

BMJ Open Early detection of congenital anomalies of the kidney and urinary tract: cross-sectional results of a community-based screening and referral study in China

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To cite: Gong Y, Zhang Y, Shen Q, *et al.* Early detection of congenital anomalies of the kidney and urinary tract: cross-sectional results of a community-based screening and referral study in China. *BMJ Open* 2018;**8**:e020634. doi:10.1136/bmjopen-2017-020634

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2017-020634>).

Received 14 November 2017
Revised 18 March 2018
Accepted 19 April 2018



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ABSTRACT

Objective To establish an effective screening model of congenital anomalies of the kidney and urinary tract (CAKUT) using ultrasound among neonates in Shanghai, China.

Design Cross-sectional study.

Setting A three-level screening model for CAKUT in neonates based on the child healthcare system was established since 2010 in Minhang District, Shanghai, China.

Participants During 2010–2015, neonates with criteria such as preterm, low birth weight and so on were eligible to participate in the study. Cases with renal pelvis dilatation (RPD) and other abnormal renal findings were managed based on presumed strategies.

Main outcome measures The proportion of RPD and other renal and urinary tract anomalies; number of diagnosed CAKUT under integrated management, especially obstructive uropathy. The anterior–posterior renal pelvic diameter (APRPD) cut-off points for likelihood of obstructive uropathy and need for surgery.

Results A total of 8827 infants were consecutively screened. Absolute and relative rates of different degrees of RPD classified by APRPD were: mild (5–9.9 mm), 984 (11.1%); moderate (10–14.9 mm), 176 (2.0%); severe (≥ 15 mm), 20 (0.2%). Of 639 followed cases with RPD, 11 were diagnosed as obstructive uropathies. Of these, nine patients underwent surgery, at median age 2 months. A total 85.4% of mild, 62.5% of moderate and 30.0% of severe RPD cases resolved spontaneously. Other renal and urinary morphological abnormalities were diagnosed in 15 (0.2%) patients. The APRPD cut-off points for significant obstructive uropathy and need for surgery were 9.7 mm and 13.5 mm, respectively.

Conclusions This three-level screening model is an effective and feasible strategy for early detection and intervention of CAKUT in the early postnatal period, especially for patients with high-grade RPD and other renal and urinary malformations. This strategy could be useful in China and other developing areas with limited medical resources.

INTRODUCTION

Congenital anomalies of the kidney and urinary tract (CAKUT) are common

Strengths and limitations of this study

- This is the first regional community-based screening programme of congenital anomalies of the kidney and urinary tract (CAKUT) among neonates in China.
- A large, nearly population-based study, nested within an organised screening and referral programme that emphasised hierarchical management of renal pelvis dilatation (RPD), for early detection and intervention of obstructive uropathy in the early postnatal period.
- Integration of medical resources promoted management of CAKUT in district-level hospitals.
- Our efforts to characterise the outcome of RPD were limited by the loss of nearly half of the cases with mild to moderate RPD, which prohibited us from drawing objective inferences.

anomalies detected prenatally, accounting for approximately 20%–30% of all prenatal anomalies and occurring in 3–6 per 1000 live births.¹ CAKUT is considered the leading cause of chronic kidney disease (CKD) in children² and can lead to end-stage renal disease (ESRD) in adults.³

Most children with CAKUT are diagnosed prenatally in developed countries,^{4,5} largely because of the widespread use of fetal ultrasonography. Recently, postnatal ultrasound screening has been reported to be a useful method in the early detection and intervention of CAKUT,^{6–9} as this technique can confirm abnormalities detected in the fetus and it can detect undiscovered abnormalities during the prenatal period,^{5,10} which may minimise renal damage and thereby improve quality of life.

It has been reported that the occurrence of CAKUT is associated with small gestational age, maternal gestational diabetes, oligohydramnios, maternal age and so on.^{11–13} Melo *et al*¹⁴ also identified prematurity, low

birth weight, oligohydramnios and CAKUT with renal involvement as independent risk factors for early mortality in patients with CAKUT.

Health checks of infants are obligatory according to the 'rules of systematic health check-ups for children 0–6 years old in Shanghai (on trial).' Newborns are visited at about 2 weeks of age by specialised nurses from local community health centres (CHCs) and parents are informed to build health records. The first infant health check is performed at about 1 month of age in a local CHC, then systematic health checks are regularly conducted up to age 6 years. CHCs and secondary hospitals (mostly maternal and child healthcare (MCH) hospitals) play vital roles in this public child healthcare network. CHCs are considered the basic network of public health surveillance and medical services, such as basic health checks and health education. However, limited medical training among staff at CHCs leads to a lack of recognition of CAKUT and CKD. Secondary hospitals are committed to guaranteeing the health of local children as they have more adequate equipment. However, staff at secondary hospitals lack experience in managing specific paediatric diseases, like CAKUT. Hence, it is imperative to propose a useful strategy to improve this situation and make rational use of medical resources.

