CHAPTER VII

RESULT

During the study period from May 1994 to April 1995,58 patients whose were met inclusion criteria were entered in the study. All the patients were stratified into three groups according to gestational age by clinical and ultrasound confirmation to be 12 weeks group (n=6) 13 weeks group (n=26) and 14 weeks group (n=26). The blocked randomization was used to allocate the patients in each strata to one of the two early amniocentesis procedure: the treatment group (Amnifiltration technique) and the control group (standard amniocentesis).Total patients in each group were 29.

The indication for prenatal diagnosis were:

1. Maternal age 35 years old and older.(n=52 ,89.65%)
2 Previous aneuploidy offspring. (n=3,5.17%)
3 Maternal age 35 years old and older plus previous aneuploidy offspring.(n=2,3.45%)
4. Family history of Down Syndrome.(n=1,1.72%)

The baseline characteristic of the study population as

shown in table1

All the baseline charateristics in the treatment and control group are not statistically significant difference.

TABLE1. CHARACTERISTIC OF THE STUDY POPULATION

	Control gr.			Treatment gr.			p*
	mean	range	SD.	mean	range	SD.	
Maternal age (yr)	35.64	20-40	3.744	36.27	24-40	2.852	0.51
Paternal age (yr)	36.89	24-49	1.147	37.28	25-55	1.323	0.80
Gravida	2.62	1-6	1.147	2.58	1-8	1.323	0.91
Parity	1.03	0-3	0.88	0.97	0-4	0.865	0.76
Abortion	0.62	0-3	0.82	0.62	0-3	0.8	0.99
Weight (Kg)	54.68	42-72	8.069	55.64	42-78	8.11	0.66
Height (cm)	153.7	142-165	5.88	153.8	135-162	5.475	0.93

P* student t test.

The multiple fetal biometry by ultrasound measurement of the study population in each gestational age were shown in table2. The ultrasound measurement was compatible with the standard measurement in general population at

Pramonkutklao hospital.

TABLE 2. THE ULTRASOUND MEASUREMENT:

Weeks	BPD mm mean,SD	HC mm mean,SD	AC mm mean,SD	HL mm. mean,SD	FL mm. mean,SD	FOOT mm mean,SD
12	22.37 (0.99)	66.32 (4.0)	52.17 (5.91)	8.07 (2.01)	8.55 (1.91)	10.97 (1.46)
13	25.57 (1.69)	75.42 (5.160)	57.89 (5.70)	10.46 (1.51)	11.29 (1.41)	12.94 (1.32)
14	28.77 (1.49)	85.15 (4.88)	67.34 (5.05)	12.75 (1.87)	13.05 (1.60)	14.39 (1.28)

NOTE: BPD= Biraietal diameter.
HC=Head circumference.
AC=Abdominal circumference.
HL=Humerus length.
FL=Femur length.
FOOT=Foot length.

The amniotic fluid Alpha-Fetoprotein was performed by ELISA technique in all patients. The result of the Amniotic AFP(Alpha-Fetoprotein) in different gestational age were found to be in normal range. The Amniotic fluid AFP were shown in table3.

TABLE 3. **AMNIOTIC FLUID ALPHA-FETOPROTEIN(IU/ml.)**

WEEKS	Min.	Max.	Mean.	SD.	Median
12	20000	31000	25375	4714.78	25250
13	17500	58000	32572	9991.18	30200
14	18500	66000	30844	11251.26	27500

The culture failure were 7 cases (12.1%), and the second trimester amniocentesis were performed in these cases. The result of the chromosome study were 46,XX.in 24 cases(41.4%),46,XY in 33 cases (56.9%) and 47,XY+21.(Down Syndrome) in 1 case (1.7%).

Comparison of the culture time between the study group (amnifiltration technique) and the control group (standard amniocentesis) was shown in table 4. Culture time duration in the treatment was statistically significant shorter than the control group by 3.26 days.

TABLE 4. **CULTURE TIME (day)**

culture time	Treatment gr. (n = 25)	Control gr. (n = 29)	Statistical difference
Min.	8	9	-
Max.	21	42	-
Mean	12.32	15.86	P*=0.006
SD.	3.35	6.42	-

*Mann-Whitney test.

