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OBSTETRIC MONITORING IN BRIANZA DI SEVESO FROM 1973 TO 1981

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REPORT ON OBSTETRIC MONITORING IN BRIANZA DI SEVESO

Total monitored pregnancies (up to 16/5/83): 21 582

Methods of investigation

The aim of this study since the beginning was to gather pregnancy data on a number as close as possible to 100% of the pregnancies of the women residing in the 11 communes. Since we were to study phenomena like the trend of the spontaneous abortion rate in small population samples, such as zones A and B, the loss of even a few cases could have appreciably affected the rates.

Our study covers all the pregnancies concluded between January 1st 1975 and December 31st 1981. The completeness of the cases reported was checked and missing cases recovered by means of:

- 1) a list of births in the eleven communes (thoroughly checked by Special Office personnel as from the third quarter of 1976 but not for the previous quarters);
- 2) the reports of spontaneous abortion (sent by law to the provincial medical authority) until June 1973 and available from July 1976. The search for reports of spontaneous abortion for the period January 1975 - June 1976 unfortunately proved fruitless. In fact they were no longer to be found in the competent offices because their preservation after the normal statistical work-over and after the entry into force of law 194 was thought to be pointless;
- 3) the recovery of clinical data from neighboring hospitals (Carate, Cantù, Garbagnate, Clinica Zucchi of Monza, Saronno) not included in the monitoring plan and from the largest hospitals in the city of Milan, attended by a significant percentage of the pregnant women of the 11 communes;
- 4) the A/D forms of all the hospitals in Lombardy. These forms are available from May-June 1975: up to end-1976 they appear incomplete whereas from '77 to '81 the standard is decidedly better. For the period after October 1980 they became

available only in March 1983. Case records for cases probably relevant to our study, have been looked for and mainly found, but still missing from this report since it is worked on data elaborated by the computer up to May 16th, 1983.

The following data about each pregnancy are always known: mother's registry office data, date of last menstrual period, date of delivery or abortion and weight of the newborn.

The date of conception can be established with good approximation by the date of the last menstrual period. The pregnancy data have been stored in the computer of the Special Office at Desio according to a program agreed in advance with the epidemiology group (figure 1).

For the study of spontaneous abortions we have chosen the statistical method that relates the number of spontaneous abortions occurring in a given period to the number of conceptions for that period, in order to exclude any factors that might affect the number of conceptions. In fact the number of conceptions in the populations under study might have been affected in varying degree, contraception having been heavily promulgated at the beginning due to fear of damaging effects of TCDD on the concept embryo.

RESULTS AND DISCUSSION

Table 1 gives the total number of pregnancies monitored and the disaggregation by year of conception and by zone of residence of the gravida at the time of conclusion of the pregnancy. Only 13 pregnancies failed to be assigned to the zones due to incompleteness of the registry office data.

The 1974 conception data are incomplete in that the numbers in the table refer only to the conceptions resulting in delivery or abortion on or after January 1st 1975. Similarly the 1981 data are incomplete because they include only the conceptions resulting in delivery or abortion by 31 December 1981.

21 582 pregnancies were monitored (all pregnancies ending in voluntary abortion have been deliberately excluded).

This table shows that the total number of conceptions was steadily declining from 1975 to 1980 in line with the national trend. 1976 only was out of line as throughout the territory and in each individual zone the figures were lower than in 1977, probably due to the heavy contraception program in the area immediately after the accident, through 1977. In zones A and B, after a low in 1976 the figure rose again in 1977 and 1978, probably by way of compensation. In 1979 and 1980 zones A and B came back into line with the rest of the territory with a progressive fall in the conception rate similar to that for the whole of the Lombardy Region. This declining trend justifies the criterion chosen for the determination of the abortion rate.

Table 2 gives the number of abortions and of conceptions by area according to the degree of pollution and by quarter of conception from the fourth quarter of 1974 to the first quarter of 1981. Table 3 gives the related percentages.

The zone A values are not studied individually because the small number of pregnancies to allow a significant evaluation.

From these tables and from graph 1 there emerges a relatively

stable trend in the non ABR zone (index of the reliability of the data), which fluctuates between 10% and 13% with only two values definitely below the lower limit (9.37% in the 2nd quarter of 1976 and 9.87% in the 2nd quarter of 1980) and two values above the upper limit (14.47% in the 4th quarter of 1976, the highest value found in the non ABR zone, and 14.24% in the 4th quarter of 1977).

If we consider the rates for A+B, R and A+B+R exceeding the upper limit found in non ABR (14.47%), we note a concentration between the 3rd quarter of 1976 and the 4th quarter of 1978 (table 3A). The peak - 33.33% - was reached in A+B in the first quarter of 1977. This behavior is indicative of an acute phenomenon adversely affecting the conceptions in A+B and R (and A+B+R) from the 3rd quarter of 1976 and lasting throughout 1978.

Throughout the period preceding the accident and since the 1st quarter of 1979 in zone R and in the whole of A+B+R there is no single rate exceeding the threshold of 14.47% (maximum value in the control zone). The situation in A+B is different. Even though here too the peak concentration of values exceeding 14.47% is found in the period immediately after the accident, we nonetheless find similar peaks ^{both} in the preceding period (2nd quarter of 1975: 18.42%; 1st quarter of 1976: 22.22%) and after 1978 (1st quarter of 1979: 14.81%; 4th quarter 1979: 19.23%; 1st quarter 1981: 15.33%). As the population sample is small, these may be thought to be fortuitous events.

However, the next table (table 3B) may suggest other hypotheses. This table highlights those quarterly rates for zones A+B, R and A + B + R as a whole, that, though not necessarily

exceeding the peak value of non ABR, exceed the rate for the non ABR zone for the same quarter. The following points are of great interest:

- 1) higher rates in R and A+B+R than in non ABR are a practically constant finding right up to end-1978, after which they occur only in the 4th quarter of 1979 and in the 3rd quarter of 1980;
- 2) in A+B the rates were higher than in non ABR in 18 of the 26 quarters studied, with a practically uniform distribution.

It could be argued that A+B has a genetically more abortion-prone population or one ^{more} chronically exposed to abortigenic factors that are expressed throughout the period under review: in the period July 1976-March 1978 this population experienced an additional factor that accentuated this predisposition to spontaneous abortion. Or it may be argued that the factor responsible for the increase in spontaneous abortions in R (and in A+B+R) in the period from the 3rd quarter of 1976 to the 4th quarter of 1978 was operative in A+B previously as well and that its action in that zone continued into 1979 and 1980.

Another line of argument is that R and A+B+R were previously exposed to factors capable of increasing the rate of spontaneous abortions and that the same factors were at work on a greater scale, or new factors were superadded with a synergic action, causing an even more striking increase in the period July 1976-December 1978.

Interestingly, as from January 1979 the rates for R (and A+B+R) were actually lower than in non ABR. This datum rules out the possibility of a greater genetic predisposition to spontaneous abortion for the inhabitants of zone R. A more likely hypoth-

esis is that the preventive measures (removal, killing of animals, prohibition on cultivation, health and hygiene regulations, etc) and reclamation took effect by eliminating the environmental factors (TCDD ? others ?) that were previously responsible for higher spontaneous abortion rates in this zone than in the control (non ABR) zone.