In the current study, we established a novel three-level screening model, composed of CHCs for identification of screening candidates, the district MCH hospital for ultrasound screening of CAKUT and the tertiary hospital, Children's Hospital of Fudan University (CHFU), for specific diagnosis and intervention. In addition, CHFU provided training for staff of the CHCs and district MCH hospital. We conducted postnatal urinary ultrasound screening and management of CAKUT based on this model in Shanghai, China.

STUDY PARTICIPANTS AND METHODS

Screening model and study design

Minhang District in Shanghai, with a population of 2.5 million and around 30 000 births per year, was selected to establish this novel screening model. The model was based on the child healthcare system and is summarised in figure 1. The model comprised the CHCs for identification of screening participants; the district hospital, Minhang MCH hospital, for urinary tract ultrasound screening of CAKUT and follow-up; and the tertiary hospital, CHFU, for specific diagnosis and intervention; we referred to this structure as a three-level network.

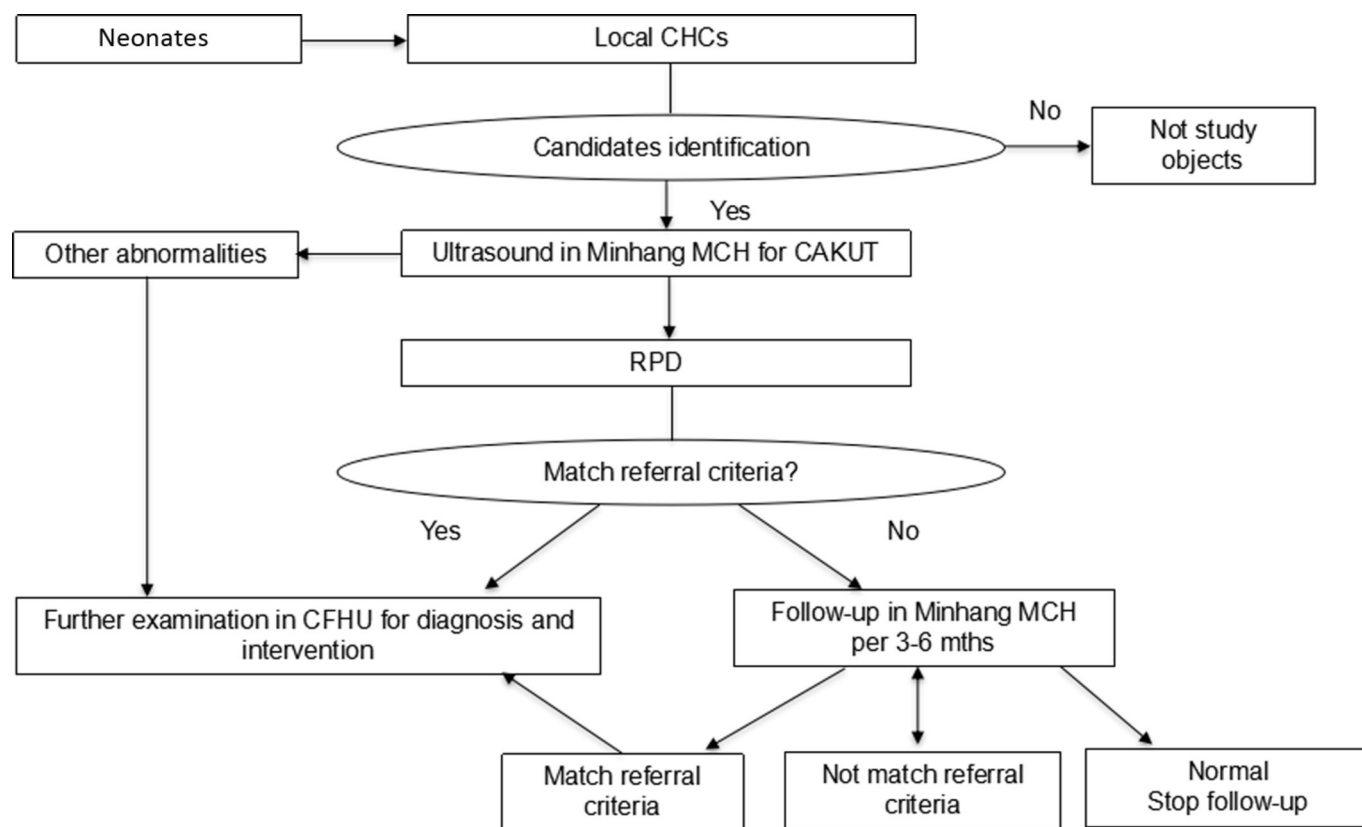


Figure 1 Procedure of the three-level screening model for congenital anomalies of the kidney and urinary tract (CAKUT) in the early postnatal period in Shanghai, China. Other abnormalities: other renal and urinary malformations, including renal agenesis, renal hypoplasia/dysplasia, multicystic dysplastic kidney, ectopic kidney, polycystic kidney, horseshoe kidney, double renal pelvis, megaureter and so on, except renal parenchyma calcification or renal calculus. CHCs, community health centres; CHFU, Children's Hospital of Fudan University; Minhang MCH, Minhang maternal and child health hospital; RPD, renal pelvic dilation.

