Incidence at birth and natural history of cryptorchidism: A study of 10,730 consecutive male infants

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ABSTRACT. Of the 10,730 neonates born in the period 1978-1997 and examined for cryptorchidism (C) at birth, 1387 were pre-term (gestational age <37 wk), and 9343 were full-term. At birth, a total of 737 neonates (6.9%) were cryptorchid, 487 had bilateral C and 250 unilateral C. The C rate of pre-terms was 10 times higher than that of the full-terms (30.1 and 3.4%, respectively). Comparing the two studied decades, a significant decrease of C rate was found in the second decade in full-term neonates. The rates of C at birth were significantly elevated for low birth weight, babies born from mothers with an age <20 or >35 yr, newborns from mothers with A Rh positive and B Rh positive blood group. Of the 737 cryptorchid newborns at birth, 613 (83%) were re-examined after 12 months from the expected date of delivery, and those born in the period 1988-1997 were also re-evaluated at 6 months of life. Late spontaneous descent occurred in 464 cases (75.7%), while 149 (24.3%) were still cryptorchid. The incidence of C at 12 months from the expected date of delivery, after survival curve calculation, in term and pre-term infants, was 1.53 and 7.31%, respectively, in the period 1978-1987, and 1.22 and 3.13% respectively, in the 2nd decade (1988-1997). In the groups also examined at 6 months of life, spontaneous descent occurred almost completely within the first 6 months of life in term infants, but not in pre-terms. No evidence of seasonal cyclicity was found. Medical and/or surgical treatment was generally started within 2-4 yr of age earlier in the second decade of the study. In conclusion, the main risk factor for C at birth and at 12 months of life seems to be preterm birth and low birth weight. If this is associated itself to a higher risk of infertility too, it remains to be defined.

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INTRODUCTION

Cryptorchidism (C), the maldescent into the scrotum of one or both testicles, is the most common disorder of the urogenital trait in males, and it takes important socio-medical significance because it is frequently associated to a higher risk of infertility and testicular cancer (1-6). C affects 3-5% of all term-born males at birth and up to 23% of pre-term or low birth-weight male infants (7-10). The overall rate of C declines to around 1% by the age of 1 yr because of the spontaneous late descent (7, 9-11). If on the one hand there is wide consensus about the fact that undescended testes should be replaced into the scrotum (by hormonal and/or surgical treatment) by the end of the 2nd yr of life (12), because at this age significant histological alterations could still occur (13-15), on the other hand there is no clear evidence that these precocious treatments are able to modify the natural history of C (1, 16, 17). A study by Scorer of some 3600 infants born in London in the early 1960s found that the incidence of undescended testis was about 0.8% at the age of 1 yr (7). Since there are no recent data about the incidence of C in Italy, in this study we evaluated the rate of C at birth, at 6 months and at 12 months of life, and the potential risk factors associated to C at birth and the absence of late spontaneous descent.

METHODS

All the male infants born between 1st January 1978 and 31st December 1997 in the S. Chiara Hospital of Pisa and admitted to the Division of Neonatology of University of Pisa were included in the study. The male infants born in other hospitals and admitted to the Division of Neonatology at the University of Pisa were also con-

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Table 1 - *Cryptorchidism at birth: boys examined at the Division of Neonatology of the University of Pisa between January 1978 and December 1997.*

Gestational age (weeks)	Male newborns examined at birth	Cryptorchid newborns at birth		
		No.	Rate (%)	
<37	1387	418	30.1	$p<0.001$
≥37	9343	319	3.4	
Total	10,730	737	6.9	