An analysis of the population by maternal age, parity, number of previous abortions elicited no significant differences in the various zones compared, as is appears from table 4. We have calculated the statistical significance of the differences found between the rates in the zones compared. To increase the statistical power of the analysis, we considered zones A, B and R globally and compared periods of four consecutive quarters, taking July 1976 as the reference date. This enables us to look at the zones we are comparing for a year before the accident and for four years after (tables 5 and 6).

The rates for the first period are identical in the zones compared. In the periods July 1976-June 1977 and July 1977-June 1978 the rates for A+B+R were higher than in non ABR.

For the statistical comparison we used the Z test according to the formula:

$$Z = 2 \sqrt{\frac{p(1-p)}{n}}$$

p = percentage rate

n = number of conceptions

The differences for the periods July 1976-June 1977

and July 1977-June 1978 are statistically significant. The difference for the period July 1979-June 1980, in which A+B+R presents lower rates than non ABR, (see diagram), is significant.

At the request of the ISC (International Steering Committee) we conducted a survey of gestational age and birthweights (as possible indicators of toxicity) in the monitored territory. Graph

2 shows exactly superposable gestational age curves for A+B+R and non ABR.

Graphs 3 and 4 (gestational age by maternal age and gestational age by parity) represent the trend of this phenomenon in the whole sample. Since there were no significant differences in respect of these factors in the zones compared, we saw no point in reproducing these graphs with a disaggregation by zone.

The birthweight study was conducted on a percentile basis. Graphs 5-11 give the curves for the 5th, 10th, 25th, 50th, 75th, 90th and 95th percentiles, comparing the global sample with A+B+R before and after 10 July 1976 and with non ABR before and after the same date. These graphs do not seem to reveal any important differences between the zones compared. The differences in the first and last weeks probably depend on the smallness of the sample for these weeks. As these data are very recent, any opinion we can express now is very superficial.

CONCLUSIONS

In the eleven communes there is one area, namely A+B+R, in which the abortion rate is higher than in the rest of the territory, the difference being statistically significant for the two years following the ICNESA accident (July 1976-June 1978). In 1979 and 1980 the rates in A+B+R were lower than in non ABR, significantly so in 1980. In the period July 1975-June 1976 the rates in the two zones compared were identical. We have no direct toxicological or biological evidence on which to base an assertion that TCDD was responsible for the difference but the time coincidence would strongly suggest that it was.

Zone A+B considered separately presents almost consistently higher

spontaneous abortion rates than does non ABR, with a peak of 33.33% in the 1st quarter of 1977. However, the phenomenon may be more apparent than real (apart from the period 1976/78) and related to the small number of cases, which results in a distribution of abortion cases in which higher percentage levels (taken one by one) are likely to be more frequent.

The scale of the phenomenon is of sufficient interest to warrant further investigation, which is now under way.

There are no sizable differences between the populations compared in regard to gestational age, birthweight or the various pathological conditions of pregnancy other than spontaneous abortion.

Figure 1

PREGNANCY DATA INPUT

CODE : individual number (registry office)
 no. maiden name, forename, husband's name
 place and date of birth
 domicile, residence

PREGNANCY STARTING DATE (last menstrual period)

ORIGINAL FORM CASE SHEET RECOVERED FORM

PRE-PREGNANCY HISTORY:

- 1) malformations
- 2) hereditary diseases - thalassemia
- 3) hereditary diseases - other
- 4) hypertension
- 5) nephropathy
- 6) other

PREGNANCY COURSE:

- 1) EPH toxemia
 - 2) hypertension (140-160)
 - 3) hypertension (over 160)
 - 4) nephropathy: cystopyelitis
 - 5) nephropathy: other
 - 6) other
 - 7) RH isoimmunisation
 - 8) threatened abortion within week 28
 - 9) threatened abortion after week 28
 - 10) radiation up to end week 24
 - 11) radiation after week 24
 - 12) exanthematous infections before end week 15
 - 13) exanthematous infections after week 15
 - 14) other viral infectious diseases
 - 15) other infectious diseases
 - 16) other diseases
 - 17) drugs taken: steroid hormones
 - 18) drugs taken: yasosuprina
 - 19) drugs taken: other (excl. Ca and vitamins)
 - * 20) Debendox taken
 - * 21) Debendox not taken
- smoking - no. of cigarettes daily

PREVIOUS PREGNANCIES

duration in weeks

:/:

OUTCOME OF PREGNANCY

commune of delivery or abortion	
date of delivery or abortion	
spontaneous abortion	induced abortion
normal delivery	non surgical
vaginal surgical	abdominal
birthweight (s)	

* Datum stored only for gravidas residing in Seregho at the specific request of the USSL 62 operators. For the other gravidas the use of Debendox is included under item 19.

Table 1

	Zone	A	B	C	NonABR	Unassign.	Total
Year							
1974		6	66	394	2.149	3	2.620
1975		11	97	603	2.839	3	3.553
1976		5	74	457	2.578	2	3.134
1977		7	100	525	2.589	2	3.224
1978		11	103	454	2.337	1	2.908
1979		4	85	458	2.197	4	2.746
1980		4	77	419	2.149	4	2.653
1981		0	17	121	601	3	742
Total		48	621	3.450	17.439	24	21.582

Number of pregnancies observed by zone of residence and by year of conception and totals by zone and by year.

Table 2

Zone	A		B		R		non ABR	
quarter	C		A		C		A	
IV.74	1	2	1	27	14	143	52	798
I	0	1	1	19	15	139	86	577
II	0	4	7	34	19	162	69	709
III	0	2	2	21	18	150	81	736
IV.75	1	4	1	23	14	152	91	717
I	0	1	4	17	15	124	62	589
II	0	3	3	22	16	131	76	672
III	0	0	0	10	19	103	85	616
IV.76	1	1	4	25	17	117	100	691
I	1	3	7	21	15	126	77	589
II	0	1	6	29	20	133	83	645
III	1	3	3	22	17	141	79	695
IV.77	0	0	2	28	17	126	94	660
I	1	1	3	26	20	109	64	596
II	0	5	2	26	19	109	61	555
III	0	3	4	26	14	124	67	611
IV.78	1	2	3	27	17	112	72	576
I	0	3	4	24	12	108	66	490
II	0	0	3	21	9	107	61	504
III	0	1	1	14	4	121	77	605
IV.79	0	0	5	26	16	122	77	598
I	0	0	2	14	7	105	63	560
II	1	3	2	19	6	67	47	476
III	0	0	3	22	16	115	62	549
IV.80	0	1	3	22	10	112	69	564
I.81	0	0	2	13	6	85	57	471

Number of conceptions ending on spontaneous abortion (A) and total number of conceptions (C) by quarter and by zone of residence.

