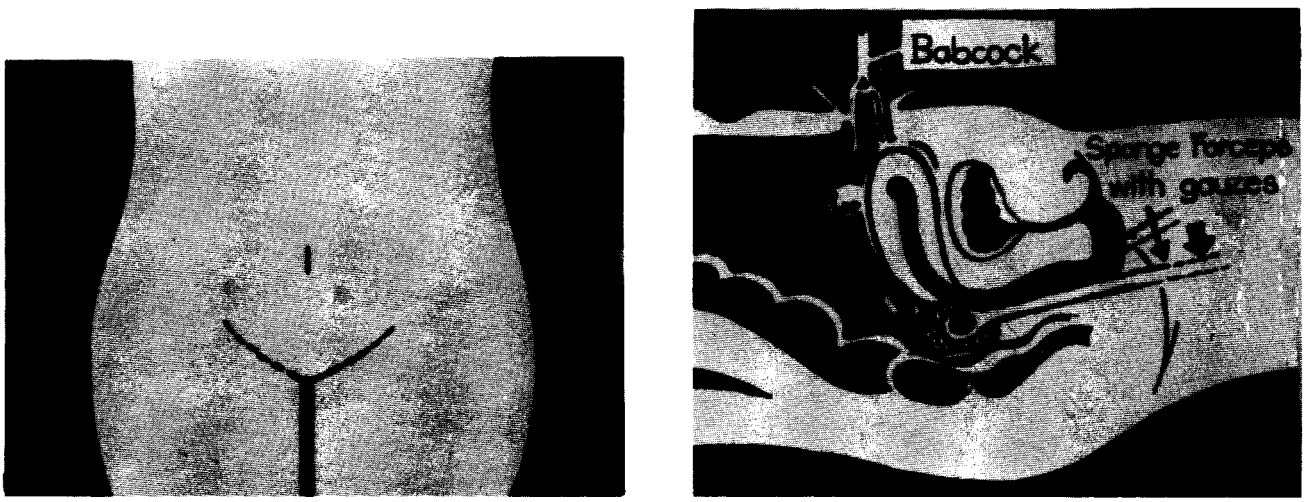

Fig. 2. The modified minilap technique.

post-operative speculum examination, which took time to stop after gauze packing.

There was no tissue trauma in the vagina or cervix in the modified minilap group. There were no complications such as uterine perforation, bladder or rectal injury in either group.

Post-operative follow up visits revealed no abnormalities or complications in either group and every patient made a satisfactory recovery.

Discussion

The effectiveness of this new modified minilap technique appears to be the same as that of the standard minilap but complications such as bleeding from muscles of the anterior abdominal wall, from uterine elevator, from clamping site on the cervix, trauma to the uterus, bladder or rectum are avoided. The modified minilap technique may be adopted in community hospitals where newly graduated doctors or general practitioners can perform interval female sterilization with confidence and safety.

This should lead to an increase in the rate of acceptance for interval female sterilization in accordance with the objective of Thailand's National Family Planning Programme.

The advantages of this technique compared to the standard technique are :

a. simple instrumentation

b. no speculum examination required

c. easy manipulation of the uterus irrespective of its position

d. avoidance of uterine perforation

e. avoidance of uterine cavity contamination

f. avoidance of bleeding from cervix at clamping site

Further multicentre trials are needed in different community hospitals to evaluate the applicability of the modified minilap technique for interval female sterilization.

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GYNAECOLOGY

Infertility Related Chlamydial and Gonococcal Infection in Infertile Couples in Southern Thailand

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ABSTRACT

Objective To study the association between prior chlamydial and gonococcal infection and infertility, and evaluate the serum levels of IgG and IgA antibodies to Chlamydia trachomatis and Neisseria gonorrhoeae (pili) in a variety of populations.

Design Cross-sectional study.

Setting Songklanagarind Hospital.

Subjects The control group was pregnant women and their husbands, the comparison groups were infertile women with and without tubal occlusion and their husbands, and female commercial sex workers.

Main outcome measures IgG and IgA antibodies to chlamydiae and gonococci pili.

Results IgG antibodies to chlamydiae and gonococci pili were significantly more prevalent ($P = 0.0073$ and $P = 0.0260$) in infertile women with tubal occlusion (65.0 and 56.6%) compared with the pregnant women (44.1 and 36.7%).

Conclusion The data suggest that women with tubal infertility frequently have serological evidence of prior infection with Chlamydia trachomatis and Neisseria gonorrhoeae. These results further support the aetiological role of infection with Chlamydia trachomatis and Neisseria gonorrhoeae in tubal infertility.

Key words : chlamydial antibody, gonococcal antibody, infertile women, tubal occlusion

Chlamydia trachomatis, like Neisseria gonorrhoeae, is capable of causing damage to fallopian tube epithelium.[1,2] It is well recognized that Chlamydia trachomatis is a major aetiological factor in female infertility. Nearly all investigators have found that more than half of the women with

documented tubal occlusion report no history of previous pelvic inflammatory disease (PID) despite serological evidence of past chlamydial infection.[3,4]

The hypothesis that sexually transmitted diseases (STD) are significantly associated with tubal infertility was supported by a large number of investigators from 14 countries who have examined the relationship between serological evidence of past chlamydial infection and tubal infertility. Despite wide variations in design, these studies have uniformly found a significant association between tubal occlusion and serological evidence of prior chlamydial infection. In addition, five of the six additional studies, which included both chlamydial and gonococcal antibodies, implied independent aetiological association between these infections and tubal infertility.[5-9]

In Thailand, the proportion of infertility directly attributes to C. trachomatis and N. gonorrhoeae is not known. Within the framework of an epidemiological study on prior chlamydial and gonococcal infection in tubal infertility, we compared antibody levels against these organisms in sera from infertile couples with and without tubal occlusion, pregnant couples, and female commercial sex workers (CSWs), as determined by enzyme-linked immunosorbent assay (ELISA).

Materials and Methods

Study population

Over a period of 24 months, between May 1990 and April 1992, we studied prospectively 60 infertile women with tubal occlusion and their partners, and 70 infertile women with non-tubal occlusion and their partners who attended the infertility clinic. The comparison group was 68 pregnant women with uncomplicated intrauterine pregnancies and their spouses who attended the antenatal care clinic. In addition, 118 female CSWs who attended the STD centre, region 12, Songkla were enrolled for the study.

Female infertility was defined as an inability to conceive after more than 1 year of regular intercourse with no contraceptive use. They were thoroughly investigated to demonstrate the cause of their infertility according to the WHO Standardized Investigation of the Infertile Couple.[10] All infertile women were divided into two groups : 1) those who had tubal occlusion demonstrated by laparoscopy and chromopertubation without other organic lesions ; endometriosis, fibroids, ovarian tumours, etc., and 2) those who had normal fallopian tubes or other organic lesions.

All subjects underwent a structured interview in which particular attention was paid to age, duration of marriage,age of first sexual intercourse, total number of sexual partners, and any history of genital tract infection.

Serology

A 10 ml sample of venous blood was obtained from the various groups. The serum was separated, frozen at -20° C, and transported to the laboratory for measurement of IgG and IgA antibodies to C. trachomatis and N. gonorrhoeae. The indirect ELISA used in this study is based on a standard WHO protocol derived from the method of Robertson et al, 1987.[11] Briefly,100 μL of purified elementary bodies of C. trachomatis serovar L1 or purified N. gonorrhoeae P9 alpha pili diluent were coated onto ELISA trays at a protein concentration of 1.0 g/well or 0.1 g/well, respectively. The plate was incubated overnight at 4° C for Chlamydia and 37° C for pili. After washing 5 times with a wash solution of 0.85% sodium chloride solution containing 0.05% Tween 20, the plate was tapped dry. A total of 100 μL of test serum diluted 1 : 100, in EIA (phosphate buffer

0.15 M, pH 7.2 containing 0.8% skim milk powder and 0.05% Tween 20), was added to each well of the antigen coated plate and was incubated 30° C for 2 hours. After washing 100 μL of anti-immunoglobulin was added. For the determination of IgG and IgA antibodies, the conjugates used were peroxidase conjugated, heavy chain specific, rabbit anti-human IgG or IgA (Dakopatts, Denmark) at a dilution of 1 : 4,000 and 1 : 2,000 in EIA diluent respectively. After being incubated at 37° C for 2 hours and washing, 100 μL of the substrate was added.

The substrate was 0.15 M tetramethyl benzidine in 0.1 M sodium acetate (pH 6.0) containing 0.003% H_2O_2. Colour was permitted to develop at room temperature (20-25° C) for 5 minutes for all antibodies except IgA antibody to Chlamydia, which required 30 minutes incubation. The reaction was stopped by the addition of 50 μL of 2 M H_2SO_4 and the optical density (OD) at 450 nm was determined with a Flow Multiskan spectrophotometer.

Each sample was assayed in duplicate. Controls included positive and negative control sera and controls for nonspecific absorption. To evaluate the results, mean background OD was substracted from the mean OD of each tested sample. This corrected OD was then used for the calculation of results.

Statistical analysis

Statistical analysis was performed using the SPSS. Univariate analysis was done for categorical variables using the X^2 - test.

Results

Demographic characteristics

Table 1 summarizes the characteristics of the four different study groups and their husbands. The mean ages of infertile women with tubal or nontubal occlusion were similar (31.0 and 33.1 years), but were significantly different to the control population (26.7 years) or to the CSWs (22.9 years). There was no statistically significant

Table 1. Characteristics of the women studied and their husbands

	No.	Mean age year (± SD)	Duration of marital/intercourse year (± SD)	Age of first intercourse year (± SD)	History of STD (%)
1) pregnant women	68	26.7 (± 5.2)	3.6 ± 3.4	23.0 (± 4.3)	6 (8.8)
their husbands	68	30.7 (± 5.8)	-	-	33 (48.5)
2) infertile with tubal occlusion	60	31.0 (± 4.4)*	5.6 ± 3.3	23.3 (± 4.9)	9 (15.0)
their husbands	60	33.1 (± 4.8)	-	-	33 (55.0)
3) infertile with non-tubal occlusion	70	33.1 (± 3.8)*	5.2 ± 3.6	27.2 (± 4.5)*	7 (10.0)
their husbands	70	35.7 (± 5.7)	-	-	32 (45.7)
4) female CSWs	118	22.9 (± 4.1)*	2.4 ± 1.7	16.7 (± 2.3)*	99 (83.8)*

* $P < 0.05$ compared with controls (pregnancy)

Table 2. Female and husband history of genital tract infection

Symptoms	Pregnancy N = 68	Tubal occlusion N = 60	Non-tubal occlusion N = 70	CSWs N = 118
Female history				
leukorrhoea	16 (23.5%)	16 (26.6%)	23 (32.8%)	48 (40.6%)*
PID	5 (7.4%)	11 (18.3%)	6 (8.5%)	58 (49.1%)*
abdominal pain with leukorrhoea	2 (2.9%)	5 (8.3%)	2 (2.8%)	19 (16.1%)*
Husband history				
dysuria	21 (30.8%)	17 (28.3%)	22 (31.4%)	
haematuria	4 (5.8%)	3 (5.0%)	6 (8.5%)	
urethral discharge	8 (11.7%)	3 (5.0%)	3 (4.2%)	

* $P < 0.05$ compared with controls (pregnancy)

Table 3. Percentage of seropositive for chlamydial (L1), gonococcal pili antibody in various groups

Groups	No. of cases	No. of positive chlamydial antibody (%)		No. of positive pili antibody (%)	
		IgG	IgA	IgG	IgA
1. pregnant women	68	30 (44.1)	27 (39.7)	25 (36.7)	15 (22.0)
husbands	68	37 (54.4)	29 (42.6)	28 (41.1)	19 (27.9)
2. tubal occlusion	60	39 (65.0)**	22 (36.6)	34 (56.6)*	19 (31.6)
husbands	60	35 (58.3)	15 (25.0)*	21 (35.0)	12 (20.0)
3. non-tubal occlusion	70	26 (37.1)	35 (50.0)	17 (24.2)	11 (15.7)
husbands	70	28 (40.0)	38 (54.2)	22 (31.4)	15 (21.4)
4. female CSWs	118	58 (49.1)	7 (5.9)**	96 (81.3)**	72 (61.0)**

* $P < 0.05$ compared with controls (pregnancy)

** $P < 0.01$ compared with controls (pregnancy)

difference in the mean ages of the male partners in any of these groups.