The set up time is the time between the procedure and the time that the culture was set up.The ideal set up time should be immediately followed the procedure. Prolong set up time after the procedure more than 6 hours will cause the long duration of the culture time in both treatment and control group.possibly due to increasing the number of death cells. The mean,range and standard deviation of the duration time in both groups was shown in table5.Numbers of cases that were set up later than 6 hours after the procedure were similar in both treatment and control group (n= 14).

TABLE 5. **COMPARISON OF CULTURE TIME IN DIFFERENCE SET UP TIME**

SET UP TIME	Mean culture time in Control group	Mean culture time in Treatment group	Statistical difference
>6hrs	17.786 (sd 7.98)	13.273 (sd 4.077)	P* =0.028
<6 hrs	13.533 (sd 3.739)	11.571 (sd2.563)	P* =0.0728

* = Mann Whitney test.

The volume of the amniotic fluid removed was

1cc/week of gestation in the control group (12-14 CC),but only 8 cc in the treatment group. The mean amniotic fluid volume circulated in the treatment group was 35.89cc. (standard deviation =7.67).

Culture failure was founded in 7 cases ,3 cases (10.35%) in the control group,4 cases (13.79%) in the treatment group. The fisher exact test show no significant.The 3cases in the treatment group showed inadequate cell in the amniotic fluid specimen,possible due to the procedure difficulty.One case experienced accidental disconnection of the connected tube during the process of fluid recirculation which caused an inadequate specimen. In two cases experienced the difficulty in withdrawing the amniotic fluid,only small amount of amniotic fluid (4-5cc) was removed and recirculated. The possibility of inadequate cell in the amniotic fluid specimen in these two cases ,may be due to the needle was slipped into the potential space between the amnion and the chorian instead of the amniotic fluid cavity.In early gestation the space between the amnion and chorian is quite large and this space will be closed together later in gestation.If these three cases with the procedure difficulty were excluded,the culture failure in the treatment group would be 1 in 26 cases(3.8%). When the comparison of culture failure between the treatment group

excluding three cases with procedure difficulty and the cotrol group was done using fisher exact test,the p value was 0.35.

The complication of early amniocentesis observed in this study were temporaly leaking of amniotic fluid in 7 cases (12.1%). No report of fetal loss or any other serious complication in both groups.The leaking of amniotic fluid was reported as an only one episode in the same day after the procedure in all cases,and spontaneous resolved after that.The amniotic fluid leaking in the treatment group was 3 cases (10.8 %) and in the control group was 4 cases (13.8%) after performing the fisher exact test it showed no significant difference with the p value=0.5.

All of the study cases were follow up at 20 weeks of gestation (6-8 weeks after the procedure),by performing the ultrasound examination for all fetal biometry (table6) and amniotic fluid pocket. All cases were shown normal amniotic fluid volume and normal growth of the fetus by ultrasound examination.The fetal anomaly scan was also performed in all cases and no abnormality was detected. The fetal active movement and normal fetal heart motion were noted in all cases at 20 weeks gestation.

TABLE 6. **FOLLOW UP ULTRASOUND AT 20 WEEKS of GESTATION**

US study	Min.	Max.	Mean.	SD.
BPD (mm.)	41.4	57.7	48.98	3.95
HC(mm.)	128.75	178.55	149.405	11.47
AC (mm)	103.03	145.68	121.118	9.88
HL (mm)	25.2	36.8	31.23	3.07
FL (mm)	25.2	45.0	32.66	3.71
FOOT (mm)	26.7	43.2	35.51	3.81
D1 (mm)	11.8	26.0	16.53	2.52
D2 (mm)	17.8	32.9	23.52	2.83
D3 (mm)	33.7	53.7	41.76	3.29
D4 (mm)	17.2	25.3	21.48	1.94
D5 (mm)	3.7	10.2	5.95	1.38
D6 (mm)	1.8	7.2	4.85	1.00

NOTE: D1 = frontal lobe length.

D2 = frontal lobe-cavum septum pellucidum distance.

D3 = Frontothalamic distance.

D4 = Transverse diameter of cerebellum.

D5 = Cisterna magna,

D6 = Skin nuchal fold.