Table 3

QUARTER	ZONE A-B	ZONE R	ZONE A+B-R	ZONE NON ABR
4/74	6.69	9.79	9.3	6.6
1/75	5.00	10.79	10.06	12.70
2/75	13.42	11.73	13.00	9.73
3/75	3.69	12.00	11.56	11.01
4/75	7.41	9.21	8.94	12.69
1/76	22.22	12.10	13.38	10.35
2/76	12.00	12.21	12.13	11.31
3/76	-	18.45	16.31	13.30
4/76	19.23	14.53	15.39	<u>14.47</u>
1/77	33.33	11.90	15.33	13.07
2/77	20.00	15.04	15.95	12.87
3/77	16.00	12.06	12.65	11.37
4/77	7.14	13.49	12.34	14.24
1/78	14.81	18.35	17.65	10.74
2/78	6.45	17.43	15.00	10.99
3/78	13.79	11.29	11.76	10.97
4/78	13.79	15.18	14.89	12.52
1/79	14.81	11.11	11.85	13.47
2/79	14.29	8.41	9.37	12.10
3/79	6.67	3.31	3.68	12.73
4/79	19.23	13.11	14.19	12.83
1/80	14.29	6.67	7.36	11.25
2/80	13.64	6.90	8.26	9.37
3/80	-	13.91	11.63	11.23
4/80	13.04	8.93	9.63	12.23
1/81	15.33	7.06	8.16	12.10

TABLE 3a

QUARTER	ZONE A-3	ZONE 2	ZONE A-2-2	ZONE NOT A22
4/74	6.89	9.79	9.3	6.6
1/75	5.00	10.79	10.06	12.70
2/75	13.42	11.73	13.00	9.73
3/75	8.69	12.00	11.56	11.01
4/75	7.41	9.21	8.94	12.69
1/76	22.22	12.10	13.38	10.35
2/76	12.00	12.21	12.18	11.31
3/76	-	13.42	15.21	13.30
4/76	19.23	14.53	15.33	14.47
1/77	33.33	11.90	15.33	13.07
2/77	20.00	15.04	15.95	12.87
3/77	16.00	12.06	12.65	11.37
4/77	7.14	13.49	12.34	14.24
1/78	14.31	18.33	17.65	10.74
2/78	6.45	17.43	15.00	10.99
3/78	13.79	11.29	11.76	10.97
4/78	13.79	15.12	14.33	12.52
1/79	14.31	11.11	11.85	13.47
2/79	14.29	3.41	9.37	12.10
3/79	6.67	3.31	3.68	12.73
4/79	19.23	13.11	14.19	12.35
1/80	14.29	6.67	7.56	11.25
2/80	13.64	6.90	8.26	9.87
3/80	-	13.91	11.63	11.23
4/80	13.04	3.93	9.63	12.23
1/81	25.13	7.06	8.16	12.10

TABLE 3b

QUARTER	ZONE A-B	ZONE 2	ZONE A-B-R	ZONE non ABR
4/74	<u>6.89</u>	<u>9.79</u>	<u>9.3</u>	6.6
1/75	5.00	10.79	10.06	12.70
2/75	<u>18.42</u>	<u>11.73</u>	<u>13.00</u>	9.73
3/75	8.69	<u>12.00</u>	<u>11.56</u>	11.01
4/75	7.41	9.21	8.94	12.69
1/76	<u>22.22</u>	<u>12.10</u>	<u>13.33</u>	10.35
2/76	<u>12.00</u>	<u>12.21</u>	<u>12.16</u>	11.31
3/76	-	<u>18.45</u>	<u>16.81</u>	13.80
4/76	<u>19.23</u>	<u>14.53</u>	<u>15.38</u>	14.47
1/77	<u>33.33</u>	11.90	<u>15.33</u>	13.07
2/77	<u>20.00</u>	<u>15.04</u>	<u>15.95</u>	12.87
3/77	<u>16.00</u>	<u>12.06</u>	<u>12.65</u>	11.37
4/77	7.14	13.49	12.34	14.24
1/78	<u>14.81</u>	<u>18.35</u>	<u>17.65</u>	10.74
2/78	6.45	<u>17.43</u>	<u>15.00</u>	10.99
3/78	<u>13.79</u>	<u>11.29</u>	<u>11.76</u>	10.97
4/78	<u>13.79</u>	<u>15.18</u>	<u>14.89</u>	12.52
1/79	<u>14.81</u>	11.11	11.65	13.47
2/79	<u>14.29</u>	8.41	9.37	12.10
3/79	6.67	3.31	3.68	12.73
4/79	<u>19.23</u>	<u>13.11</u>	<u>14.12</u>	12.88
1/80	<u>14.29</u>	6.67	7.56	11.25
2/80	<u>13.64</u>	6.90	8.26	9.37
3/80	-	13.91	11.63	11.29
4/80	<u>13.04</u>	8.93	9.63	12.23
1/81	<u>15.33</u>	7.06	8.16	12.10

TABLE 4a

PERCENTAGE DISTRIBUTION OF PREGNANCIES BY RESIDENCE ZONE

A) BY MATERNAL AGE GROUP

	20-	21-25	26-30	31-35	36-40	41-45	46-50	50-
A-B-R	14,27	35,74	29,93	12,90	5,94	1,15	0,04	0,00
non ABR	10,30	35,71	31,53	14,60	6,18	1,35	0,09	0,00
Unassign.	46,15	23,07	30,76	0,00	0,00	0,00	0,00	0,00
TOTAL	11,28	35,70	31,21	14,25	6,12	1,31	0,08	0,00

B) BY NUMBER OF PREVIOUS PREGNANCIES

	0	1	2	3	3+
A-B-R	60,31	24,87	9,00	3,81	1,99
non ABR	64,65	22,53	8,56	2,58	1,66
Unassign.	75,92	23,07	0,00	0,00	0,00
TOTAL	63,81	22,99	8,53	2,82	1,72

C) BY NUMBER OF PREVIOUS ABORTIONS

	0	1	2	2+
A-B-R	92,50	5,89	1,28	0,31
non ABR	92,71	5,69	1,16	0,43
Unassign.	92,30	7,69	0,00	0,00
TOTAL	92,57	5,73	1,18	0,40

TABLE 4b

DISTRIBUTION OF PREGNANCIES BY RESIDENCE ZONE AND BY AGE GROUP

	20-	21-25	26-30	31-35	36-40	41-45	46-50	50-	TOTAL
A+B-R	322	306	673	291	134	26	1	0	2253
non ABR	967	3237	2902	1344	569	125	9	0	9203
Unassign.	5	3	4	0	0	0	0	0	13
TOTAL	1295	4096	3581	1635	703	151	10	0	11471

DISTRIBUTION OF PREGNANCIES BY RESIDENCE ZONE AND BY NUMBER OF PREVIOUS PREGNANCIES

	0	1	2	3	3-	TOTAL
A+B-R	1360	361	203	86	45	2255
non ABR	5950	2074	788	238	153	9203
Unassign.	10	3	0	0	0	13
TOTAL	7320	2638	991	324	198	11471