Of the 68 pregnant women, 21 (30.8%) had early sexual intercourse (less than 21 years old) when compared with 21/60 (35.0%) of the infertile women with tubal occlusion, 5/70 (7.1%) of the infertile women with non-tubal occlusion, and 110/118 (93.2%) of the female CSWs. Of the 68 pregnant women, 4 (5.8%) had multiple sexual partners when compared with 10/60 (16.6%) of the infertile women with tubal occlusion ($P < 0.05$), and 2/70 (2.8%) of the infertile women with non-

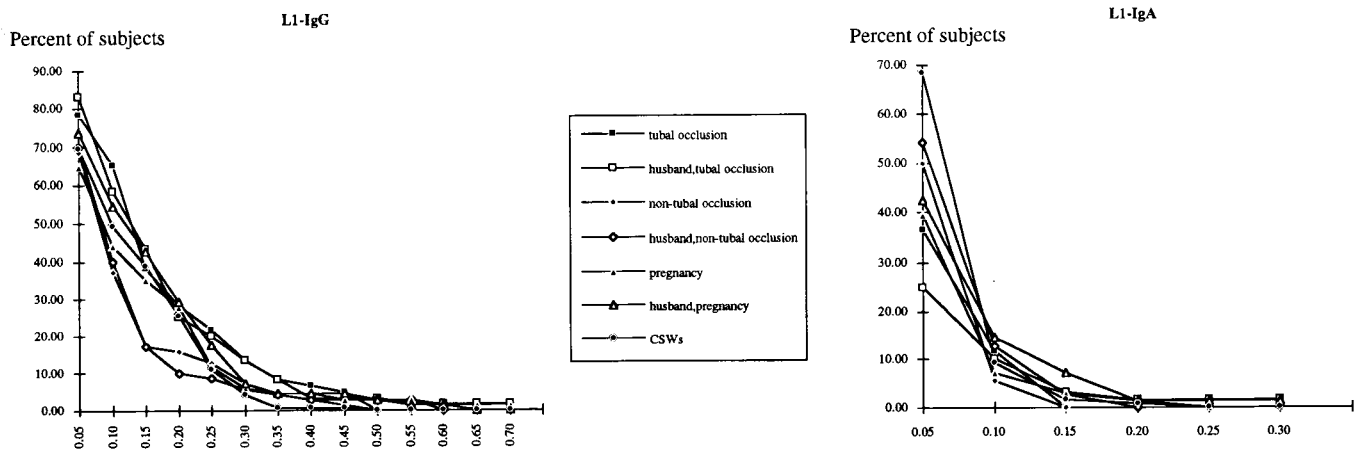

Fig. 1. Graphs showing the influence of ELISA cut off on the prevalence of chlamydial (L1) antibody. Cut-off selected were 0.10 (L1-IgG) and 0.05 (L1-LgA).
(*corrected OD = optical density of tested sample-optical density of controls)

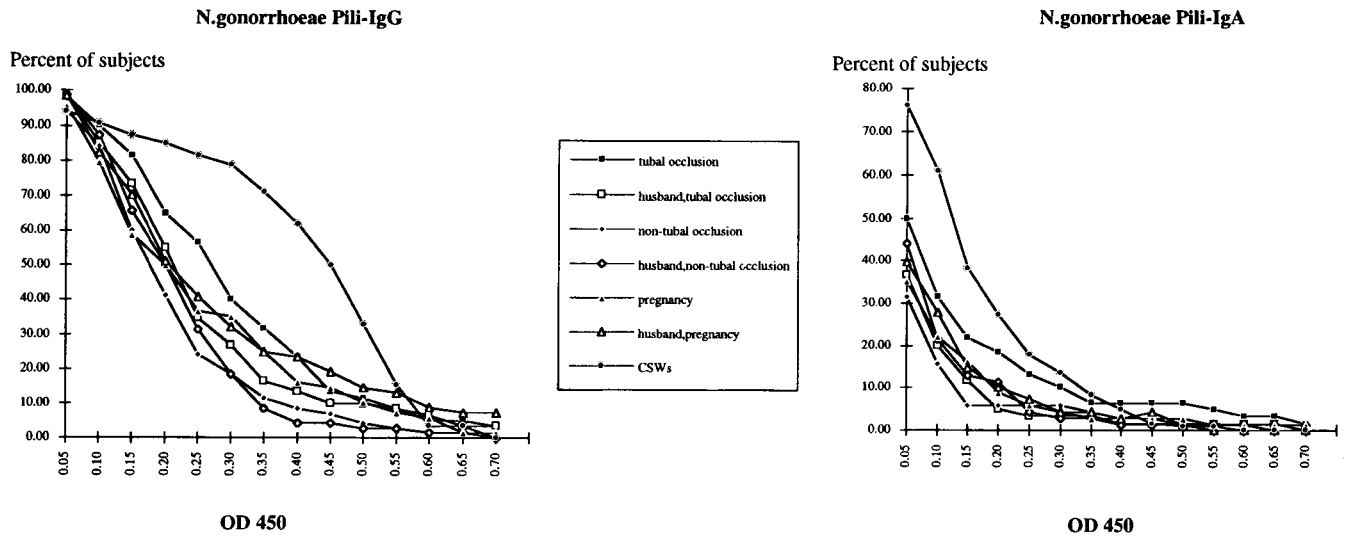

Fig. 2. Graphs showing the influence of ELISA cut off on the prevalence of gonococcal pili antibody. Cut-off selected were 0.25 (Pili-IgG) and 0.1 (Pili-IgA).
(*corrected OD = optical density of tested sample-optical density of controls)

tubal occlusion ($P > 0.05$). Nearly half of the female CSWs (46.6%) had 5 or more sexual partners per week.

Table 2 shows the history of genital tract infection in the four study groups and their husbands respectively. One or more episodes of verified or suspected PID, leukorrhoea, and abdominal pain with leukorrhoea in the females were reported ; including dysuria, haematuria, and urethral discharge in their husbands. A history of prior PID was found 11/60 (18.3%) in tubal occlusion group ($P > 0.05$), and 6/70 (8.5%) in the non-tubal occlusion group ($P > 0.05$), compared with 5/68 (7.4%) in the pregnant group.

Each tested sample was simultaneously assayed for IgG chlamydial / pili antibodies and IgA chlamydial / pili antibodies. The corrected OD determined in tested samples obtained from the variety of groups is shown in Figure 1 and Figure 2. The ELISA cut-off providing the best discrimination between the study groups was used to calculate the prevalence of chlamydial and gonococcal antibodies. The results at cut-off optical densities of 0.1/0.25 for IgG chlamydial/pili antibodies and 0.05/0.1 for IgA chlamydial/pili antibodies are shown in Table 3. By using the selected cut-off levels, positive results were demonstrated.

Discussion

Serology is essential for assessing the role of C. trachomatis and N.gonorrhoeae in infertility because it is unlikely that patients will still be demonstrated infective with the organism that caused the original salpingitis by the time their infertility becomes apparent. Serum IgG antibodies, being long-lived, reflect the cumulative history of past exposure of the patients to infection and are therefore useful in epidemiological studies. Numerous studies have confirmed the increased prevalence of antibody to C. trachomatis in the sera of infertile women with tubal obstruction compared to such women without tubal obstruction or to fertile women. Between 40 and 75% of infertile women with tubal obstruction have serological evidence of past chlamydial infection.[12-15]

In this study, IgG antibodies to chlamydiae and gonococcal pili were significantly more prevalent ($P < 0.01$ and $P < 0.05$) in infertile women with tubal occlusion (65.0 and 56.6%) compared with the pregnant women (44.1 and 36.7%). We concluded that both C. trachomatis and N. gonorrhoeae are important causes of tubal pathology in Thai women. Women with tubal infertility had a higher prevalence of IgG antibody to C. trachomatis than to N. gonorrhoeae. The presence of chlamydial antibodies was a more accurate predictor of tubal occlusion than other historical risk factors thought to cause permanent tubal damage.

In contrast, the measurement of IgA antibody to chlamydiae was significantly less prevalent ($P < 0.05$) in the husbands of infertile women with tubal occlusion (25.0%) compared with the husbands of pregnant women (42.6%). This implies that the husbands of pregnant women had antibody to current rather than to past chlamydial infection, due to the variants of the study.

IgA antibodies have reported to be of particular importance in the serological diagnosis of acute chlamydial infection.[16] The determination of current chlamydial infection will be effective in predicting "at risk" individuals among gynaecologic patients before they develop tubal dysfunction. The long courses of antibiotics needed to treat genital chlamydial infection should indicate the prospects of controlling infertility due to C. trachomatis.

IgA antibody to chlamydiae was highly significant less prevalent ($P < 0.0001$) in the female CSWs (5.9%). This suggests that the female CSWs in our region had low prevalence of antibody to current chlamydial infection. In contrast, IgG and IgA antibody gonococci were significantly more prevalent ($P < 0.0001$ and $P < 0.0001$) in the female CSWs (81.3 and 61.0%) compared with the pregnant women (36.7 and 22.0 %).

Determination of antibody to C. trachomatis and N. gonorrhoeae appears to be clinically useful in evaluating women with infertility. Our suggestion is that patients with the positive serological test most likely have tubal disease and are candidates for directly proceeding to laparoscopic examination,

therefore bypassing hysterosalpingography.

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REPRODUCTIVE SCIENCE

Ultrarapid Freezing (Vitrification) of Human Embryos : A Preliminary Report

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ABSTRACT

Objective To report a simple and economical ultrarapid freezing technique, the so-called vitrification technique, on cryopreservation of cleavage stage human embryos, and to report the first successful pregnancy resulted from this promising technique.

Design Retrospective study.

Setting University hospital.

