African Journal of Urology (2016) **22**, 183–188

African Journal of Urology

Official journal of the Pan African Urological Surgeon's Association
web page of the journal

www.ees.elsevier.com/afju
www.sciencedirect.com

Pediatric Urology
Original article

The incidence of apparent congenital urogenital anomalies in North Indian newborns: A study of 20,432 pregnancies

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Received 15 April 2015; received in revised form 15 May 2015; accepted 18 May 2015
Available online 18 July 2016

KEYWORDS
Congenital anomalies;
Hypospadias;
Epispadias;
Exstophy bladder;
Hydrocele;
Cryptorchidism;
Exstrophy–epispdias;
Prune belly syndrome;
Ambiguous genitalia

Abstract
Introduction and objectives: Over the last few decades, congenital anomalies of the urogenital system have increased globally as a consequence of advanced maternal age at pregnancy and developments in assisted reproductive techniques. The aim of this study was to determine the incidence of apparent congenital urogenital anomalies in North Indian newborns and the causative factors.
Subjects and methods: The data of all newborns delivered at our institute between September 2012 and August 2014 were collected for this prospective study. The predetermined data format included the newborns' birth weight and gestational age, the maternal age, parity and infertility treatment, if any. Newborns weighing less than 1000 g or born before 32 weeks of gestation were excluded from the study.
Results: During the study period, 20,432 deliveries were recorded (10,952 male and 9480 female babies). Apparent urogenital congenital anomalies were diagnosed in 799, with an incidence of 39.1 per 1000 newborns. The most common anomaly was cryptorchidism found in 678 newborns, while hypospadias was noted in 61, ambiguous genitalia in 34, congenital hernia/hydrocele in 20 and an exstrophy–epispadias complex in 5 children. Prune belly syndrome was seen in 1 newborn. Newborns weighing less than 2500 g had a higher proportion of anomalies (9.64%) in comparison to those weighing over 2500 g (1.99%) ($p = 0.0001$). A maternal age >30 years, parity >2 and infertility treatment were recorded in 5.40%, 4.93% and 9.80%, respectively, and all were independently associated with an increased risk of urogenital anomalies ($p = 0.0001$).

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Peer review under responsibility of Pan African Urological Surgeons' Association.

http://dx.doi.org/10.1016/j.afju.2015.05.007

Conclusions: The incidence of apparent congenital urogenital anomalies was 3.91%. Infertility treatment, parity >2 and a maternal age >30 years were independently associated with an increased risk of congenital urogenital anomalies.

Introduction

According to the WHO, the term "congenital anomalies" should be confined to structural defects present at birth. External risk factors have been well established and can be avoided, yet, the exact etiology of congenital anomalies remains unknown. A general surveillance program, carried out since 1960 in order to monitor the incidence of congenital anomalies in various populations around the world, has shown birth prevalence of congenital anomalies to vary significantly from country to country [1]. These variations are due to social, racial, ecological and economic factors [2,3]. Congenital anomalies contribute significantly to preterm birth and are a leading cause of fetal death, as well as of childhood and adult morbidity. Congenital anomalies have increased globally in the last few decades due to advanced maternal age at pregnancy and developments in assisted reproductive techniques. Studies suggest that the use of fertility drugs and progesterone support in pregnancy increase the risk of premature birth, small for gestational age embryos and birth defects [4–6]. An advanced maternal age at pregnancy and a parity $\geq$2 are known risk factors for congenital urogenital anomalies. It has also been found that there is a higher incidence of congenital anomalies in male compared to female children and in children with a below-normal birth weight at delivery [7]. The most common congenital urogenital anomalies mentioned in the literature are undescended testis in 1–4% of full term and 1 to 45% of preterm male newborns [8,9], hypospadias in 3–5/1000 live births [10], exstrophy–epispadias complex in 1/10,000–50,000 live births [11], prune belly syndrome in 1/29,000–40,000 live births [12] and congenital inguinal hernia/hydrocele in 1.2% [13]. In an epidemiological study carried out in Germany, the incidence of ambiguous genitalia was found to be 2/10,000 births per year. [14]

It is important to know the distribution and incidence of various congenital anomalies for every country and even for every community. To improve the quality of life, early recognition of correctable anomalies is essential to make sure that they can be treated in time. This prospective study was carried out in order to determine the incidence of various apparent congenital anomalies of the urogenital system in North Indian newborns and to identify probable risk factors leading to the same.

Subjects and methods

For this prospective cohort study, we collected the data of all newborns delivered at our institute between September 2012 and August 2014. After clearance from the institution's Ethical Committee and obtaining the informed consent from the parents, all newborns were examined clinically by a trained pediatric and urology resident right after birth and before discharge from the hospital. Neonates with recognized anomalies were re-examined for confirmation by a consultant urologist. The predetermined format for data collection included the newborns' birth weight and gestational age as well as information on the mothers such as age, parity and infertility treatment, if any (clomiphene citrate, progesterone or any other drug), and any previous history of a malformed baby. To keep the study sample representative of the normal population, newborns with a birth weight of less than 1000 g and/or born before 32 weeks of gestation were excluded as these children are known to have a higher incidence of anomalies in comparison to full-term babies.

Cryptorchidism was defined as the absence of one or both testes in the scrotum. The presence of a retractile testis was excluded. Hypospadias was defined as the presence of an abnormal ventral opening of the urethral meatus with dorsal hooding. Genital phenotypes where the external genitalia did not have the typical appearance of either a boy or a girl were considered as ambiguous and were mainly divided in male or female predominant genitalia. Male predominant genitalia included proximal hypospadias with no palpable gonads and hypospadias with micropenis, no palpable gonads or one palpable gonad. Female predominant genitalia were considered in newborns with female external genitalia and a gonadal mass in the labia or labial fusion and/or clitoral enlargement. Exstrophy–epispadias, cloacal exstrophy, superior vesical fissure, classical exstrophy and epispadias were noted as per the standard definitions. Congenital inguinal hernia/hydrocele were defined as translucent inguinal/inguinoscrotal swelling with cough impulse.

The incidence of hypospadias, undescended testis and congenital hernia/hydrocele was calculated using live male births as denominator, but the incidence of exstrophy–epispadias complex, prune belly syndrome, ambiguous genitalia and the overall incidence of apparent congenital urogenital anomalies were calculated per total live births. The Chi-square test was used for comparative analysis, while logistic regression analysis was used to determine independent factors predictive of reproductive disorders, with a p value <0.05 considered as statistically significant. All statistical analyses were performed using the SYSTAT software.

Results

In total, 20,432 deliveries (10,952 males and 9480 females) were registered during the study period. The sex ratio was 866 female per 1000 male children. In 34 newborns the sex could not be determined, and these infants were considered as having ambiguous genitalia. The incidence of congenital urogenital anomalies was 39.1 per 1000 births (3.91%; $n = 799$). The most common urogenital anomaly was undescended testis seen in 678 babies, followed by hypospadias diagnosed in 61 and congenital hernia/hydrocele in 20 children. An exstrophy–epispadias complex was found in 5 children with one patient having isolated epispadias. Only one child had prune