DISTRIBUTION OF PREGNANCIES BY RESIDENCE ZONE AND BY NUMBER OF PREVIOUS ABORTIONS

	0	1	2	2-	TOTAL
A+B-R	2086	133	29	7	2255
non ABR	8533	324	107	39	9203
Unassign.	12	1	0	0	13
TOTAL	10631	538	136	46	11471

TABLE 5

half year	A+B+R			non ABR		
	A	C	%	A	C	%
I.75	42	395	11.70	155	1386	11.16
II.75	36	352	10.33	172	1453	11.84
I.76	38	298	12.75	138	1271	10.86
II.76	41	256	16.02	185	1307	14.15
I.77	49	313	15.65	160	1234	12.97
II.77	40	320	12.50	173	1355	12.77
I.78	45	256	17.58	125	1151	10.86
II.78	39	294	13.26	129	1137	11.71
I.79	28	263	10.65	127	994	12.78
II.79	26	264	9.15	134	1203	12.80
I.80	18	228	7.89	110	1036	10.62
II.80	29	272	10.66	131	1113	11.77

Number of conceptions ending in abortion (A), total number of conceptions (C) and rate (%) by half year of conception and by residence zone.

TABLE 6

period	A+B+R			non ABR		
	A	C	%	A	C	%
July 75-June 76	74	650	11.38	310	2724	11.38
July 76-June 77	90	569	15.82	345	2541	13.58
July 77-June 78	95	576	16.49	298	2506	11.99
July 78-June 79	67	557	12.03	266	2181	12.20
July 79-June 80	44	512	8.59	264	2239	11.79

Number of conceptions ending in spontaneous abortion (A), total number of conceptions (C) and rates (%) by one-year period before and after the ICMESSA accident in zone A+B+R and in zone non ABR.

CALCULATION OF STATISTICAL SIGNIFICANCE - MODEL

Comparison of spontaneous abortion rates in zone A+B+R and in zone non ABR in one-year periods before and after the ICMSA accident according to the Z test.