Subjects Eleven infertile patients with 44 surplus embryos of 2- to 8-cell stage. All embryos were cryopreserved using the vitrification protocol which has been tested previously. The medium was consisted of 5.6 M dimethyl-sulphoxide (DMSO), 0.25 M sucrose and 20% fetal calf serum in phosphate-buffered saline. Two to three minute equilibration of the embryos with the cryoprotectant was carried out at 4 °C. After ultrarapid freezing and thawing, the embryos were morphologically evaluated and selectively transferred into a natural ovulatory cycle with the average number of 2.4 embryos per patient.

Main outcome measures Cryosurvival rates and pregnancy outcome.

Results Seventy percent (31/44) of the frozen-thawed embryos did not degenerate. More than eighty percent (26/31) of these survived embryos with at least 50% intact blastomeres were transferred to 11 patients. Two patients became pregnant, one biochemically and another gave birth to a healthy fullterm baby in January 1995.

Conclusion This is the first series showing that cryopreservation of human embryos by vitrification technique resulted in a successful pregnancy. This simple and easy-to-do ultrarapid freezing technique seems to be more practical than the conventional slow freezing protocol.

Key words : ultrarapid freezing, vitrification

Cryopreservation of human embryos has become a useful assisted reproductive technique. Not only does it increase cumulative pregnancy rates, but also substantially reduce the risk of ovarian hyperstimulation syndrome.[1] Conventionally, the slow cooling protocols require a high-cost programmable freezer and consume at least 2-3 hours.[2] Therefore, a number of rapid cooling protocols have been developed.[3,4] The rapid freezing protocols allow embryos to be equilibrated with specific cryoprotectants for only a few minutes and then plunged directly into liquid nitrogen from temperatures of O°C or above without an aid of any sophisticated machine.[5]

Rapid cooling methods usually require the presence of higher concentrations of cryoprotectants than the slow cooling procedures and have been used successfully to preserve mammalian embryos ranging from the pronuclear to blastocyst stages of development.[6] Among these rapid or ultrarapid cooling methods, vitrification technique has been extensively studied only just recently.[4,7] Basically, vitrification is defined as a physical process by which a highly concentrated solution of cryoprotectants solidifies during cooling without the formation of ice crystals. The solid, called "glass", retains the normal molecular and ionic distribution of the liquid state and can be considered to be an extremely viscous supercooled liquid. Vitrification has certain advantages over freezing because it avoids the damage caused by intracellular ice formation and the osmotic effects caused by extracellular ice formation. The theories behind vitrification as a method for cryopreservation have been described by several workers.[8-11]

Vitrification has been used for mammalian embryos for nearly one decade, but the results were initially very variable, due mainly to cryoprotectant toxicity. Not until the vitrification protocols had been modified, i.e. shorter exposure times and at lower temperatures of equilibration, that constant and successful results were obtained.[7] Recently, a number of very successful vitrification of mouse,[12,13] rabbit,[14,15] sheep[16] and bovine[17] embryos have also been reported. For vitrification of human embryos, a feasibility test has been, for the first time, carried out by our group and very promising results have just been reported.[18] This study is, therefore, a continuing phase of that preliminary report. As a result, a successful pregnancy completed in a healthy fullterm female baby, born in January 1995, was obtained from this innovative assisted reproductive technology.

Materials and Methods

Human embryos

This study was carried out at our centre during the period of 18 months, from January 1993 to June 1994. The protocol was approved by the Departmental Ethics Committee and every patient gave informed consent. From eleven patients with tubal infertility who were scheduled for in vitro fertilization, 44 surplus human embryos of 2 - to 8-cell stage were cryopreserved using the vitrification technique described hereafter. These embryos were in excess at the moment of intrauterine transfer following our routine in vitro fertilization programme.

Cooling procedure

The cooling protocol was nearly the same as that reported previously. Briefly, the cryoprotective solution contained 5.6 M dimethylsulphoxide (DMSO) and 0.25 M sucrose in Dulbecco's phosphate buffered saline (PBS) with 20% fetal calf serum (FCS). The surplus embryos were transferred from growth medium (AO-medium, unpublished data) into the vitrification medium described above (Fig.1), at 4°C, and drawn into a

0.25 ml clear plastic straw. After 2-3 minutes of equilibration, the straw was heat-sealed and quickly plunged into liquid nitrogen.

Warming procedure

The warming protocol was exactly the same as that reported previously. Briefly, the straws were rapidly removed from liquid nitrogen after a storage period of 1-14 months and warmed very rapidly in a waterbath at 37°C for 3-5 seconds. The embryos were then gently transferred into PBS/FCS solution containing 0.5 M sucrose at room temperature for 5 minutes. Thereafter, the embryos were transferred into 0.25 M sucrose in PBS/FCS solution at room temperature for another 5 minutes, before being washed in sucrose-free PBS/FCS solution for the last 5 minutes. After the final wash, the embryos were incubated in growth medium, at 37°C, in an atmosphere of 5% CO_2 in air.

Morphological evaluation

Two to four hours following the post-thaw

Fig. 1. A 4-cell human embryo showing shrunken cytoplasm following equilibration with vitrification medium at 4°C for 2-3 min (200x).

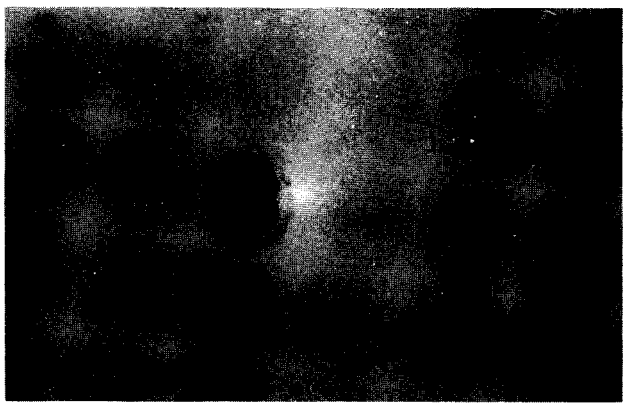

Fig. 3. A frozen-thawed 4-cell embryo with 75%-intact blastomeres. One degenerated blastomere (Arrow-head) is shown while the remainders are still intact (200x).

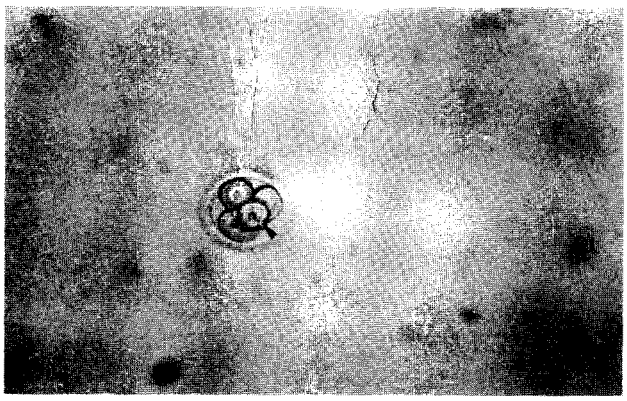

Fig. 2. A frozen-thawed 4-cell embryo with 100%-intact blastomeres. All normal-looking blastomeres are shown. A slightly out-of-focus blastomere is noted (200x).

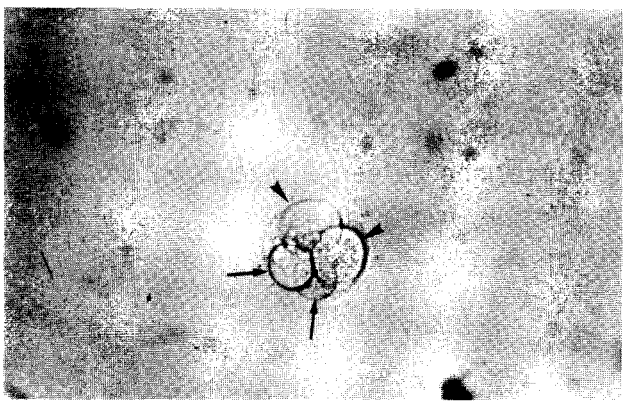

Fig. 4. A frozen-thawed 4-cell embryo with 50%-intact blastomeres. Two degenerative blastomeres showing swelling cytoplasm (Arrow-heads) are clearly seen close to the other two intact blastomeres (Arrows) 200x.

Table 1. Cryosurvival of human embryos vitrified in 5.6 M DMSO and 0.25 M sucrose

	No. of frozen-thawed embryos	%
Degenerated	13 / 44	30
Cryosurvived	31 / 44	70
100% intact blastomeres (Fig. 2)	21 / 31	68
75% intact blastomeres (Fig. 3)	3 / 31	10
50% intact blastomeres (Fig. 4)	2 / 31	6
25% intact blastomeres	5 / 31	16

Table 2. Pregnancy outcome after vitrification of human embryos

No. of patients transfer	11
Total no. of transferred embryos	26
Mean transferred embryos per patient	2.4
No. of achieved pregnancies	2
Pregnancy rate (%)	18
Biochemical pregnancy	1
Delivery (live birth)	1

incubation, morphological parameters of these vitrified embryos were assessed. Although most of the criteria used to assess the appearance of each embryo are subjective in nature, there is substantial evidence that only the normal morphological embryos with the majority of blastomeres intact and with identical blastomere size will implant. Thus, only the "well-looking" frozen-thawed embryos were selected for intrauterine transfer. All of the embryo transfers were performed in the natural cycles, 72 hours after the spontaneous luteinizing hormone surge. Pregnancy was then determined by measuring the serum level of beta-hCG on the 12th day following the transfer.

Results

The survival of human embryos after vitrification are shown in Table 1. Of 44 frozen-thawed embryos, thirty-one (70%) survived, with at least one-fourth of the blastomeres remaining intact. More than eighty percent (26/31) of these survivors, showing at least 50% intact blastomeres, were transferred to 11 patients (mean number of transferred embryos per patient : 2.4, Table 2). Two patients became pregnant (pregnancy rate per transfer : 18%), one unfortunately ended up with biochemical pregnancy while the remainder achieved her 39 weeks' pregnancy and gave delivery to a female baby of 3300 g birthweight in January 1995.

Discussion

The present study confirms our previous feasibility test that high survival rates can be achieved with the vitrification of early human embryos.[18] Furthermore, in the present study we have shown that a high percentage (70%) of the vitrified embryos survived, and a number of these embryos could develop into normal healthy babies.

Only recently have ultrarapid freezing methods been studied and used to cryopreserve mammalian embryos with successful results.[19,20] Initially, the concentrations of the cryoprotective

solutions were low, varying from 2.5 M,[21] 3.0 M,[22] 3.5 M[23] up to 4.5 M[6] ; all of which are not high enough for vitrification to occur. This may explain why the results of ultrarapid freezing in the past were not so satisfactory, since rapid ice-formation, either intracellularly or extracellularly, has enormous detrimental effects, both mechanically and biochemically, to the frozen-thawed cells.[24] In addition, it has also been reported that, chromosomal abnormalities of the rapidly frozen-thawed embryos may be associated with the concentration of cryoprotectant of less than 4.5 M DMSO.[25] Hence, the concentration of the cryo-protectant used in this study was 5.6 M DMSO which was previously tested to be true vitrification medium (data not shown) and also gave satisfactory results in our preliminary report.[18]

In addition to DMSO, 0.25 M sucrose which is an extracellular cryoprotectant was also added to our vitrification media in order to shrink the cell osmotically, thus preventing intracellular ice formation.[26] According to equilibration time, it has been recently demonstrated that a 3- to 5-minute period is required for the 2-4 cell embryos, and 1-2 minutes for those one- and eight-cell stages.[27] Therefore, we have chosen the 2-to 3-minute equilibration time for our vitrification protocol. Since cryoprotectant toxicity definitely occurs at higher temperature and it is required that higher concentration be needed during vitrification, equilibration of the embryos at low temperatures (0°C-4°C) is recommended to avoid such toxicity.[10] This is also the case in our study.