To propose a screening strategy suitable for low/middle-income countries with a large population, we carried out a cross-sectional ultrasound screening for CAKUT based on the three-level network in neonates, with certain criteria for priority screening, listed in box 1.

Study participants

All neonates who met the criteria (box 1) were theoretically eligible to participate in the study, conducted from September 2010 to September 2015. Participants were identified in local CHCs when they were first registered, at about 1 month. Identified neonates were then transferred to Minhang MCH hospital for urinary ultrasound screening. Allowance was made for conducting ultrasound screening at up to 3 months of age, to ensure that the vast majority of neonates were examined.

Informed consent was obtained from all parents or guardians before all procedures in this study.

Test methods and classification

Ultrasound tests were carried out by ultrasonographers at Minhang MCH hospital. Each year, these staff receive 1-week training, including practice and specialised lecture courses, taught by professional ultrasonographers at CHFU. All study participants were screened using a GE Voluson 730 scanner (GE Healthcare, Little Chalfont, UK) with a 5–7 MHz convex-type transducer. Recordings consisted of six bilateral renal images,⁸ including one longitudinal and two transverse images obtained in the supine position. The anterior–posterior renal pelvic diameter (APRPD) was measured on transverse images of the kidneys, to evaluate the severity of renal pelvis dilatation (RPD). The urinary bladder was also observed in the supine position. Images were recorded when abnormalities were identified.

The following indexes were measured and obtained via ultrasonography: (1) number, size and location of kidneys, (2) RPD and caliectasis, (3) echogenicity and (4) other positive findings indicating cysts or tumours. The shape and wall thickening of the urinary bladder, as well as ureterectasis (inner diameter of the ureter ≥ 5 mm) were also recorded.

Box 1 Criteria for priority screening

Criteria

- ▶ Low birth weight (birth weight less than 2500 g).
- ▶ Macrosomia (birth weight more than 4000 g).
- ▶ Premature delivery (gestational weeks less than 37 weeks).
- ▶ Oligohydramnios.
- ▶ Malposition/cephalopelvic disproportion.
- ▶ Pregnancy at advanced age (more than 35 years old).
- ▶ Gestational diabetes mellitus.
- ▶ Gestational hypertension syndrome/proteinuria.
- ▶ Intracranial haemorrhage or infection.
- ▶ Neonatal hyperbilirubinaemia.

RPD was defined as APRPD ≥ 5 mm and was further classified into three degrees: mild (5–9.9 mm), moderate (10–14.9 mm) and severe (≥ 15 mm).¹⁵

Management and follow-up

When abnormalities were detected, the guardians of the affected infants were informed. Depending on the severity, we explained the situation and recommended a protocol including follow-up and further examination.

1. For cases with isolated unilateral APRPD ≥ 15 mm, bilateral APRPD ≥ 10 mm with or without caliectasis, ureterectasis or parenchymal thinning, unilateral APRPD 5–14.9 mm or bilateral APRPD 10–14.9 mm with caliectasis and/or ureterectasis, or other abnormal findings of the kidneys, ureters and bladder, guardians were recommended to transfer the infants to CHFU immediately for further examination, to obtain a specific diagnosis and suitable intervention. Additional examinations performed at CHFU included repeated ultrasound, urinalysis, diuretic-loaded diethylenetriamine pentaacetic acid renography, magnetic resonance urography and micturating cystourethrography or dimercaptosuccinic acid renal scintigraphy, if necessary.
2. For cases with isolated unilateral APRPD 5–14.9 mm or bilateral APRPD 5–9.9 mm, ultrasound follow-up was performed at Minhang MCH hospital every 3–6 months combined with regular health checks, and guardians were told to take infants for urine testing immediately if unknown fever occurred.
3. During regular follow-up, if RPD deteriorated in cases with conditions listed in (1) above, cases with persistent unilateral APRPD 10–14.9 mm up to 1 year, or in whom febrile/recurrent urinary tract infection developed, the case would be transferred for further examination, as mentioned above.