period July 1975-June 1976: A+B+R rate non ABR rate= 11.38

period July 1976-June 1977

$$13.53 \pm 2 \sqrt{\frac{.3.52 (100 - .3.52)}{2541}}$$

confidence limits: 12.13 ——— 15.03

rate for A+B+R = 15.82 SIGNIFICANT

period July 1977-June 1978

$$11.89 \pm 2 \sqrt{\frac{16.49 (100 - 16.49)}{2506}}$$

confidence limits: 10.41 ——— 13.37

rate for A+B+R = 16.49 SIGNIFICANT

period July 1978-June 1979

$$12.20 \pm 2 \sqrt{\frac{12.03 (100 - 12.03)}{2131}}$$

confidence limits: 10.31 ——— 13.59

rate for A+B+R = 12.03 NON SIGNIFICANT

period July 1979-June 1980

$$11.79 \pm 2 \sqrt{\frac{8.59 (100 - 8.59)}{2039}}$$

confidence limits: 11.00 ——— 12.39

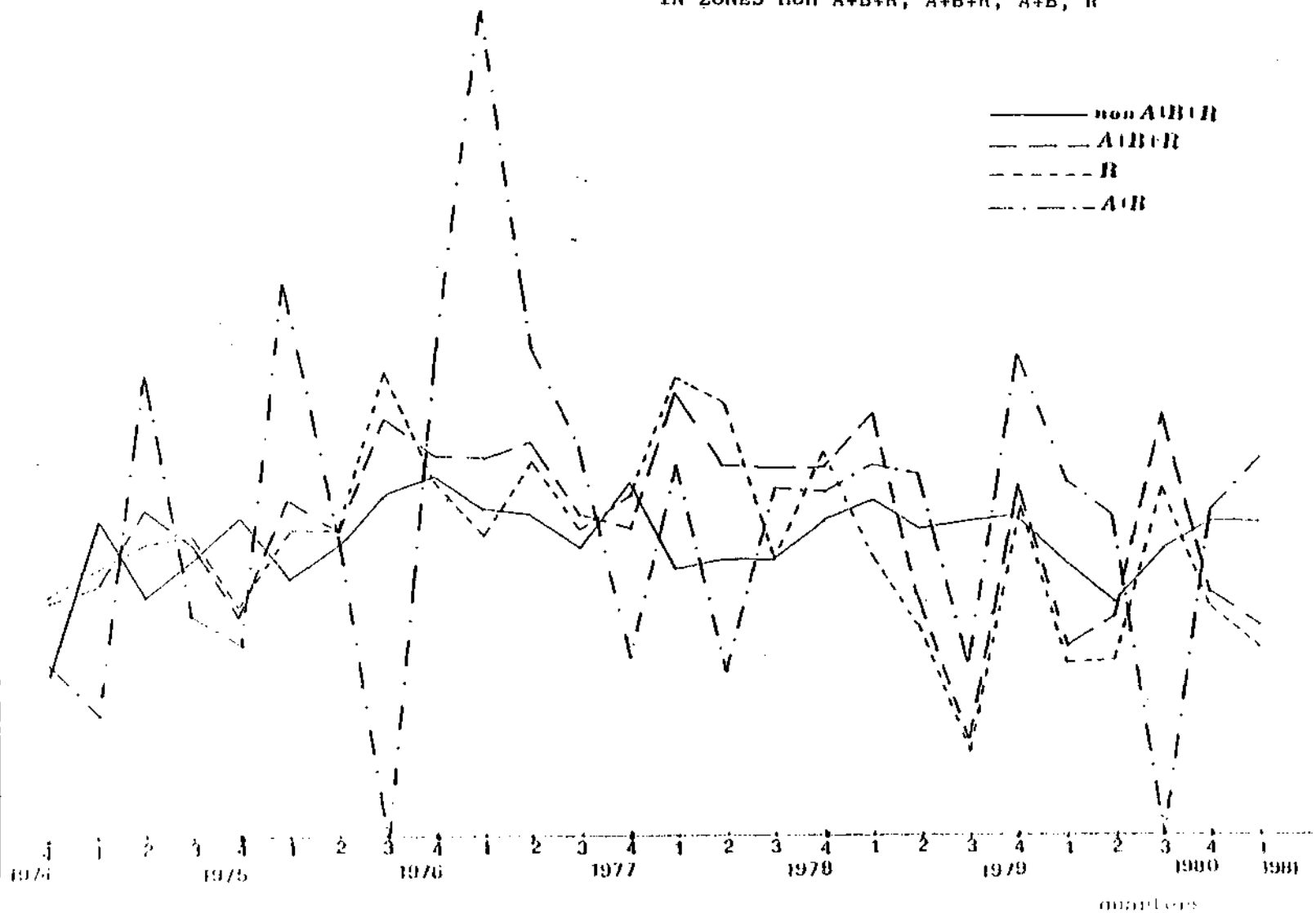
rate for A+B+R = 8.59 SIGNIFICANT

ABORTION RATES BY QUARTER

Graph 1

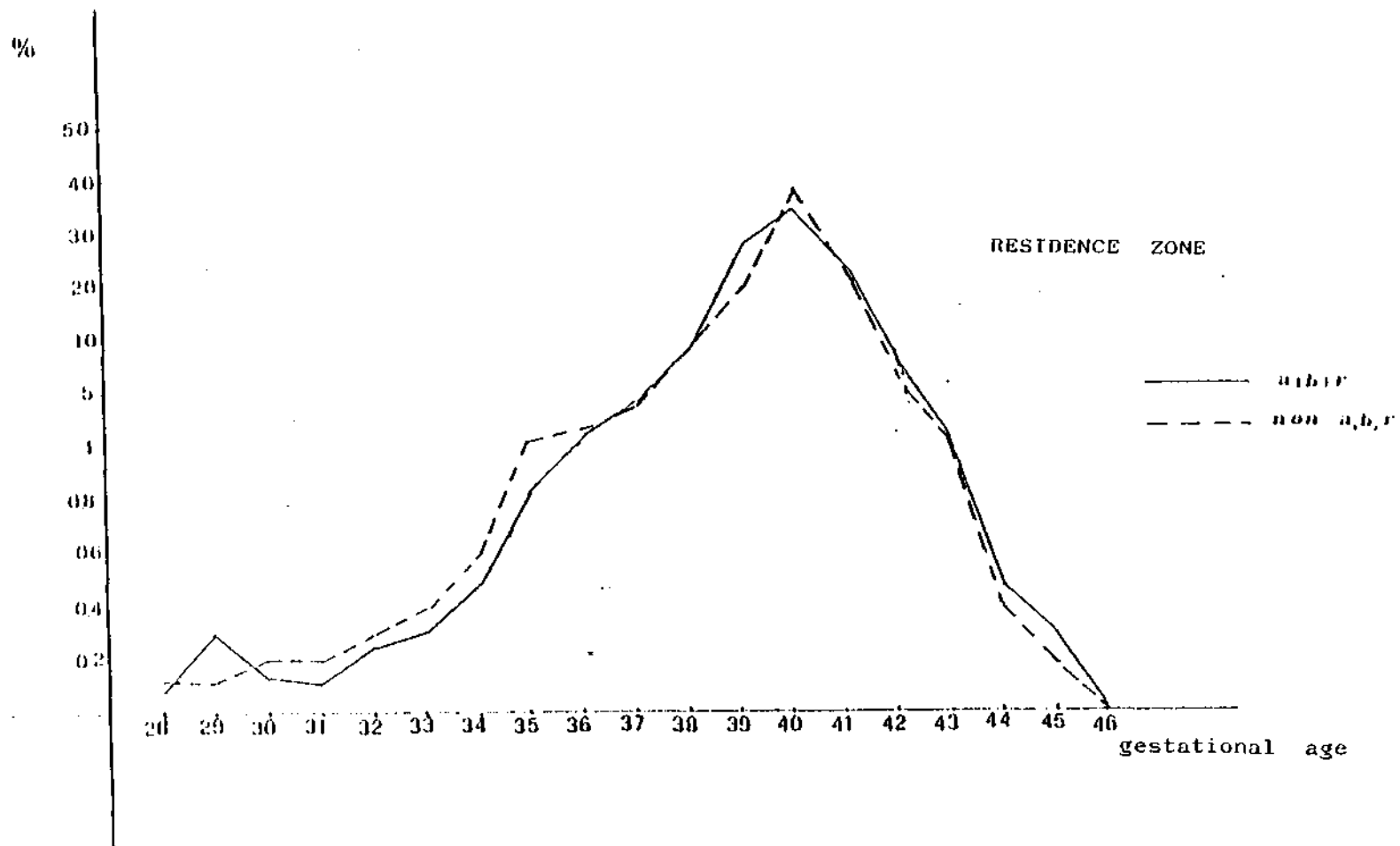
IN ZONES non A+B+R, A+B+R, A+B, R

— non A+B+R
- - - A+B+R
- - - R
- - - A+B



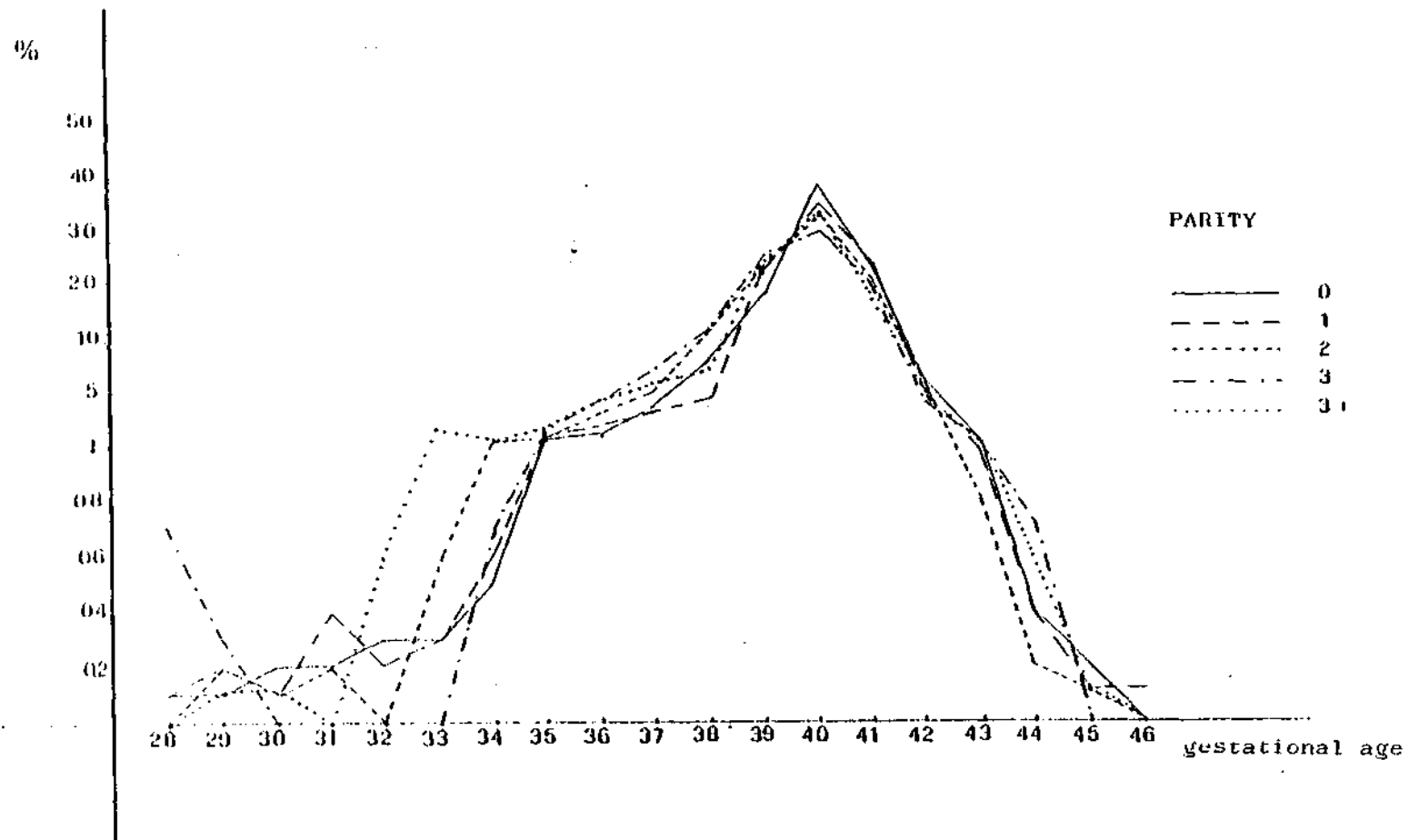