Compared to those of conventional slow freezing methods,[28-30] no difference in the successful results of the ultrarapid freezing of human embryos have been shown in a few recent reports.[31,32] While we recognize the limitations of the present study in comparing the viability of frozen embryos with non-frozen embryos or the viability obtained by other methods, we consider that our vitrification technique is likely to be at least as effective as any other method of cryopreservation and considerably simpler and less expensive. We believe that this ultrarapid freezing technique can be further improved and represents a very interesting alternative for some centres with limited resources in Thailand.

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REPRODUCTIVE SCIENCE

The Significance of Basal Follicular Stimulating Hormone and Luteinizing Hormone of Previous Cycle in Prediction of the Outcome of In Vitro Fertilization

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ABSTRACT

Objective To determine the effect of basal follicular stimulating hormone level on day 3 of previous cycle on the ovarian response and clinical pregnancy rate in the treament of infertility by IVF-ET.

Design A prospective descriptive study.

Setting A tertiary infertility service in an academic university hospital.

Subjects Thirty-eight infertile patients without male factor treated with IVF-ET under long protocol using GnRH agonist. Blood samples were taken on day 3 of previous cycle prior to ovarian stimulation.

Main outcome measures Numbers of ampoule of FSH and hMG, peak serum E_2 , numbers of oocytes collected, and clinical pregnancy rate.

Results Numbers of ampoule of FSH and hMG used were significantly lower in high FSH group (> 8 IU/L). Clinical pregnancy rate in the low, medium, and high FSH group were 20%, 11.8%, and 0% respectively.

Conclusion The resullts suggested that a high basal serum FSH level is associated with a higher cancellation rate, a lower peak serum E_2 level, lower number of oocytes retrieved and a lower clinical pregnancy rate.

Key words : In Vitro Fertilization, FSH, LH, outcome prediction

Multiple variables affect the likelihood of conception from assisted reproduction. Several investigators have demonstrated the role of hormonal regulation during ovulation, fertilization, and implantation period.[1] Since the advent of in vitro fertilization (IVF), improved pregnancy rates

per embryo transfer have remained a constant but elusive goal. Despite the rapid development in assisted reproduction, the pregnancy rate has remained at about 15-20% per treatment cycle.[2] Much research has been done recently to look for prognostic indicators in vitro fertilization. Various authors have shown that a high serum follicular stimulating hormone (FSH) level after clomiphene citrate correlated to cancellation of the cycle[3] due to a poor ovarian response[4,5] and is predictive of pregnancy outcome.[6] We used gonadotropin stimulation protocol which consisted of both FSH and LH for ovarian stimulation. Toner et al[7] and Khalifa et al[8] also reported on the predictive value of basal FSH levels but patients with different stimulation protocols were included. Hughes et al[9] have shown that for those patients with a poor response to stimulation with clomiphene citrate and gonadotropins, they appeared to benefit from the use of gonadotropin releasing hormone agonist (GnRH-a) treatment. Hence, whether basal serum gonadotropin level is predictive of IVF outcome with this regimen of ovarian stimulation needs to be clarified. The purpose of this report is to assess whether basal FSH and luteinizing hormone (LH) are predictive of the ovarian response and outcome during treatment with IVF when GnRH-a are also used in the stimulation protocols.

Materials and Methods

From October 1994 to April 1995, infertile patients without male factor treated with IVF at the Department of Obstetrics and Gynaecology, Chulalongkorn University Hospital, were recruited for the study. Blood was taken for serum FSH, LH, and estradiol (E_2) on day 3 of the previous cycle prior to ovarian stimulation. Treatment was started in the next cycle when there was no abnormality detected by ultrasound and the baseline E_2 level was below 50 pg/ml. Intranasal Buserelin (Suprefact; Hoechst AG, Germany), 600 mg daily, was started on day 21. On day 2 of the next cycle, 150 IU of FSH (Metrodin ; Sereno, England) and 150 IU of human menopausal gonadotrophin (hMG; Humegon, Organon, The Netherlands) were given for three days, followed by 150 IU of hMG daily. (Fig.1)

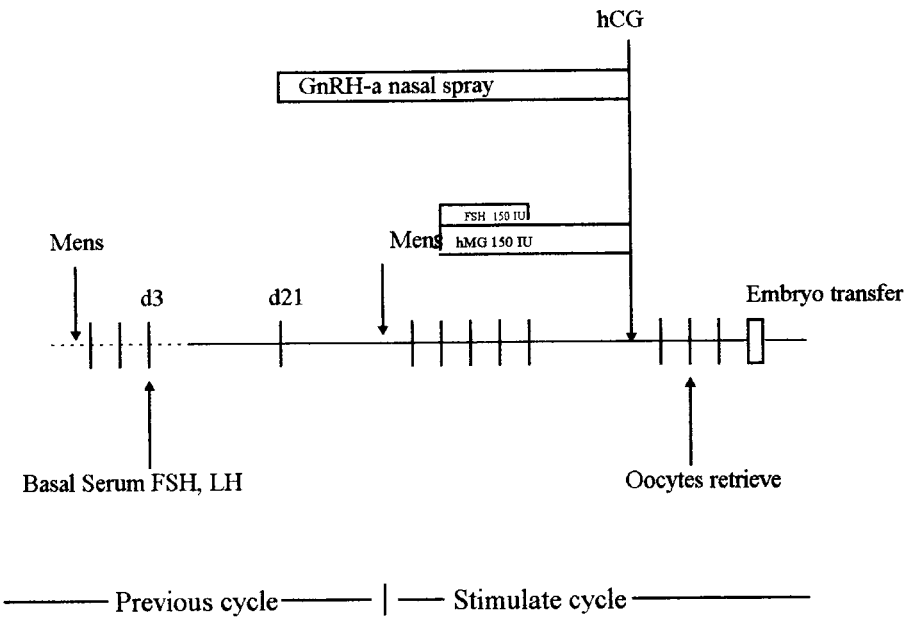

Fig. 1. Diagram of ovarian stimulation protocol.

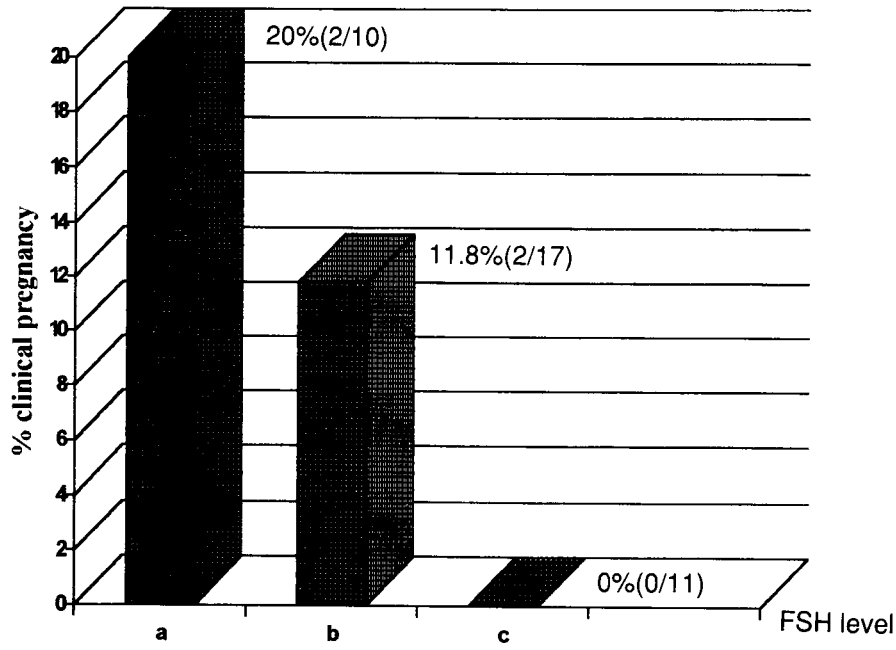

Fig. 2. Clinical pregnancy in patients of each group, (a) Low FSH (< 4 IU/L), (b) Medium FSH (4-8 IU/L), (c) High FSH (> 8 IU/L).

Table 1. The comparison of age and the parameters of ovarian response in patients with different day 3 serum FSH levels

	Basal day 3 serum FSH		
	Low (< 4 U/L)	**Medium (4-8 IU/L)**	**High (> 8 IU/L)**
Age (year)	33.2 ± 4.8	35.3 ± 5.4	36.2 ± 5.1
No. of ampoule FSH, hMG	19.1 ± 4.3	22.6 ± 9.4	28.6 ± 10.2*
Peak serum E_2 (pg/ml)	3,104 ± 1,012	2,480 ± 1,403	1,981 ± 1,214*
No. of oocytes retrieved	16.2 ± 5.4	12.8 ± 6.2	8.4 ± 4.2*
% of fertilization	61.4 ± 30.8	61.2 ± 34.6	62.1 ± 31.4
Cancel cycle	0	0	1
	N = 10	N = 17	N = 11

*Statistically significant, $P < 0.05$

The ovarian response was monitored with daily serum E_2 level and ultrasonogram starting on day 4. After day 8, serum LH, and E_2 were measured daily and pelvic ultrasonogram was also performed. Human chorionic gonadotrophin (hCG ; Pregnyl, Organon, The Netherlands) 10,000 IU, was given intramuscularly in the evening when (a) the leading follicle was > 18 mm in diameter, (b) the serum E_2 was > 600 pg/ml, and (c) there were at least three follicles.

Transvaginal ultrasound - guided oocyte retrieval was performed 34-36 hr after hCG injection. The oocytes were incubated for a period of 4 to 6 hr before insemination. Up to four cleaving embryos were transferred about 48 hr after insemination.

Serum FSH, LH and E_2 levels were measured by fluorescent immunoassay.

Analysis of data and statistics were performed using SPSS/PC plus software. The results were expressed as mean ± standard deviation. The differences in the means between the different groups were compared by Student t-test.

Results

Thirty-eight cycles of IVF in patients excluding male factor were evaluated.

All of our patients' serum FSH levels were below menopausal range. The patients were subdivided into three groups based on the day 3 serum FSH levels (a) low, < 4 IU/L (b) medium, 4-8 IU/L (c) high, > 8 IU/L and their ovarian response and outcome are shown in Table I. There was statistically significant differences in the amount of FSH/ hMG required, peak serum E_2 level, number of follicles aspirated, number of oocytes obtained, number of embryos replaced, percentage of cycles canceled, and number of clinical pregnancies per cycle initiated between the low and high - basal serum FSH groups

However, when based on cycle day 3 serum LH levels, the patients were again divided into three groups, the same as FSH. There was no statistically significant difference in the number of ampoules of FSH/hMG used, the peak serum E_2 level, the number of oocytes obtained, or clinical pregnancies among the three groups.