Screening of CAKUT and follow-up of cases with RPD at Minhang MCH hospital was conducted by the department of child care, whereas severe cases in CHFU were managed jointly by the department of nephrology and urology, and partially by Minhang MCH hospital to ensure more cases under follow-up.

Data collection and statistical analysis

All demographic and clinical data in the model were collected from Minhang MCH and CHFU hospitals. Enumeration data were presented as median (P_{25} , P_{75}) and rate. The proportion of RPD and other renal and urinary tract abnormal findings was calculated in the study population, and the number of patients diagnosed and treated surgically was determined for individual groups of cases with RPD.

In cases with RPD, the subsequent diagnostic and therapeutic measures were analysed. The receiver operating characteristic (ROC) curve was plotted to enable us to define an appropriate APRPD cut-off point to select for children requiring further surveillance, and to detect patients who require surgical treatment. Statistical analysis

was performed using Prism V.6 software (GraphPad Software, La Jolla, California, USA).

Patient involvement

No patients were involved in setting the research or the outcome measures, nor were they involved in developing the recruitment, design or implementation of the study. No patients were asked to advise on interpretation or writing up of results. We will disseminate the results of the study through academic communication and medical popular science education.

RESULTS

Overall condition

Between September 2010 and September 2015, a total of 12 350 consecutive newborns met the criteria, accounting for about 8% of all births during the study period. Of these, 10 858 neonates were transferred to Minhang MCH hospital on schedule, and urinary ultrasound screening was performed in 8827 infants

(sex ratio=1.3:1). The mean screening rate was 81.3% (8827/10858), which increased each year and reached 96% in 2015 (figure 2). The median age at screening was 40 (33.60) days. Infants with presumed risk factors, such as premature delivery and/or low birth weight, accounted for 61.4% of participants, followed by those with macrosomia (23.7%).

RPD was found in 1180 (13.4%) infants, with an approximate sex ratio of 2.2:1. Classified by APRPD, the incidence rates of RPD in individual groups were as follows: mild (5–9.9 mm), 984 (11.1%) cases; moderate (10–14.9 mm), 176 (2.0%) cases and severe (≥ 15 mm), 20 (0.2%) cases.

Follow-up data of RPD

Among cases with RPD, 70 met any referral criterion for further examination. Of these, 36 were followed at CHFU, according to the previous procedure, and another 30 patients remained under observation, mainly at Minhang MCH hospital. Therefore, the total case-management