Graph 2

DISTRIBUTION OF DELIVERIES BY GESTATIONAL AGE AND RESIDENCE ZONE



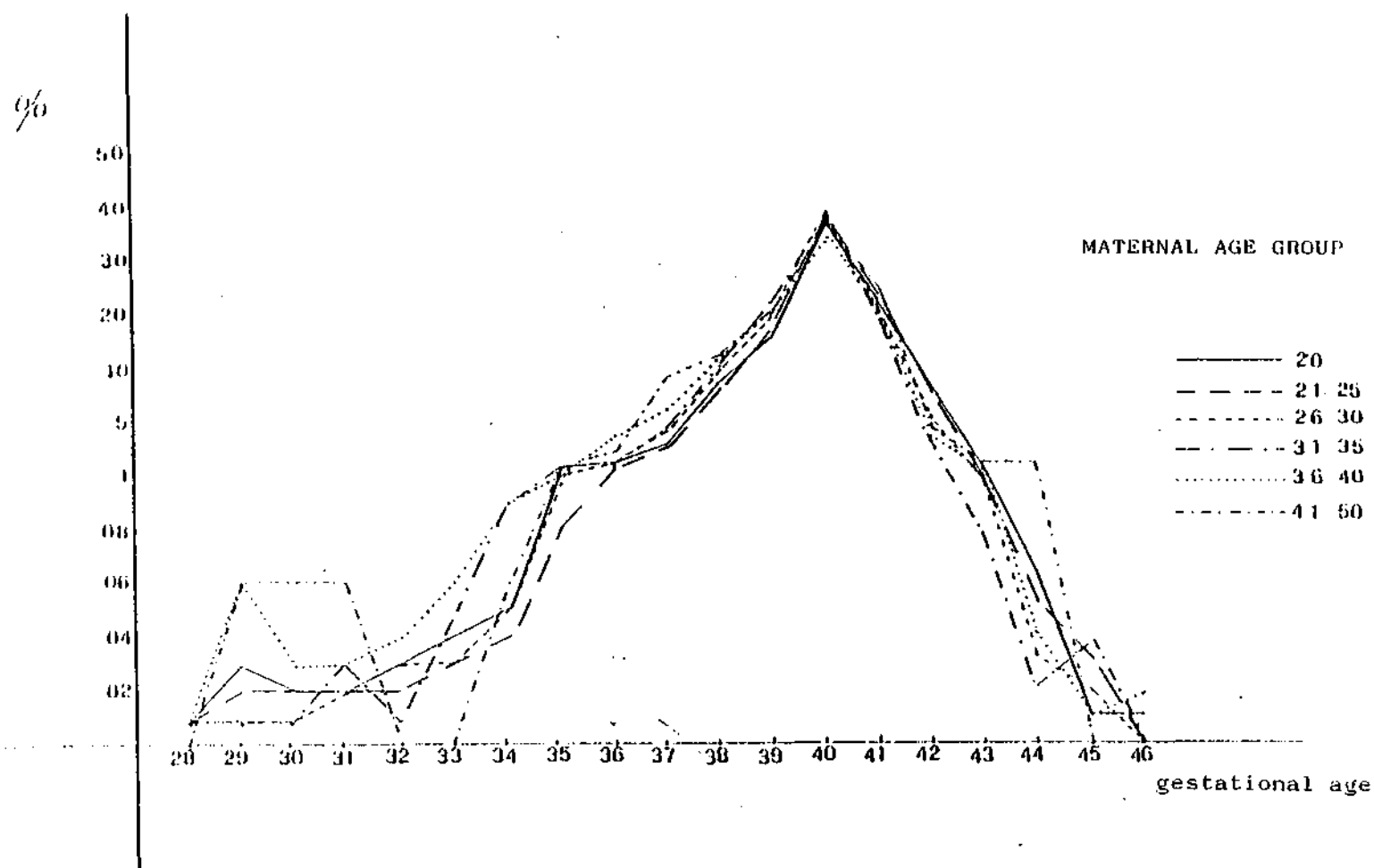
Graph 3

DISTRIBUTION OF DELIVERIES BY GESTATIONAL AGE AND PARITY



Graph 4

DISTRIBUTION OF DELIVERIES BY GESTATIONAL AGE AND MATERNAL AGE GROUP



light

Graph 5

5th PERCENTILE

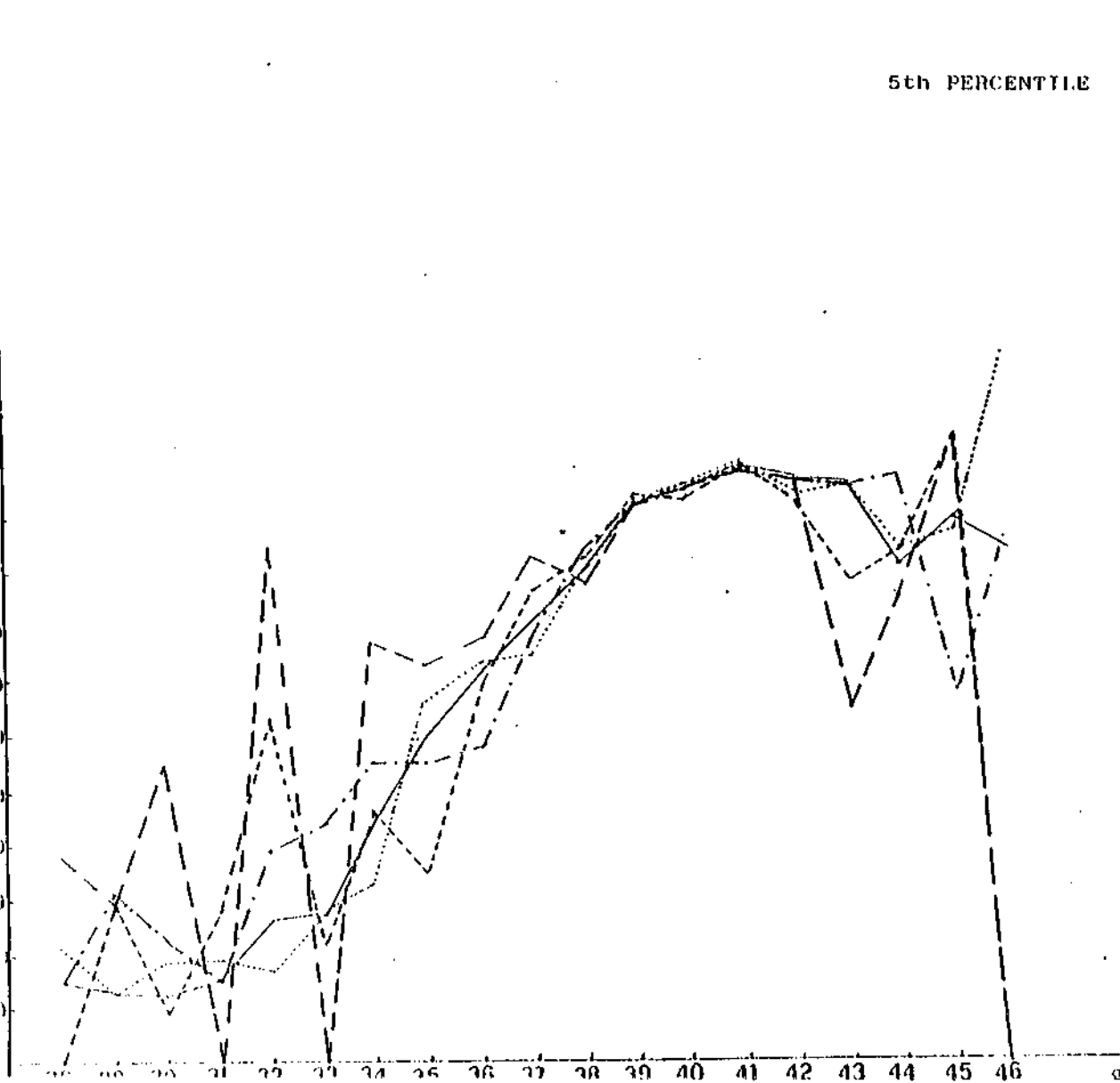
4400
4200
4000
3800
3600
3400
3200
3000
2800
2600
2400
2200
2000
1800
1600
1400
1200
1000
800