Discussion

The results in this study showed that in patients stimulated with a combination of GnRH agonists and FSH and hMG in an IVF programme, a high basal serum FSH level is associated with a higher cancellation rate, a lower peak serum E_2 level, lower number of oocytes retrieved and embryos replaced, and a lower clinical pregnancy rate. These results agreed with those previously reported in patients on various types of treatment regimens for ovarian stimulation.[5,6] Unlike the results of Hughes et al,[9] our results showed that the addition of GnRH - a to the stimulation regimen could not correct the poor ovarian response. All these results point to the fact that the level of day 3 serum FSH is an indicator of the functional potential of the ovary. The basic control of LH and FSH is by a negative feedback system involving the hypothalamus, anterior pituitary, and ovary. Each component can adjust its activity in proportion to the output of the other components in a dose - related manner. Though none of the patients studied here had FSH level in the menopausal range, a relatively higher level might indicate a lower ovarian functional reserve. This may explain the observation of a poorer ovarian response, which would definitely affect the peak serum E_2 levels, number of oocytes retrieved, and number of embryos replaced. Gindoff and Jewelewicz[10] stated that serum FSH is the most sensitive marker to delineate perimenopausal state and thus it would not be surprising that basal FSH levels could also predict the pregnancy rate.

There was no significant relationship between the ovarian response and the day 3 serum LH. It was shown previously, in patients undergoing IVF treatment given clomiphene citrate and hMG for ovarian stimulation, that the fertilization rate and implantation rate were significantly reduced in those with high basal serum LH.[11] Urinary LH cycles was higher than those in conception cycles.[12] These observations are all

consistent with our findings. However, the predictive value of day 3 serum FSH was better than that of serum LH.

In conclusion, the day 3 serum FSH level is one prognostic indicator in IVF treatment and is especially useful in predicting the ovarian response. It may help the clinician to adjust the ovarian stimulation regimen on an individual basis and also provide further information for counselling of couples who wish to be enrolled in the IVF programme. Although a high day 3 serum LH may be associated with a poor outcome, it is not useful in predicting ovarian response and pregnancy.

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ICSI

WORKSHOP IN ASSISTED FERTILIZATION BY INTRACYTOPLASMIC SPERM INJECTION

April 30-May 3, 1996

Organized by :

Division of Infertility
Department of Obstetrics & Gynaecology
Siriraj Hospital, Mahidol University

Co-organizer :

The Queen Elizabeth Hospital
Department of Obstetrics & Gynaecology
The University of Adelaide, Australia

In collaboration with :

The Royal Thai College of
Obstetricians and Gynaecologists

Organizing Committee
Chairman
Assoc. Prof. Somboon Kunathikom

Registration deadline : April 5, 1996

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CASE REPORT

Prenatal Diagnosis of the Arnold-Chiari Malformation with Spina Bifida : A Case Report

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ABSTRACT

A pregnant woman prenatally diagnosed with the Arnold-Chiari malformation with spina bifida at 18 weeks of gestation was reported. Sonographic evaluation was performed for routine screening. The sonographic findings demonstrated ventricular dilatation, a lemon-shaped cranium (lemon sign), obliteration of the cisterna magna (banana sign) and a dysraphic defect in the lower lumbar spine. The pregnancy was terminated. Postnatal finding confirmed the diagnosis.

Key words : Arnold-Chiari malformation with spina bifida, prenatal diagnosis

Spina bifida refers to a defect in the spine resulting from failure of the two halves of the vertebral arch to fuse. These lesions usually occur in the lumbosacral and cervical regions. Lemon sign, banana sign, and ventricular dilatation were cranial and intracranial findings which attribute to the Arnold-Chiari malformation and have proven to be extremely useful for predicting the presence of spina bifida. Spina bifida is a major type of neural tube defect; the prevalence has been noted, with the highest rates reported in the United Kingdom and the lowest rate in Japan.[1,2] The vast majority of neural tube defects are sporadic and are believed to be multifactorial in origin.[2,3]

Case report

A pregnant woman was seen at the antenatal clinic, Nakornpathom Hospital and was prenatally diagnosed with the Arnold-Chiari malformation with spina bifida at 18 weeks' gestation. Medical and obstetric history were unremarkable and there was no history of familial disease. The demographic data, sonographic findings and postnatal appearance are summarized as follows :

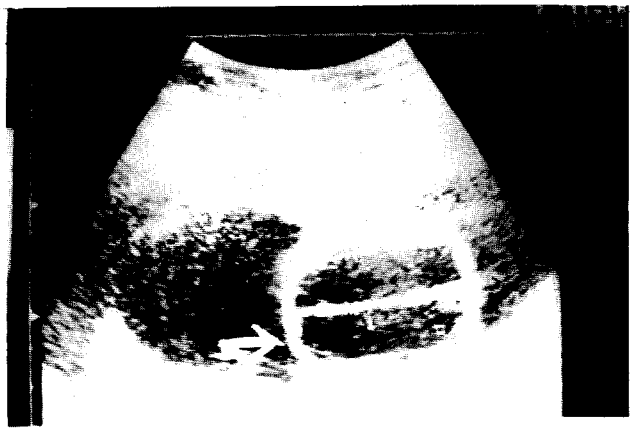

Fig. 1. Ventricular dilatation and lemon sign.

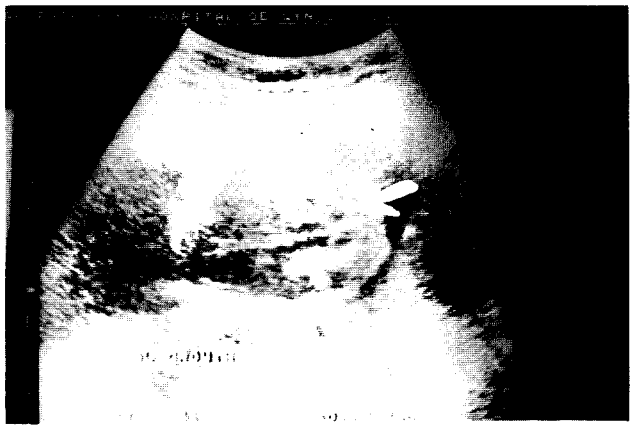

Fig. 2. Banana sign.

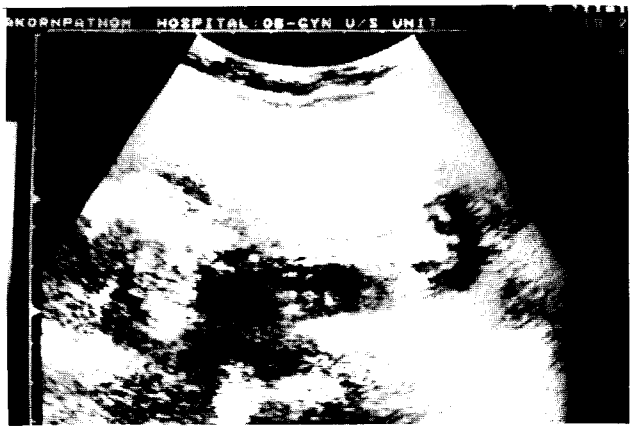

Fig. 3. Dysraphic defect of lumbar spine.

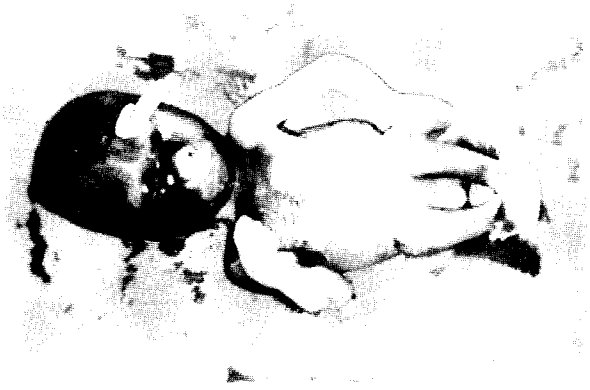

Fig. 4. Photograph with lemon-shaped cranium.

Fig. 5. Photograph with spina bifida.

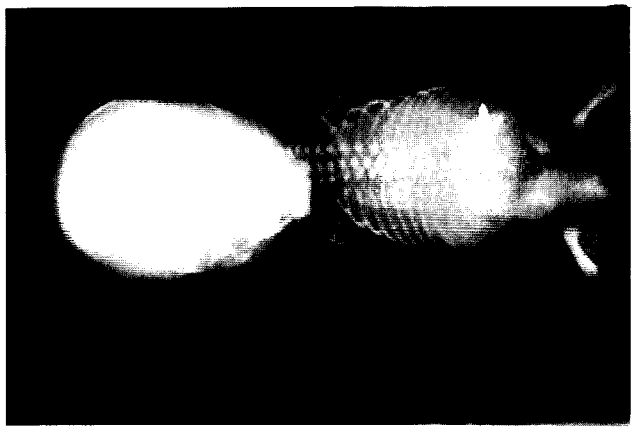

Fig. 6. Radiograph with spinal defect.

Table 1. Mechanism of sonographic findings of the Arnold-Chiari malfomation

Sonographic findings	mechanism/pathophysiology
ventricular dilatation	- obstruction to subarachnoid pathway
lemon sign	- low intracerebral pressure and relatively malleable frontal calvarium
banana sign	- part of the cerebellum displaced into the cervical canal related to tethering of spine

Age 33 Years
Parity 3-0-0-2
Weeks of gestation.....18
Maternal complication.....none
Indication for sonographic examination.....screening
Sonographic finding
- Single viable fetus with breech presentation
- Fetal head : BPD = 41.5 mm
  ventricular diameter 15.5 mm
  lemon- shaped cranium
  banana-shaped cerebellum
- Femur length = 25.1 mm
- Amniotic fluid volume : normal
- Placenta : posterior, upper (grade I)
- Dysraphic defect in the lower lumbar spine

Mode of termination.....prostaglandin with oxytocin
Fetal outcome.....male, stillbirth (300 g)
lemon-shaped cranium
lumbar spinal defect

Based on the sonographic features, the diagnosis of Arnold-Chiari malformation with spina bifida was made and termination of pregnancy was carried out after counseling. Postnatal appearance and radiographs were consistent with prenatal sonographic findings. (Fig. 1-6)

Discussion

In this case, based on sonographic findings (ventricular dilatation, lemon-shaped cranium, banana-shaped cerebellum and dysraphic defect in the lumbar spine), the diagnosis of Arnold-Chiari malformation with spina bifida can definitely be made. The mechanism or pathophysiology of sonographic findings are summarized in Table 1.[4-7]

Of these sonographic findings, the banana sign is highly predictive of spina bifida and is present regardless of the fetus imaged before or after 24 weeks' gestation.[6] In contrast, the lemon sign may disappear after a pregnancy interval of 24 weeks and invariably disappear by 34 weeks.[4]

The case presented was picked up during a routine second trimester ultrasound screening. When detected at such an early stage of pregnancy the condition is invariably incompatible with life. The patient and her partner should be counselled with termination of pregnancy in mind.

Although routine ultrasound screening is accepted in Europe and North America much study is required to evaluate the cost-benefit if it were to be introduced in developing countries such as in Thailand.