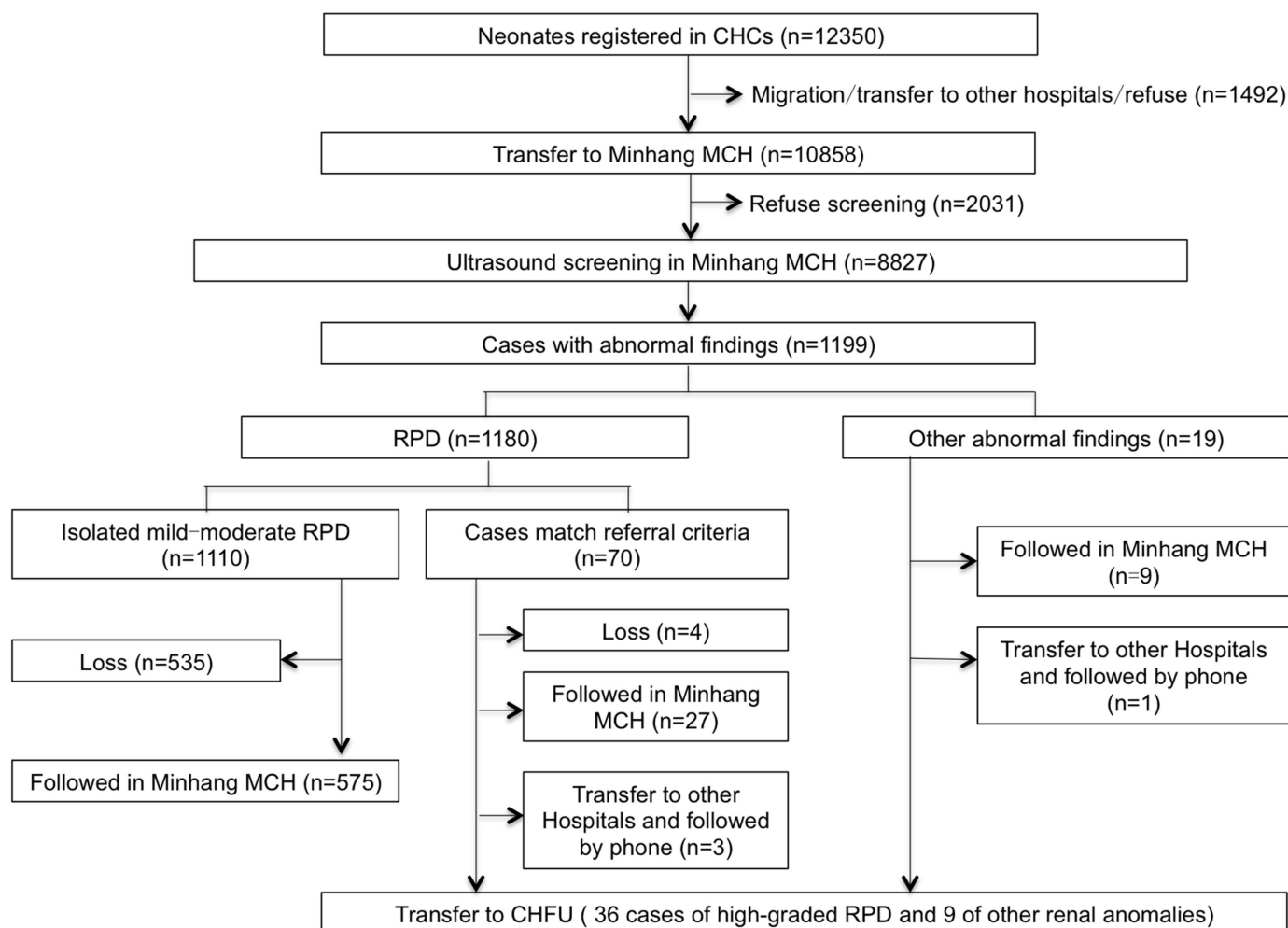


Figure 2 General data of the screening model. Other abnormal findings: other renal and urinary malformations, including renal agenesis, renal hypoplasia/dysplasia, multicystic dysplastic kidney, ectopic kidney, polycystic kidney, horseshoe kidney, double renal pelvis, megaureter and so on, except renal parenchyma calcification or renal calculus. CHCs, community health centres; CHFU, Children's Hospital of Fudan University; Minhang MCH, Minhang maternal and child health hospital; RPD, renal pelvic dilation.

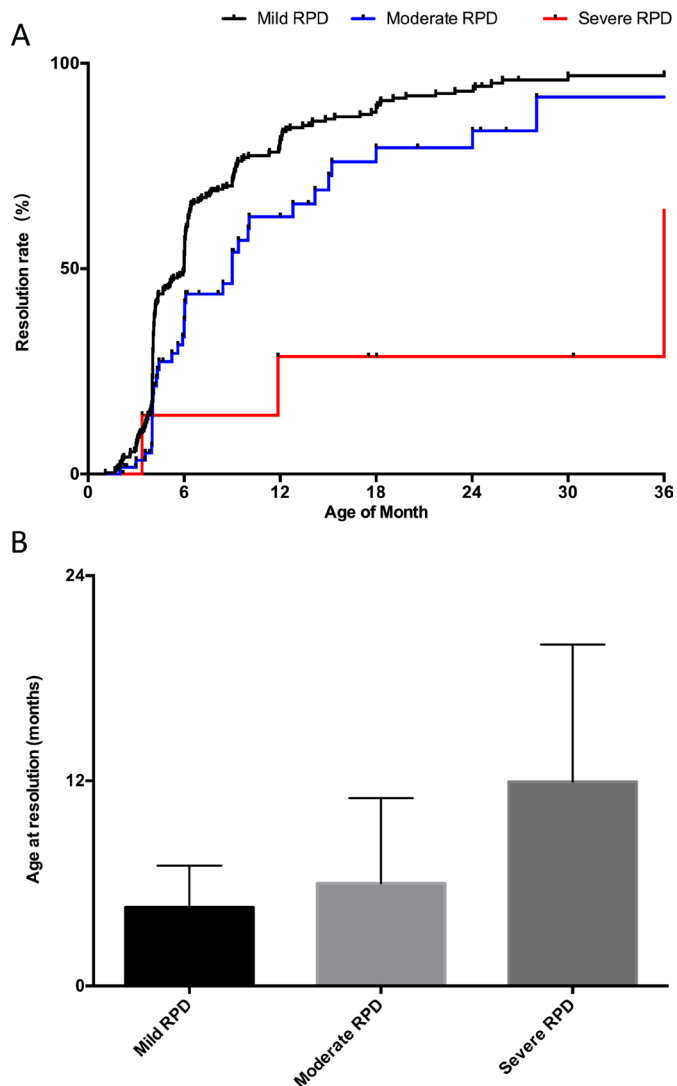


Figure 3 Resolution of renal pelvic dilation (RPD). (A) Kaplan-Meier curve for RPD patients with normalisation of ultrasound findings. (B) Resolution time of different degrees of RPD (median with IQR).

rate of severe patients reached 94.3%, based on the three-level network. A total of 575 cases (approximately 51.8%) with isolated mild to moderate RPD were followed up at Minhang MCH hospital.