sidered for the study. Among the 10,730 neonates recorded, considering both the twins and the singletons, 1387 (12.9%) were pre-term [gestational age (GA) <37 wk] and 9342 (87.1%) were full-term (GA 37-41 wk). All the neonates with C were included in the study, meaning for cryptorchid the testis which was permanently out from the scrotum or that, manipulated into the scrotum, went up immediately out of the scrotum without tension being applied. The abnormal position of each testis was classified as follows: 1) non-palpable; 2) inguinal, palpable; 3) pre-scrotal, palpable; 4) ectopic, localized out of the pathway of normal anatomical descent. Newborns with multiple congenital malformations were not examined as part of the study. Cryptorchid boys were examined at birth, during the first yr of life, 1 yr after their expected date of delivery, and at 2-21 yr of age, by one of four pediatricians involved in this study (P.G., M.F., L.G., A.B.). We assessed the rate of C at birth, the rate of children with late spontaneous testes descent, the rate of C 12 months after the expected date of delivery, and finally, the time of medical and/or surgical treatment. The infants with C born in the period 1988-1997 were also examined at 6 months of life. Moreover, we verified among the eligible boys if any perinatal characteristics [(pre-maturity, birth weight, intrauterine growth restriction (IUGR)], and/or maternal factors (age, blood group, diseases during pregnancy) could be considered as potential risk factors for undescended testicles at birth and absence of late spontaneous descent. We considered IUGR a birth weight below the 3rd percentile according to the neonatal standards of Pedrotti *et al.* (18). Statistical comparisons were made by Chi-square test (χ^2) and Z test. Analysis of follow-up data was made by Kaplan-Meier method and log-rank test was applied to compare survival curves (19). Seasonality of cryptorchid births was calculated by the method of Walter and Elwood (20).

RESULTS

Of the 10,730 eligible boys, 737 (6.9%) were found to have one or both testes undescended at birth (Table 1).

Perinatal characteristics

The incidence of C was higher in pre-term than in full-term newborns (30.1 and 3.4%, respectively) with a significant difference ($p<0.001$). Table 2 shows that, at birth, the overall rate of C in full-term newborns had declined significantly in the 2 studied decades (1978-1987 and 1988-1997), with a lower decrease in pre-term infants. The C rate at birth decreased progressively with the increase of GA, being 84.7% in babies below the 28th wk of GA, and 3.4% in full-term newborns (Table 3). In pre-term infants, bilateral C (BC) was predominant at each GA. Considering the unilateral C (UC), left undescended testis was more easily discovered at examination between the 28th and the 32nd wk of gestation, while, after the 35th wk of GA, the right one was found more undescended. In full-term infants, a BC rate of 48% (153/319) was found, while 52% of term infants (166/319) showed UC (Table 4). Familial C among the first and second-degree relatives was found in about 25% of the children cryptorchid at birth.

With regard to the relationship between birth weight and C, a higher incidence of C (87.6%) was found in very low birth weight newborns weighing ≤900 g. The incidence of C was higher in boys with IUGR than in appropriate for gestational age (AGA) boys, with a significant difference ($p<0.01$) (Table 5).

Maternal factors

Maternal age

The rate of C at birth was significantly higher in babies born from mothers with an age below 20 or above 35 yr ($p<0.02$ and $p<0.03$, respectively), than in those born from mothers of 20-35 yr (Table 6).

Maternal blood group

Regarding the correlation between C and the more frequent maternal blood groups (Table 7), we found a higher significant incidence of undescended testes in babies born from A Rh positive (+) and B Rh+ mothers than those born from mothers with a 0 Rh+ blood group (Table 7).

Maternal diseases

Metrorrhagia during pregnancy was the maternal disease more frequently associated with cryp-

Table 2 - *Overall rate of cryptorchidism at birth, both in full-term and pre-term newborns in the 2 studied decades.*

Year	No. of male pre-term newborns	Cryptorchid pre-terms			No. of full-term newborns	Cryptorchid full-terms		
		No.	Rate (%)			No.	Rate (%)	
1978-1987	438	140	32.0	NS	4323	184	4.3	$p<0.01$
1988-1997	949	278	29.3		5020	135	2.7	

Table 3 - *Overall rate of cryptorchidism at birth by gestational age.*

Gestational age (weeks)	Newborns examined at birth	Cryptorchid No.	Cryptorchid Rate (%)
≤27	98	83	84.7
28-29	106	68	64.1
30-32	278	111	39.9
33-34	292	78	26.7
35-36	568	78	13.7
≥37	9388	319	3.4

torchidism (18.2%). Gestosis and gestational diabetes in the mother were present in 7.9 and 3.8% of cryptorchid boys, respectively.