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CASE REPORT

Dilatation and Curettage of Interstitial Pregnancy under Abdominal Ultrasonography and Laparoscopy

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ABSTRACT

Conservative management of unruptured ectopic pregnancies have been well described, especially that of ampullary ectopic form. Traditional management of unruptured interstitial pregnancy was salpingectomy with or without cornual resection, or by hysterectomy. In this paper we present a case report on conservative management by dilatation and curettage followed by methotrexate (MTX) intramuscular injection.

Key words : interstitial pregnancy, conservative management, ectopic pregnancy

Interstitial or cornual pregnancy is a rare occurrence, the incidence being approximately 2 to 4% of ectopic pregnancies.[1-3] Because of the severe and massive haemorrhage after rupture, the traditional management is salpingectomy and cornual resection.[3,4] There are reports of the detection of unruptured interstitial pregnancies by ultrasonography and successful management by conservative methods.[5,6] In this paper, we present an approach for conservative management of an unruptured interstitial pregnancy and review the literature concerning conservative management of interstitial ectopic pregnancies.

Case Report

An 18-year-old woman, attended the outpatient department in November 1994 complaining of bleeding per vagina and dull aching pelvic pain for 14 days. The last menstrual period was 8 weeks previously and there was no history of contraception. Her first pregnancy resulted in spontaneous abortion at 12 weeks' gestation. She had no significant past gynaecological, medical, or surgical illness.

On examination the patient looked weak with normal vital signs and a slight tenderness over the suprapubic region. Bleeding was seen through

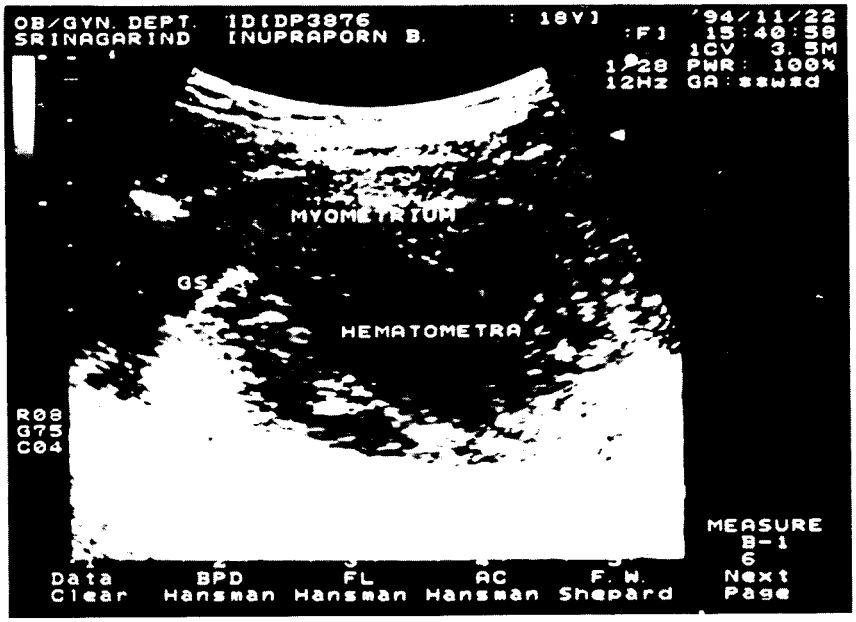

Fig. 1. Pelvic ultrasonography revealed many blood clots in the enlarged uterine cavity and a clearly discernible right cornual gestational sac (GS).

the congested cervix by speculum examination. Pelvic digital palpation revealed an 8 weeks uniformly enlarged, mildly tender uterus. No adnexal masses were detected and there was no bulging in the cul-de-sac. The provisional diagnosis was threatened abortion. The urine pregnancy test was positive. A pelvic ultrasonography revealed blood clots in the enlarged uterine cavity and a clearly discernible right cornual gestational sac measuring 1.94 x 0.74 x 1.2 cm with positive fetal heart appearance. (Fig. 1)

After 24 hours in the gynaecological ward the patient complained of severe abdominal pain. It was found that the uterine fundus enlarged to such an extent that it was at the level of the umbilicus. Laparoscopy was performed in order to determine the cause of the severe pain, the location of the pregnancy and to provide the surgeon with possible options for management. It revealed the presence of a 4 cm right cornual and proximal tubal portion bulging consistent with an unruptured cornual or interstitial pregnancy

Under laparoscopic visualization and abdominal ultrasound, gentle transvaginal uterine curettage was performed. Approximately 200 ml of clotted blood was found in the uterine cavity and the conceptus was removed from the dilated interstitial portion of the right tube. Examination after the procedure revealed minimal vaginal bleeding and a firm, normal sized uterus. The estimated blood loss from the procedure was 400 ml. The patient made an uneventful recovery. Methotrexate (MTX) 30 mg was injected intramuscular daily after for the following 5 days.

At four weeks follow up, the patient looked normal. The uterus was of normal size and there was no vaginal bleeding. The adnexa had no abnormal mass and no tenderness, the serum β-hCG decreased to under 10 mIU/ml. One year later, she became pregnant and delivered a normal child.

Discussion

Ectopic pregnancy, a common obstetric

complication occurs in approximately 1 in 64 live births.[7] Rare interstitial pregnancy has an incidence of 2-4% of all ectopic pregnancies.[1-3]

The nomenclature of interstitial and cornual gestation may be confusing.[8] In Te Linde's, the two are reported to be difficult to distinguish, and many authors suggest they should be classified together.

The ultrasonographic signs of interstitial ectopic pregnancies derive from their location within the intramural portion of the fallopian tube. Thus, they are typically seen to be closely related to the uterus, even partially surrounded by myometrium, while located at the uterine periphery. Because the quality of the nutrient blood supply is superior to that of the free portion of the fallopian tube, interstitial ectopic pregnancies typically manifest with growing gestational sacs and frequently with living embryos. The descriptive phrases utilized in the literature with regard to interstitial pregnancy include "Fundal, and very lateral location of sac".[9-11] The differential diagnosis includes ovarian and abdominal pregnancies as well as pregnancy in one horn of a bicornuate uterus.[12] The diagnosis is confirmed by laparoscopy.

Traditionally, interstitial pregnancies are managed by exploratory laparotomy and cornual resection.[1-3,13,14] However, in the haemodynamically stable patient, conservative management can be used with successful treatment. A case of hysteroscopic removal of an interstitial gestation has been reported.[15] The pregnancy confirmed by laparoscopy was removed using hysteroscopic forceps. Another case of laparoscopically guided curettage and the successful intrauterine pregnancy following the treatment has been reported.[16] There are many reports supporting the successful treatment of interstitial pregnancies by MTX locally or systematically.[17-19]

In this paper, we present a case of laparoscopic and abdominal ultrasound guided curettage of an interstitial pregnancy. We used MTX 30 mg administered intramuscularly for treatment of the remaining conceptive products. This method allows preservation of the tube and avoids a laparotomy. The success of this treatment resulted in the patient becoming pregnant and delivered a healthy infant one year later. Ultimately, the management of interstitial pregnancies must be dictated by the size and site of implantation, the extent of trauma to pelvic organs, and the patient's desire for future fertility.

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REVIEW

Sonohysterography : An Evaluation of the Uterine Cavity

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Until recently, investigation of the uterine cavity was dependent upon various paraclinical investigation such as hysterosalpingography (HSG), more rarely CT scanning and magnetic resonance imaging, and dilatation and curettage, all of which have their drawbacks, risks, or deficiencies.[1,2] Transvaginal sonography (TVS) has completely transformed the diagnostic approach of the uterine cavity. Because of the proximity of the probe to the organs being explored, the images obtained are of high resolution.[1,3] In certain physiological and nonphysiological situation, intracavitary fluid discharges (fluid retention) distend the uterine cavity and improve sonographic contrast.[4] Distension can also be obtained artificially by instilling a solution into the cavity inducing a veritable sonographic hysterography (Sonohysterography, SH) for evaluating the uterine cavity and describing intracavitary abnormalities.[5-7] Sonohysterography was described in 1984 by Richman et al,[8] who used transabdominal technique for determining tubal patency. The development of transvaginal transducers has made it possible to refine this technique as a result of improved depiction of the endometrial cavity. Sonohysterography increases the diagnostic sensitivity and specificity of transvaginal ultrasound potentially decreases the number of invasive procedures, while helping direct appropriate management in cases requiring tissue diagnosis.[9] Indications for sonohysterography include both clinical and sonographic findings. Clinical indications include abnormal vaginal bleeding, in case of menometrorrhagia in women of child-bearing age or postmenopausal bleeding, or unexplained infertility. Sonographic findings indications include a thickening of the endometrial interface that is out of phase with the patient's menstrual history, the presence of a uterine leiomyoma of indeterminate location, or a poorly defined endometrium.[9]

Timing of the examination

The timing of sonohysterography is dictated by the clinical situation. In the infertile patient, the procedure is usually performed within the first 10 days of the menstrual cycle, similar to the timing of hysterosalpingography. This timing is used to minimize the possibility of disrupting an early intrauterine pregnancy and many of the pathologic conditions are best examined with the background of a periovulatory endometrium. However, for women with irregular cycles, such timing may not be feasible. In these patients, the procedure can be performed after negative result of a pregnancy test is obtained. For patient with suspected polyps,

sonohysterography is best performed during the proliferative phase of the menstrual cycle, since the thin endometrial interface does not further distort the endometrial cavity. For women with suspected leiomyomas, the timing of the examination is subject to discussion. Leiomyomas are often hypoechogenic relative to the myometrium. This may be better assessed in the secretory phase because the thickened, echogenic endometrial lining provides an excellent interface for their detection.

Description of the technique

No special preparation of the patient before the procedure is required. Although there is a theoretical risk of infection, no immediate or delayed infection to date is noted, and prophylactic antibiotics are not used in uncomplicated cases. Because an existing infection could possibly be exacerbated, the examination is deferred in women with active pelvic inflammatory disease. Women with chronic pelvic inflammatory disease or a history of mitral valve prolapse or other cardiac disorders are given prophylactic antibiotics ; similar to the management of such patients before hysterosalpingography. Sedatives or analgesics are not needed during the procedure as there is no significant pain or discomfort. Nonsteroidal anti-inflammatory durgs can be used for occasional cramping.

Fig. 1. Conventional transvaginal sonography demonstrated an thickened endometrial interface (arrow) in a patient who presented with abnormal vaginal bleeding.

First, a baseline transvaginal sonographic examination is performed. (Fig. 1) This examination demonstrates the sonographic characteristics of the endometrium as well as its thickness, the presence of leiomyomas and any associated ovarian abnormality. It also serves to exclude a patient with an unsuspected intrauterine pregnancy. Following the baseline examination, the transvaginal probe is removed and a sterile speculum is inserted. The cervix is cleaned with antiseptic solution, and a catheter is introduced into the uterine cavity to the level of the uterine fundus. The choice of catheter is dictated by clinical situation. For most women, a 5-F paediatric feeding tube will suffice. This catheter is easily inserted, even in the postmenopausal patient, and has the added advantage of low cost. The other catheters which may also be used are hysterosalpingography catheters or insemination catheters or polyethylene catheter. After the catheter is in place, the speculum is removed and sonographic probe is applied. The probe can either be transabdominal[10] or transvaginal.[7,9,11] The position of the catheter in the endometrial cavity is ascertained before instillation of the saline is commenced. The catheter is connected to a syringe containing 50 ml of sterile saline. Sterile saline is then injected into the catheter under continuous sonographic visualization, distention is continued until all of the uterine cavity is clearly observed. To provide high quality imaging the amount approximetely 5-30 ml is required. The average time to perform sonohysterography is 10-15 minutes.