Combining all followed-up data of RPD cases, 11 of the 36 patients transferred to CHFU obtained a specific

diagnosis, as follows: six cases of ureteropelvic junction obstruction (UPJO), three cases of renal duplication with ipsilateral RPD and two cases of megaureter. Surgery was performed in nine cases at median age 2 months (online supplementary file 1). As for other RPD cases (table 1, figure 3A), 85.4% of mild, 62.5% of moderate and 30.0% of severe cases resolved spontaneously, mainly within 12 months of age (figure 3B). Persistent pelvic dilatation continued significantly longer in moderate and severe cases than in mild ones ($p=0.0134$).

Other abnormal findings of the renal and urinary system

Other abnormal findings were detected in 19 cases, as follows: 15 (0.2%) were diagnosed with CAKUT, 7 with unilateral renal aplasia (URA), 2 with renal duplication, 2 with renal dysplasia (1 was bilateral), 1 with multicystic dysplastic kidney, 1 with renal ectopia, 1 with ureterectasia (diagnosed as ureterovesical junction obstruction) and 1 with renal cyst. One patient with URA, combined with ipsilateral vesicoureteral reflux (VUR) stage V, developed renal damage and underwent surgery at 11 months, thereby preventing further kidney deterioration. The patient with bilateral renal dysplasia developed ESRD at 6 years and was monitored. The remaining four cases were normal by repeated ultrasound at CHFU within 1 month; two had unclear boundaries of the renal cortex and medulla, one had a ureterocele and the last patient had ureterectasia.

Data of the ROC curve

The ROC curve for postnatal ultrasound screening was plotted, and the area under the curve (AUC) calculated AUC=0.901, 95% CI 0.813 to 0.990 (figure 4).

Based on the ROC, the ideal APRPD cut-off point for the detection of significant obstructive uropathy appears to be 9.7 mm or more, with sensitivity 81.8% (95% CI 48.2% to 97.7%), specificity 80.3% (95% CI 77.0% to 83.3%), positive likelihood ratio (+LR) 4.13 and negative likelihood ratio (-LR) 0.23.

When the need for surgical intervention was indicated, the AUC was 0.9334 (95% CI 0.850 to 1.017) (figure 5). The ideal APRPD cut-off point appears to be 13.5 mm or more, with sensitivity 77.8% (95% CI 40.0% to 97.2%), specificity 96.5% (95% CI 94.8% to 97.8%), +LR 22.3 and -LR 0.2.

Table 1 Outcome of RPD case follow-up				
	Mild	Moderate	Severe	Total
No followed-up (% no RPD)	507 (51.5)	113 (64.2)	20 (100.0)	640 (54.2)
No of diagnosed (% no followed-up)	2 (0.6)	3 (2.7)	6 (30.0)	11 (1.7)
Diagnosis	MU (1) RD (1)	UPJO (1) RD (2)	UPJO (5) MU (1)	UPJO (6) RD (3) MU (2)
No resolution (% no followed-up)	433 (85.4)	70 (62.5)	6 (30.0)	509 (79.5)

Of all RPD cases followed up, 85.4% with mild, 62.5% with moderate and 30.0% with severe RPD resolved spontaneously; the remaining cases were either still in follow-up or were only followed for a period. MU, megaureter; RD, renal duplication; RPD, renal pelvis dilatation; UPJO, ureteropelvic junction obstruction.

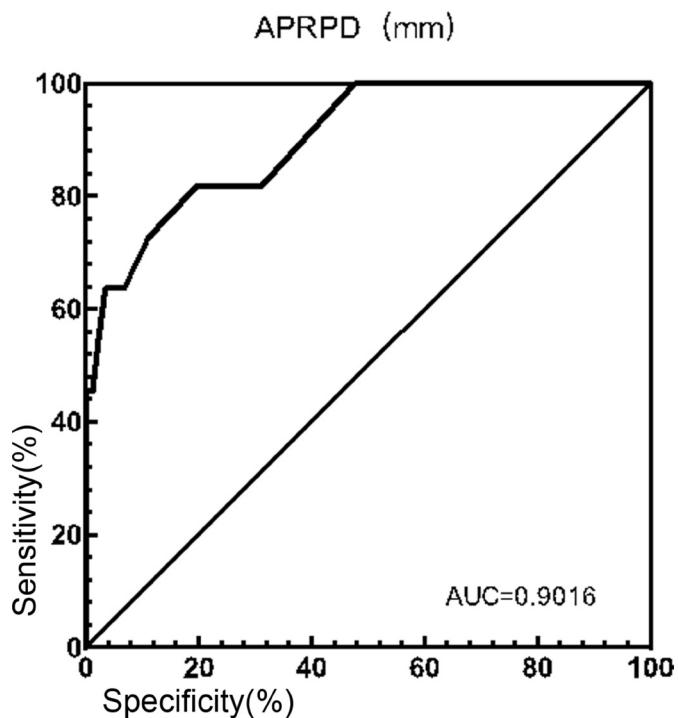


Figure 4 ROC curve based on the anterior–posterior renal pelvic diameter (APRPD) index as an indicator of obstructive uropathy. AUC, area under the curve; ROC, receiver operating characteristic.