Seasonality

The distribution of month of birth of boys with C was examined. There was no evidence for heterogeneity between the months (χ^2_{11}=11.40, p=0.45), even if a peak was observed in October. There was no evidence of seasonality (χ^2_2=0.97, p=0.61).

Follow-up

The infants with C at birth have been re-examined to value the incidence of late spontaneous testes descent, the rate of cryptorchidism 12 months after the expected date of delivery, and the time of medical and/or surgical treatment. The infants with C born in the period 1988-1997 were also examined at 6 months of life. Of the 737 infants with C at birth, 613 have been re-examined. For 77 children, we had controlled information about spontaneous descent or surgical treatment by their general practitioners, 20 very pre-term infants deceased, and finally, for 27 subjects we did not have any definitive information. Of the re-examined infants, 464 (75.7%) had had a late spontaneous descent, while 149 (24.3%) were still C after 12 months from the expected date of delivery. Late spontaneous descent was more frequent in infants born pre-term than in infants born at term (Table 8). The incidence of C at 12 months from the expected date of delivery in term and pre-term infants, obtained after survival analysis, was 1.53 and 7.31, respectively, in the 1st decade (Table 9), and 1.22 and 3.13%, respectively, in 2nd decade (Table 10), significantly higher in pre-term infants (p<0.001). In the groups also examined at 6 months of life, spontaneous descent occurred almost completely within the first 6 months of life in term infants, but not in pre-terms (Table 10). Medical and/or surgical treatment was generally started within 2-4 yr of age, earlier in the second decade of the study (Table 11).

DISCUSSION

Aetiology of C is widely unknown although anatomical and/or genetic factors are involved in some cases (21). An abnormal development of the *gubernaculum*, fetal ligament that leads the testis within the scrotum, and the associated structures can interfere with the normal testicular descent (22-24). Inguinal hernia, that can result from an incomplete closure of the *processus vaginalis*, has been clinically associated with C (25-28). The association between undescended testicles and chromosomal abnormalities is common. C has been reported in Down's syndrome in between 14 and 27% of cases and in 84% of cases of Prader-Willi syndrome (29). Endocrine factors are suspected to play a role in C, and several hypotheses have been suggested, including an absence of stimulation of maternal gonadotropins during the last period of pregnancy, a congenital error of fetal T biosynthesis, disorders of pituitary gland, and elevated abnormal levels of estrogen hormones that can be associated with testicular hypoplasia and consequently with testicu-

Table 4 - *Results of examination for undescended testes at birth by gestational age and laterality.*

Gestational age (weeks)	No. of cryptorchid newborns	Bilateral cryptorchidism No.	Bilateral cryptorchidism Rate (%)	Unilateral cryptorchidism Right	Unilateral cryptorchidism Left
≤27	83	77	92.8	3	3
28-29	68	59	86.8	3	6
30-32	111	85	76.6	10	16
33-34	78	60	76.9	9	9
35-36	78	53	67.9	16	9
≥37	319	153	48	90	76
Total	737	487	66.1	131	119

Table 5 - *Relationship between cryptorchidism and birth weight.*

Birth weight (g)	No. of examined newborns	No. of cryptorchid newborns	Rate(%)	
≤900	81	71	87.6	
901-1200	104	80	76.9	
1201-1500	163	81	49.7	
1501-2000	239	99	41.4	
2001-2499	602	79	13.1	
≥2500	9438	327	3.5	
IUGR	548	94	17.1	$p<0.01$
AGA	10,182	643	6.3	

AGA: appropriate for gestational age; IUGR: intrauterine growth restriction.