Vaginal spotting of blood is not an infrequent finding. The patient is asked to contact the physician should frank bleeding, increasing pelvic pain and fever occur. For women who experience

uterine cramping, nonsteroidal anti-inflammatory drugs can be used.

Sonohysterography is especially valuable for depicting intraluminal, endometrial, or submucosal lesion. In the normal finding, The uterine cavity is symmetrically distended. No masses distorting the cavity or within cavity are seen. The endometrium appears symmetrical, with a single-layer thickness being half the expected double-layer thickness for the phase of the menstrual cycle at the time of the procedure. In the abnormal uterine cavity, the anechogenic interface provided by the saline allows an improved determination of the site of abnormality that was inferred from a thickened or distorted endometrial interface seen at conventional transvaginal sonography (Fig. 2). Abnormal lesion which could be identified by sonohysterography are uterine adhesions, uterine polyps, uterine leiomyomas, uterine septum and endometrial hyperplasia or atrophy.[7,9]

Limitations of the technique

Limitations of sonohysterography may be encountered in certain clinical situations. In women with cervical stenosis, it may be difficult to introduce the catheter through the endocervical canal.

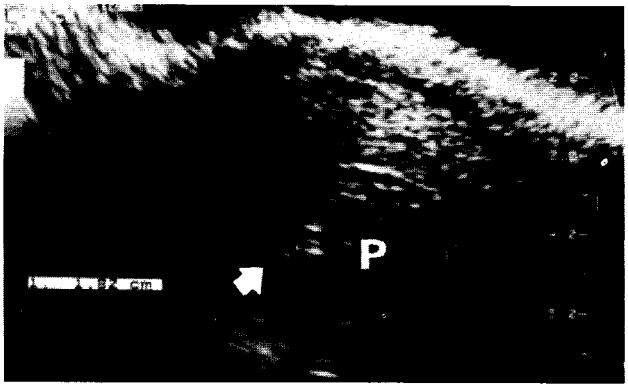

Fig. 2. In the same patient, sonohysterography demonstrated an intraluminal mass surrounded by a small amount of fluid (arrow). This finding is consistent with an endometrial polyp (P).

Occasionally, dilatation of the cervix may be required. inadequate distention of the uterine cavity is another problem that is common in women with uterine adhesions or large leiomyomas. The latter may partially obliterate the uterine cavity. Sonohysterography is of limited use for assessment of tubal patency. It is difficult to follow saline tract which coursing into the tubal ostia with gray-scale images. Study has suggested that colour Doppler sonography with contrast agents may help identify the flow within the fallopian tubes.[12]

A further theoretical risk resides in the possibility of retrograde seeding cancer cells via the fallopian tubes in patients with possible endometrial neoplasm. However, the slow, gradual instillation of saline solution and the low intrauterine pressures induces by small quantities of instilled fluid limit this theoretical risk. In addition, this risk does not appear greater than that involved in hysterosalpingography and the survival of patients with endometrial carcinoma is the same of women who have undergone hysterosalpingography and those who have not.[13]

Sonohysterography represents a new technique for the investigation of the uterine cavity. It is minimally invasive, simple, safe, relatively easy to perform and well tolerated by the patient. It has the potential of altering the management of large numbers of patients with suspected endometrial abnormalities and those being evaluated for infertility. Sonohysterography complements conventional transvaginal sonography and supersedes hysterosalpingography for investigation of the uterine cavity.

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COMMENTARIES

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International Committee of Medical Journal Editors*

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Type the manuscript double-spaced, including title page, abstract, text, acknowledgements, references, tables, and legends.

Each manuscript component should begin on a new page, in the following sequence; title page ; abstract and keywords ; text ; acknowledgements ; references ; tables (each table complete with title and footnotes on a separate page) ; and legends for illustrations.

Illustrations must be good-quality, unmounted glossy prints, usually 127 x 173 mm (5 x 7 in.), but no larger than 203 x 254 mm (8 x 10 in.).

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The title page should carry (a) the title of the article, which should be concise but informaative ; (b) first name, middle initial, and last name of each author, with highest academic degree and institutional affiliation; (c) name of department(s) and insititution(s) to which the work should be attributed; (d) disclaimers, if any; (e) name and address of author responsible for correspondence about the manuscript; (f) name and address of author to whom requests for reprints should be addressed or statement that reprints will not be available from the author; (g) source (s) of support in the form of grants, equipment, drugs, or all of these; and (h) a short running head or foot line of no more than 40 characters (count letters and spaces) placed at the foot of the title page and identified.

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Authorship credit should be based only on substantial contributions to (a) conception and design, or analysis and interpretation of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is also not authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author.

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Below the abstract provide, and identify as such, 3 to 10 key words or short phrases that will assist indexers in cross-indexing the article and may be published with the abstract. Use terms from the medical subject headings (MeSH) list of *Index Medicus* ; if suitable MeSH terms are not yet available for recently introduced terms, present terms may be used.

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The text of observational and experimental articles is usually-but not necessarily-divided into sections with the headings Introduction, Methods, Results, and Discussion. Long articles may need subheadings within some sections to clarify their content, especially the Results and Discussion sections. Other types of articles such as case reports, reviews, and editorials are likely to need other formats. Authors should consult individual journals for further guidance.

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State the purpose of the article. Summarize the rationale for the study or observation. Give only strictly pertinent references, and do not review the subject extensively. Do not include data or conclusions from the work being reported.

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Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid sole reliance on statistical hypothesis testing, such as the use of P values, which fails to convey important quantitative information. Discuss eligibility of experimental subjects. Give details about randomization. Describe the methods for and success of any blinding of observations. Report treatment complications. Give numbers of observations. Report losses to observation (such as dropouts from a clinical trial). References for study design and statistical methods should be to standard works (with pages stated) when possible rather than to papers in which the designs or methods were originally reported. Specify any general-use computer programs used.

Put general descriptions of methods in the Methods section. When data are summarized in the Results section specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid nontechnical uses of technical terms in statistics, such as "random" (which implies a randomizing device), "normal," "significant," "correlations," and "sample." Define statistical terms, abbreviations, and most symbols.

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Lillywhite HB, Donald JA. Pulmonary blood flow regulation in an aquatic snake. Science. In press.

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International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. N Engl J Med 1991; 324: 424-8.

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COMMENTARIES

Continuing Medical Education (CME) : Ten Ways of Running an Interactive Session

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Participants at CME meetings value interactive sessions. These sessions not only keep them awake (especially important after lunch) but also stimulate learning. Planning an interactive session is much more demanding than planning a formal presentation such as a lecture. This paper describes 10 ways of structuring such a session.

1. Presentation/s + case discussion ("Ruleg")

One or more brief presentations are made on a clinical topic. At the end of the presentation/s, the participants are split up into leaderless groups of 5 to 8 (usually within the same room) and provided with printed case vignettes (half to one page). The groups are asked to appoint a reporter and then to work on the task specified in the printed material (e.g. decide on diagnosis and/ or management) for each case. In a plenary session, the groups report back and their proposed management, for example, is commented on by the expert. The session ends with some practical "take home messages" from the expert. The format takes its name from its sequence-presentation of the "rule" followed by examples (e.g.).

Key features :

Suitable for small to medium groups
Cases must relate to presentation/s
Expert's role is straightforward
Skilled leader required
Reporting back from many groups can become boring

2. Case discussion + presentation/ s ("Egrule")

At the start of the session, participants are split into leaderless groups of 5 to 8 (usually within the same room) and provided with case vignettes. The groups are asked to appoint a reporter and then to work on the task specified in the printed material (e.g. decide on diagnosis and/or management) for each case. In a plenary session, the groups report back and their selected management, for example, is commented on by the expert , who then goes on to give a brief presentation on the topic/s raised by the cases. The session ends with a question and answer session. The format takes its name from its sequence-work on examples (e.g.) followed by development of the "rule".

Key features :

Suitable for small to medium groups
Cases are relatively easy to select
Expert must be flexible
Skilled leader required
Reporting back from many groups can become boring

3. Case discussion using an audience response system

An audience response system is a system used to collect responses on a question from the members of an audience by electronic means. The components of the system are a set of keypads for participants, linked to a computer and then to a display system so that the pattern of response is displayed. More detailed advice on preparation of material for use with an audience response system is available from College House.

A brief summary of a case is presented (e.g. pertinent history, physical examination, investigations etc.) both verbally and visually (e.g. colpophotographs, CTG tracings, hysterosalpingograms). At key decision points, participants are presented with a series of multiple-choice options (e.g.possible investigations, diagnosis, management options) and asked to indicate which option they would choose in their practice. The pattern of response is displayed and commented on by a panel of experts. Comment from the floor is then encouraged. Further case information is then presented and another decision point presented. In this way, a single case may extend for 30 or 40 minutes if it has a number of decision points. This format typically leads to lively discussion but may drag if the presenter does not maintain a reasonable pace.

Key features :

Suitable for large groups
Limited to multiple-choice options
Skilled Quiz Master required
Expert input usually restricted to comments
Expensive

4. Quiz with audience response system

The knowledge of the participants is tested using multiple choice questions, sometimes linked to visual material such as slides (e.g. colpophotographs) or video recordings (e.g. ultrasound scans). The session is typically run by a "Quiz Master," who advises participants of the correct response and manages any interaction with members of the audience. A panel of experts may be used to comment on the pattern of response and select the correct answer. The success of this format depends very much on the skill of the "Quiz Master" as an entertainer.

Key features :

Suitable for large groups
Limited to multiple-choice options
Skilled presenter required
Expert input usually restricted to comments
Expensive

5. Presentation + survey with audience response system

The audience response system is used to survey the participants to establish how many of them use a particular test or have access to particular services. While the case discussion format is often used exclusively for an entire session, the survey format is more often used intermittently to enliven a lecture presentation. Used in this way, it is popular with audiences but it must usually be used sparingly. It is also commonly used at the end of a session to evaluate the perceived effectiveness of the session.

Key features :

Suitable for large groups
Limited to multiple-choice options
Used intermittently within a format presentation
Expensive

6 . Nominal group technique

This is small group technique used to increase participation by all members of the group, while reducing the effect of dominant members. It is called a "nominal group technique" because members of the group work in the presence of others but do not talk to each other except at specified times.

The leader starts the process by asking participants to respond to a question or task, e.g. "Which antenatal screening tests should we routinely use ?". Without discussion, each participant lists his or her responses. The leader then asks each participant, one at a time, to state one item from his or her list and this is written on whiteboard or newsprint. This continues until all the items no each participant's list has been recorded. Discussion of items is not allowed and no attempt is made to reduce overlap of items at this time. The group then goes on to discuss the items listed on the newsprint or board for purposes of clarification, elaboration or addition of new items. The final stage involves participants voting on the priorities for each of the items listed and deciding on the most important items. An expert or panel of experts can then comment on the decision of the group.