DISCUSSION

Our rationale for CAKUT screening was to perform screening before the occurrence of renal damage and in as many neonates as possible. In Japan, health checks at 1 month are very popular because public health plans cover the fee. Yoshida *et al*⁸ proposed that mass screening for CAKUT at the 1-month health check was timely and technically appropriate; more than 90% of infants born at their hospital received renal ultrasound screening as part of their routine health checks during the study period. Tsuchiya *et al*⁹ also advocated an established ultrasonographic screening system for CAKUT in Japan. Similarly, Caiulo *et al*⁶ conducted ultrasound screening in Italy at age 2 months, combined with routine health checks. According to ‘management of high-risk infants (low birth weight) in Shanghai’ (on trial), routine health checks after birth are performed in CHCs at age 1 month, which are supervised by the district MCH hospital. Furthermore, the district MCH hospital monitors data of all newborns’, especially those with presumed risk factors of preterm, low birth weight and so on. In the present study, we conducted our screening in combination with the public child healthcare system in Shanghai, with urinary ultrasound screening as part of routine health checks during the study period. More than 80% of candidate neonates were examined in their first 3 months of life. It was remarkable that the screening rate increased gradually and reached 96% in 2015, indicating increased awareness about the importance of early detection of CAKUT

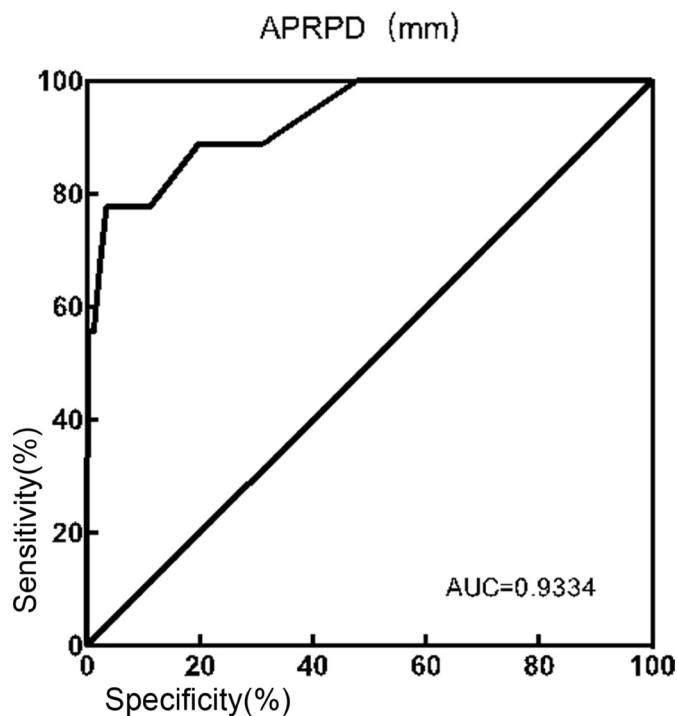


Figure 5 ROC curve based on the anterior–posterior renal pelvic diameter (APRPD) index as an indicator of the need for surgical intervention. AUC, area under the curve; ROC, receiver operating characteristic.

in CHCs, MCH hospitals and among guardians. Moreover, the district hospital, Minhang MCH hospital, was actually the central hub of the screening model, with screening candidates identified in CHCs and the MCH hospital conducting follow-up of cases with mild to moderate RPD and transferring severe cases to the tertiary hospital. At the same time, Minhang MCH hospital played a significant role in medical and social education, which was reflected in the increasing screening rates seen over the study period. CHFU was responsible for diagnosing and treating cases with CAKUT and used for designing, training and quality supervision. Such a screening model is an example of integration with an existing child healthcare delivery system and a tertiary children’s hospital, forming a working hierarchical management model and making more rational use of medical resources. Regarding follow-up, nearly all severe cases met the criteria for referral and were transferred or followed up with in cooperation with CHFU and Minhang MCH hospitals. Ours is the first community-based screening programme of CAKUT in China.