Table 6 - *Relationship between cryptorchidism and maternal age on the date of delivery.*

Maternal age (years)	No. of male newborns	No. of cryptorchid newborns	Rate (%)	
<20	239	26	10.9	$p<0.02$
20-35	9315	610	6.5	
>35	1176	101	8.6	$p<0.03$
Total	10,730	737	6.9	

lar descent failure (21, 22, 30, 31). The C rate at birth of 6.9% in our study was higher than in Scorer's (4.3%) (11) and 2 other studies, the John Radcliffe Hospital Cryptorcidism Study (8) and the Mount Sinai Hospital Study (32) (5.01 and 3.68%, respectively). This increased incidence at birth is likely due to the presence of a larger number of pre-term babies in our study. In fact, considering the rate of cryptorchid pre-terms (30.1%), it appears 10 times higher than full-term babies (3.4%). The C rate at birth of both full-term and pre-term babies in the two studied decades decreased significantly in the 2nd decade in full-term babies. Environmental and hormonal factors could be involved. Taking the laterality, BC represents 80% of whole undescended testes in preterms, while its rate decreases to 48% in full-terms. In UC, left sided C is more frequently found below 33 wk of GA, while over 35 wk the right one is more represented. This could mean that, before 32 wk of GA, the right testis precedes the left one during testicular descent, for this reason resulting less frequently cryptorchid, while the higher rate of right UC above 35 wk of GA and in full-term newborns, could mean that an anatomical obstruction or an ectopy occurs more easily on the right side. Low birth weight and preterm birth are factors frequently associated to C; both in our study and in others (11, 25, 26, 33, 34), C rate at birth is about 10 times higher in preterm or in low birth weight newborns than in full-term babies with appropriate weight. Berkowitz *et al.* (32) reported that, at 12 months from the expected date of delivery, C rate is slightly more elevated in low birth weight babies and in preterms. In our study, the incidence of C at 12 months from the expected date of delivery in full-term newborns is slightly more elevated than Scorer's historical values (0.8%) (11), and in preterm babies, although the reduction in absolute value is higher than in full-term newborns, the incidence remains in any case, about 2-3 times higher than full-term ones. The higher incidence of C at 1 yr, after survival analysis, in pre-term infants during the first studied decade compared with the second decade data is probably due to a higher number of cryptorchid babies lost during the follow-up. It is possible that factors connected to pre-term birth are at the roots of a higher risk of C at 12 months of life. This aspect seems to be important because the same factors that eventually cause a higher risk of C at 12 months from the expected date of delivery in preterm newborn could associate to a higher risk of

Table 7 - *Relationship between cryptorchidism and maternal blood group.*

Maternal blood group	No. of male newborns	No. of cryptorchid newborns	Rate (%)	
A Rh+	3357	243	7.2	
A Rh-	524	31	5.9	
B Rh+	856	69	8.1	$p<0.03$
B Rh-	112	7	6.2	$p<0.03$
0 Rh+	3606	207	5.7	
0 Rh-	543	41	7.5	
AB Rh+	336	20	5.9	
AB Rh-	49	2	4.1	

Table 8 - *Cryptorchid infants 12 months after the expected date of delivery.*

	Re-examined	Late spontaneous descent		Cryptorchid infants	
Pre-terms	326/418 (78%)	294 (90.2%)	UC 63 BC 231	32 (9.8%)	UC 15 BC 17
Full-terms	287/319 (90%)	170 (59.2%)	UC 79 BC 91	117 (40.8%)	UC 75 BC 42

BC: bilateral cryptorchidism; UC: unilateral cryptorchidism.