—— total
- - - A₁B₁R⁺
- - - A₁B₁R⁻
- · - non A₁B₁R⁺
····· non A₁B₁R⁻

· born up to 1/7/76

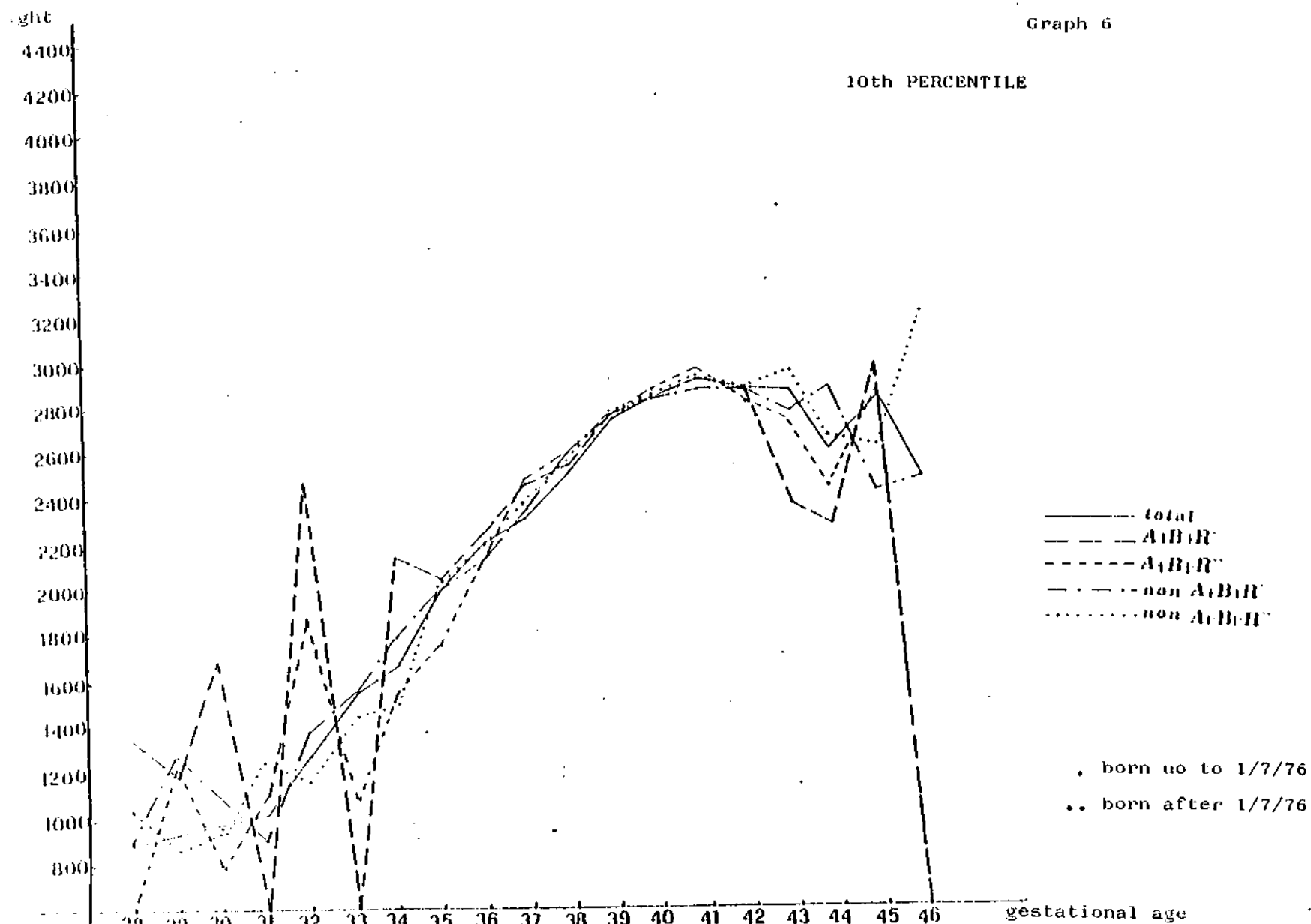
·· born after 1/7/76

gestational age

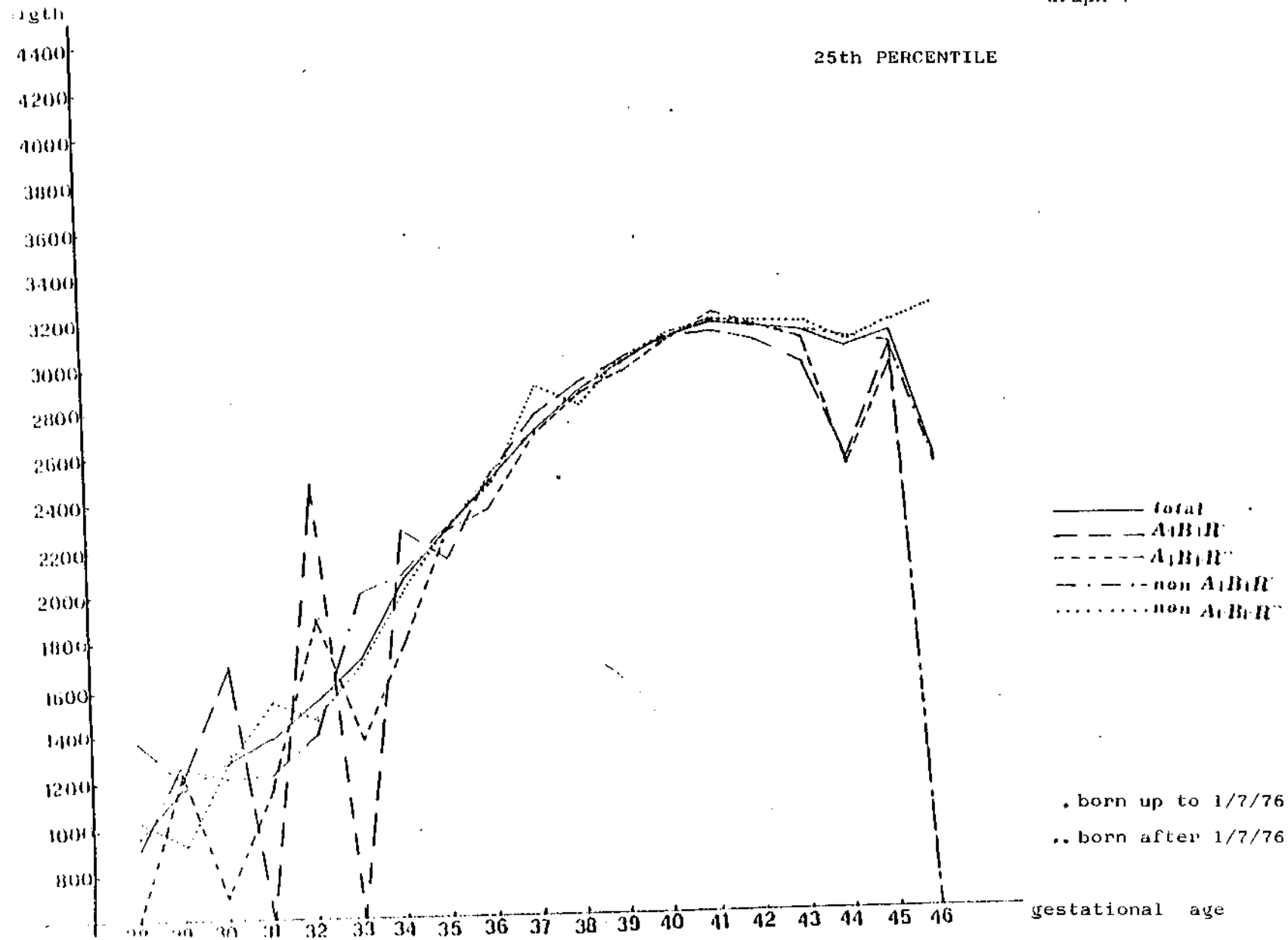


Graph 6

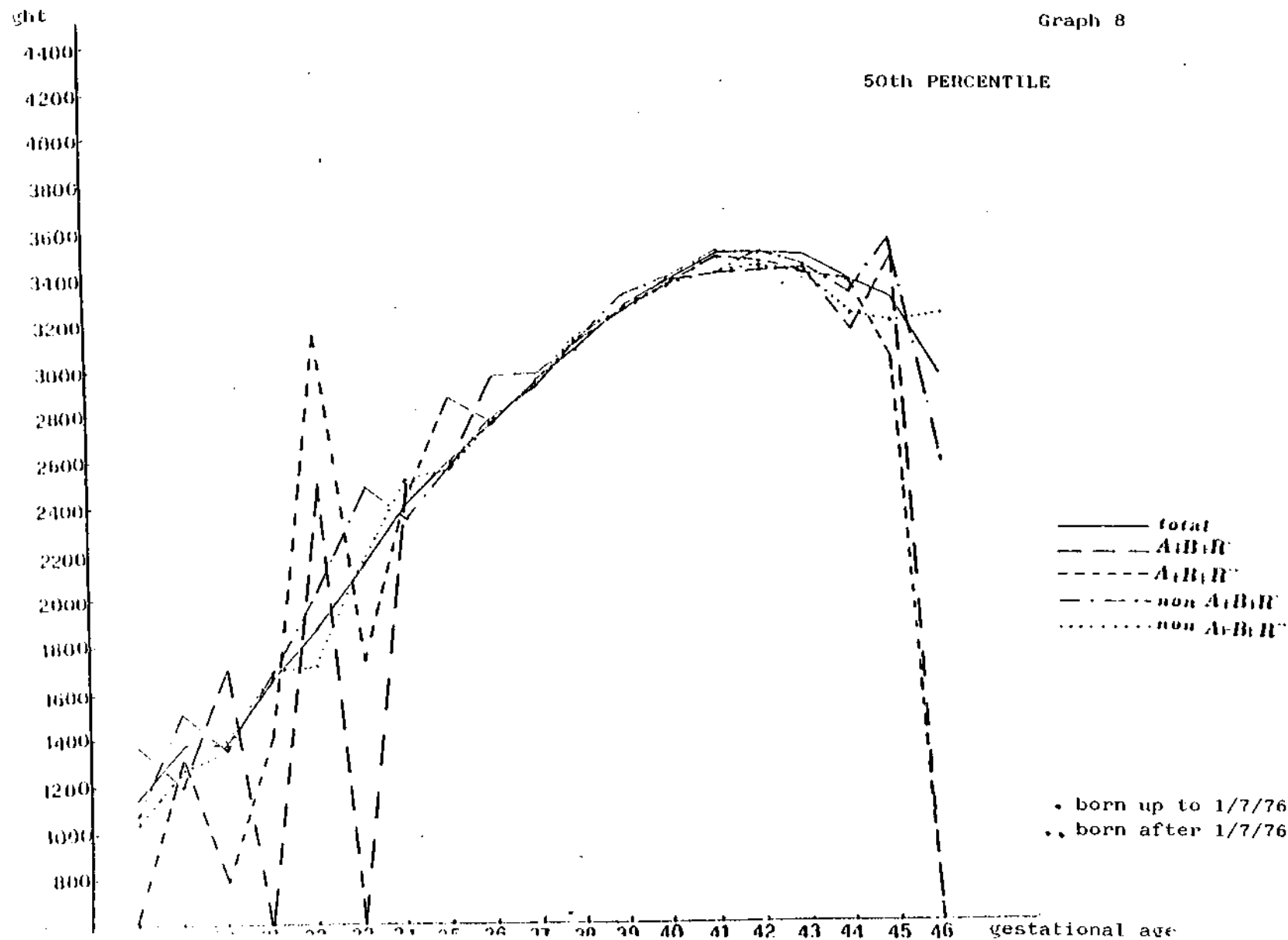
10th PERCENTILE



Graph 7



Graph 8



weight

Graph 9

75th PERCENTILE