Key features :

Suitable for small groups only
Useful for problem definition
Confident leader ("ringmaster") required

7. Snowball discussion

This is a variant of the Nominal Group Technique in which participants are presented with a task which they work on silently and independently by writing on a piece of paper. At the end of this phase, the participants discuss their conclusions in pairs and agree on the most important items. Next, pairs join together to form groups of four and take the task a further step forward. Finally, the groups of four report back in a plenary session, where a synthesis of the deliberations of groups of four is constructed by the leader. This simple 1-2-4 approach is always effeective if the tasks for the three phases are selected carefully so that each phase takes the task a further step forward.

Key features :

Suitable for small to medium groups
Encourages participation by all members
Confident leader ("ringmaster") required
Selection of linked tasks not easy

8. Metaplan symposium

The group is presented with a contentious clinical problem. Each member is provided with a red sticker and asked to "vote" on a management practice by placing a sticker on a sheet of newsprint divided into four boxes labelled *Never, Occasionally, Usually* and *Never.*

Those who voted *Never* or *Occasionally* are then asked to briefly (30 seconds) state one reason why they do not favour this management. Each reason is summarised in a few words (e.g. "causes endometrial cancer") on a white card which is pinned o the board under the *Never* heading. Other participants are encouraged to object to a reason by stating briefly why it is invalid (e.g. "does not cause endometrial cancer if

progestogens are used"). These objections are summarised on a red card which is pinned next to the white card listing the reason.

Those who voted *Usually* and *Always* are then asked to justify their selection. Once again, white cards are used to summarise reasons (e.g. "prevents osteoporosis") and red cards are used to record objections. These are pinned to the board under the *Always* heading.

In this process, participants learn about the management preferences of other participants and the validity of the justifications used by those with alternative views. Finally, the problem and preferred management options can be commented on by an expert or a panel of experts.

Key features :

Suitable for small to medium groups
Considerable physical movement (milling around)
Confident leader ("ringmaster") required
Problem must be contentious

9. Structured discussion of a paper or papers

The expert writes a paper of 4-6 pages, subdivided into the traditional sections of a scientific paper (*Introduction, Methods, Results* and *Discussion*). This paper forms the basis of the session. He or she is given 10 minutes (no more) to present the key features only of the paper. The chairman then asks participants to indicate by raising their hands if they have questions or comments relating to each section in turn. These intentions to speak are recorded on the board or overhead projector. The chairman then asks for the first question or comment on the *Introduction* and proceeds from there through the paper. The expert is given the opportunity to make a final statement at the end of the discussion of his or her paper. Several papers may be covered in a single session with 10 minutes introduction from the author followed by 20 minutes discussion from the participants.

Key features :

Suitable for small to large groups
Paper must stimulate discussion
Initial presentation must be brief
Skilled chairman required

10. Case auction

This is a variant of the "Egrule" format. The leader prepares a series of short (half page) case vignettes relating to the topic under consideration. These range in complexity from the relatively straightforward to the downright difficult. The leader announces that he or she has a series of cases for discussion by individual participants and that they will be "auctioned" one by one to volunteers in the audience. He or she also warns the audience that they will be presented for "auction" in order of increasing difficulty so it is better to buy early in the "sale". The leader also warns the audience that if a case is not "sold", it will be allocated to someone suitable in the audience.

The cases are then displayed one by one on the overhead projector and "sold" to participants. No discussion is permitted until all cases have been "sold" The "buyer" of the first case is then asked to outline his or her preferred management for that case. The leader encourages comment or questions from the floor after each case and adds his or her comments at the end of the discussion or asks for comment from an expert or panel of experts. Finally, after all of the cases are discussed (possibly a dozen or more cases in a one hour ses-

sion), the leader provides a brief summary of the main issues involved, including some "take home messages". Alternatively, the leader or an expert may conclude with a formal presentation, illustrated by reference to some of the cases presented.

Key features :

Suitable for small to large groups
Requires cases of varying complexity
Requires skilled leader
Expert (if used) must be flexible

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COMMENTARIES

Giving Birth "from one extreme to the other"

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The above title which may at first appear confusing will become more apparent as one reads on. Obstetrics or midwifery is an art. Above all it is a gentle art. One of the essential features of the practice of obstetrics is the fact that there can be no hard and fast rules to govern management. In almost any situation there are always alternative methods to choose from. The process of decision making and management depends on other factors, the obstetrician's own belief and experience, the facilities available in the practices and the clinical setting at the time. Furthermore, unlike any other branch of medicine it is expected that the parents should play a significant role in the decision making particularly regarding the mode and conduct of delivery of their babies.

Private vs non private care

Over the past few decades consumerist movements on both sides of the Atlantic have become increasingly organized and increasingly vocal. There is a movement towards natural child birth and away from mechanistic medical obstetrical practices. In Thailand, obstetric practice is performed either in private hospitals or in non private government hospitals. The type of practice in government hospitals is considered by many, too medically intrusive with the patient's comfort and mental support well down the list of priorities. However, this conveyor belt approach which we know is far from desirable may be appropriate in an institute where resources are very limited. In such circumstances, expectant mothers have no role to play in any decision making. On the contrary, in private hospitals where resources are plentiful, expectant mothers who pay for their services have a much greater role in the decision making process.

The title of this article "Giving birth, from one extreme to the other" was chosen because of the presence of a wide spectrum of practices. In general, obstetricians serve two groups of patients. The first, and by far in the majority are the local Thai mothers, many of whom will ask their obstetricians to perform an elective caesarean section. The reason given is usually one of the following : stars and the horoscope pre-set the best date and time of delivery, fear of labour pain and fear of having a laxed vaginal wall which will subsequently adversely affect sexual performance. The patient's own parents or their in-laws, also have a strong influence on the decision making. The

second group, are the mothers from overseas, some of whom are advocates of the "natural child birth approach". How do we deal with these situations will further be discussed.

Elective caesarean section for the reasons mentioned above, are far from "natural". Medically it is unsound and whilst a caesarean section is now safer than it has ever been in terms of sophistication in anaesthesia and surgery it can never be entirely safe. Maternal mortality rates after caesarean section in both the United States and the United Kingdom are 0.05%, a figure 11 times that for vaginal delivery.[1] It is not, therefore an alternative to vaginal delivery. Patients who request for such an operation should be told so. It is the obstetrician's duty to counsel and give proper advice to his patients, but if the patient insists (and they usually do) on having an elective caesarean section then at least he/she has performed his or her duty. Unfortunately, there seems to be a growing concern among consumers that far too many unnecessary caesarean sections are being performed, some at the patients' request, some with the obstetricians'blessing or even encouragement.

Labour room care

Recently, there has been much discussions on natural child birth. More and more parents, particularly those from overseas are becoming aware of the term and are concerned about facing an unnecessary caesarean section. In addition, they are concerned that the mother will not be able to keep the baby in her hospital room afterwards but instead have to visit the baby in a nursery, which they fear may affect the bonding process and may hinder breast feeding. Consequently, they are now shopping around for a hospital which offers a much more natural approach to delivery. First of all, let it be clear what natural child birth is. Abroad a number of patients belong to an organization called the Natural Child Birth Trust (NCT). On admission to the labour ward each mother-to-be completes a written request of the things she wishes, such as no administration of intravenous fluid, no rupturing of the membranes artificially ; no monitoring of the baby heart rate pattern ; no or minimal analgesia ; no episiotomy ; various birthing positions and the use of instruments such as forceps and caesarean section must really only be used as a last resort. Usually, the patient's wishes are respected as long as there appears to be no risk to the mother and her baby.

The situation in Thailand is different. It is the writers' opinion that by far the majority of mothers from overseas in fact do not belong to or cannot be classified as being from the N.C.T. However, what they do want may be considered by most obstetricians here in Thailand as demanding a natural child birth,but elsewhere it is merely a normal routine obstetric practice in any hospital. The fact is, obstetric practice in Thailand is often too medically intrusive. An example of such a case :-

- On admission, giving an enema is still universally practiced despite evidence from randomized controlled trials suggesting that an enema does not reduce neonatal infection, and is often both uncomfortable and degrading.[2]

- Shaving of pubic hair is again widely practiced, the stated purpose is to lessen the risk of infection and presumably to make suturing easier and safer. Studies have failed to support these assumptions and it is concluded that there is no evidence to support the continuation of this outmoded practice, which causes discomfort and embarrassment for women.[3-5]

- Once in labour the patient is usually confined to bed.

- Once the membranes have ruptured the patient is definitely confined to bed.

- Artificial rupturing of membranes is usually performed quite early on in labour. A recent randomized trial has shown hat routine early amniotomy although it moderately shortens labour it has little effect on important maternal or fetal outcomes.[6]

- An intravenous fluid administration is almost routine.

- The patient cannot have anything to eat or drink from the onset of labour.

- Episiotomy is performed in all cases.

- Rooming in, i.e. having the baby in the same room as the mother post-delivery rather than in the nursery, is not readily available.

The writers' opinion and guidelines regarding "childbirth" and obstetrics practice are :-

- Elective caesarean sections are performed for medical indications.

- Spontaneous labour "gives a head start." A patient is more likely to achieve vaginal delivery if she goes into labour herself. Induction of labour is only reserved for patients for whom delivery is considered necessary.

An alternative approach to basic care in the labour room should be

(i) No shaving ; an enema is optional.

(ii) Patient can have sips of plain water throughout labour.

(iii) Patient is encouraged to walk about in early labour.

(iv) If, after the membranes have ruptured, the patient can still walk about, she can do so if she wishes.

(v) Husband can stay with the patient for as long as he wishes and may be present at the birth of the baby.

(vi) The patient may optionally not to have the membranes ruptured if she so wishes.

(vii) The baby's heart rate is monitored periodically by stethoscope.

(viii) Progress of labour is monitored by examination at regular intervals.

(ix) Analgesia either in the form of injection or an epidural anaesthesia is readily available.

(x) Episiotomy is usually performed but is not necessary in all cases.

(xi) The baby is given to the mother as soon as he/she is born. Sucking is encouraged almost immediately.

(xii) Rooming-in facilities must be available. After the baby is born, provided she/he is fit and well, the baby and mother should be in each other's company to promote bonding and facilitate breast feeding where possible. Thai mothers however, seem content to leave their babies in the nursery and only visit them for feeding. This is quite the opposite to those from overseas who almost without exception request rooming-in.

The writers wish to emphasize that in our opinion child birth should be as natural as possible as long as there is minimal risk to the mother and her baby. There is no such thing as a "no risk pregnancy and delivery" however, the majority of pregnancies and deliveries are low risk. We have all witnessed the fact that unnecessary and untimely medical intervention can often lead to complications. An obstetrician's duty is to detect when a low risk situation turns into a high risk situation. Common sense is the key word. Delivery, using instruments or by caesarean section is performed only when it is considered beneficial. Having a caesarean section for a good reason is not a failure on the mother's part. Above all, the obstetrician is there to help and not to harm.

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