Table 9 - *Examination at birth and 12 months after the expected date of delivery of cryptorchid infants born in the first decade (1978-1987).*

Gestational age (weeks)	Male newborns examined at birth	Cryptorchid newborns			
		At birth		12 months*	
		No.	Rate (%)	No.	Rate (%)
<37	438	140	32	8	7.31°
≥37	4323	184	4.3	60	1.53°°

*After 12 months from the expected date of delivery.°Nine very pre-term infants deceased; 48 infants declared by their family pediatrician as having descended testes; for 15 infants we did not have definitive information about cryptorchidism. °°Nineteen infants declared by their family pediatrician as having descended testes; for 6 infants we did not have definitive information about cryptorchidism.

infertility and/or testicular neoplasia, also in an independent manner from the evolution of C in itself. The association between C at birth and maternal age on the date of delivery below 20 and above 35 yr could lead to a relative hormonal insufficiency that occurs at the extremes of the reproductive age. Nevertheless, considering the children always cryptorchid after 1 yr of life, there is no association with maternal age. This suggests that the possible maternal hormonal insufficiency at the roots of the C at birth associates, in the major part of the cases, with late spontaneous descent, probably because the hypothalamic-pituitary-gonadal axis of the newborn is normal and produces a normal T increase in the first months of life. With regard to the maternal blood group, A Rh+ and B Rh+ groups are significantly associated with a higher frequency to C at birth. However, cryptorchid babies without late spontaneous descent did not show any association with a maternal blood group. These data are partly in accordance with the results of Swerdlow *et al.* (25). With regard to maternal diseases during pregnancy, we found that babies with C at birth

Table 10 - *Examination at birth, at 6 months, and at 12 months after the expected date of delivery of cryptorchid infants born in the second decade (1988-1997).*

Gestational age (weeks)	Male newborns examined at birth	Cryptorchid newborns					
		at birth		6 months		12 months*	
		No.	Rate (%)	No	Rate (%)	No.	Rate (%)
<37	949	278	29.3	77	9.27°	22	3.13°°
≥37	5020	135	2.7	61	1.22§	59	1.22§§

*After 12 months from the expected date of delivery. °Eleven very pre-term infants deceased. °°Five infants who left the area declared by their family pediatrician as having descended testes; for 4 infants we did not have definitive information about cryptorchidism. §Three infants who left the area declared by their family pediatrician as having descended testes. §§Two infants who left the area declared by their family pediatrician as having surgical treatment in the 2nd year of life; for 2 infants we did not have definitive information about cryptorchidism.

Table 11 - *Time of medical and/or surgical treatment in infants followed after 1 year of age.*

Years	Cryptorchid infants at 1 year of age	Medical and/or surgical treatment					
		at 1-2 years		at 2-4 years		after 4 years	
		No.	Rate (%)	No.	Rate (%)	No.	Rate (%)
1978-1987	68	7	10.3	41	60.3	20	29.4
1988-1997	81	28	34.6	44	54.3	9	11.1

are frequently born from mothers that have had metrorrhagia and, with lower degree, gestosis during pregnancy. This correlation could be justified by the fact that both metrorrhagia and gestosis are frequently associated to pre-term birth and so to a higher probability of showing C at birth. Diabetes mellitus has been reported in some studies to be associated to a higher risk of C. In our cases, when it is associated to C, it seems to occur more frequently in cryptorchid full-term babies. Follow-up has shown that late spontaneous testicular descent has been over 3 times more frequent in pre-term babies with BC than in pre-term babies with UC or full-term infants with UC or BC. With regard to seasonal cyclicity, this has been found in a number of studies although with remarkable differences regarding the months with the peak of incidence: September (8), January-March (33), and October-November (35); other studies do not report any seasonal cyclicity. In our study, we did not observe a seasonal variation in the incidence of C, even though a peak of cryptorchid births was found in boys born in October. The differences among several studies could be due to regionally different climate conditions. These could influence the maternal hormonal secretions and/or T secretion of fetus and neonate in the first months' life causing C. Medical and/or surgical treatment was generally started within 2-4 yr of age, earlier in the second decade of the study. However, although there is no reason to wait and not treating a cryptorchid boy during the second yr of life, on the other hand there is no clear evidence that a precocious treatment is able to modify the natural story of C.

In conclusion, the main risk factor for C at birth and at 12 months of life seems to be pre-term birth and low birth weight. Whether this in itself is also associated to a higher risk of infertility remains to be defined.

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