Yoshida *et al*⁸ indicated that RPD of ≥ 5 mm was sufficient to find all dilated systems. However, evaluation would be made easier by increasing the specificity, setting the criterion for abnormal RPD at $\text{APRPD} \geq 10$ mm, according to the recent multidisciplinary consensus regarding a urinary tract dilation classification system, which proposes that the renal pelvis is considered normal with $\text{APRPD} < 10$ mm postnatally.¹⁶

With APRPD ≥ 5 mm as the criterion for RPD used in our study, 1180 infants (13.4%) were classified as having RPD. Several studies have used APRPD ≥ 10 mm as the threshold, with frequency ranging from 1.1% to 2.8%^{6 17 18}; other studies have chosen Society for Fetal Urology grade 2 or higher, such as Tsuchiya *et al*⁹ who screened 5700 infants aged 1 month, yielding 114 RPD cases (2.0%). What is more, all these studies showed similar diagnostic rates (12%–13%) in cases with RPD, mainly consisting of UPJO (20%–70%), VUR (30%–60%) and other obstructive uropathies (20%–30%). In our study, the incidence of RPD decreased to 2.2% if the criterion was changed to APRPD ≥ 10 mm, similar to previous findings. However, we had only nine cases (4.6%) with specific diagnoses. Compared with the study by Tsuchiya *et al*,⁹ which reported that 8 (53.3%) of 15 cases required surgery for severe uropathies, that proportion in our study was 88.9%. The relatively low diagnosis rate might be attributed to our strict indications for further examination and low parental compliance. In addition, we detected a total 0.2% of cases with other types of CAKUT, similar to other studies.^{7 9} As to follow-up data of patients with mild to moderate RPD,¹⁸ we found that those with APRPD 5–9.9 mm (85% of cases) had undergone spontaneous normalisation, as demonstrated by renal ultrasound before age 12 months. Even in patients with APRPD ≥ 10 mm, about 60% achieved resolution.

Based on the ROC curve, we calculated that the ideal APRPD cut-off points for detection of significant obstructive uropathy and indication for surgical intervention were 9.7 mm and 13.5 mm, respectively, which contradict the analyses in some studies.^{7 19} In the case of a screening test, the most important parameter is its sensitivity. In fact, we diagnosed two patients with CAKUT who had APRPD 5–9.9 mm; one was diagnosed with renal duplication with mild ipsilateral RPD and ectopic ureteral orifice, and the other had remarkable ureterectasia detected on follow-up ultrasounds. Therefore, we propose APRPD ≥ 10 mm as the criterion for determining those patients with RPD who require follow-up and further examination, as well as APRPD 5–9.9 mm to detect those with ureterectasia or other abnormal findings. For isolated cases with APRPD ≥ 5 –9.9 mm, education about urinary tract infection is even more important in cases of pathological abnormalities, such as VUR.

Sheih *et al*²⁰ estimated that renal ultrasound screening of children in elementary and junior high schools would cost US\$0.36 per child, with a benefit to cost ratio of nearly 8.0; our ratio was approximately 3, based on a similar calculation method. In addition, data from questionnaires of the study group of ultrasonographic screening for CAKUT in Japan indicate that the screening cost per child would be JPY 1200 (US\$15), and three potential dialysis patients would be identified per 55 000 children. If dialysis in these three patients could be delayed for 3.7 years, screening would pay for itself.⁹ These

findings indicate that our screening would achieve better cost benefit if we could decrease the cost, standardise the criteria, examine the outline and improve adherence.

There were several limitations in this study that must be addressed. We conducted our study among neonates with presumed risk factors, such as preterm, low birth weight and so on; therefore, this was not an actual population-based study. We aim to promote ultrasound screening for CAKUT in all neonates in a future study. As nearly half of patients with mild to moderate RPD lacked follow-up data, we could not predict the exact morbidity of CAKUT among all births. In addition, cost-effectiveness should be calculated in detail in future research.

CONCLUSION

A screening model for CAKUT among neonates based on the present three-level network in Shanghai, China integrates the medical resources of CHCs, district MCH hospital and tertiary children's hospitals. This model proved to be effective for the early detection, follow-up and intervention of CAKUT, particularly for cases with high-grade RPD and other renal and urinary anomalies in the early postnatal period. This replicable and reliable approach is applicable to CAKUT screening programmes in other developing areas.

Acknowledgements Thanks go to all doctors in the Department of Child Health of all the CHCs in Minhang District and Minhang MCH hospital for their contribution.

Contributors HX: conceptualised and designed the study, critically reviewed and revised the manuscript, and approved the final manuscript as submitted. YG: carried out the work of screening and management, data collection, the initial analysis, drafted the initial manuscript, and approved the final manuscript as submitted. YZ: carried out the work of screening and management, data collection and the initial analysis, and approved the final manuscript as submitted. QS and LX: coordinated and supervised data collection, critically reviewed and revised the manuscript, and approved the final manuscript as submitted. YZ, YB, JS and HC: carried out the work of management, coordinated data collection and approved the final manuscript as submitted. YL: carried out the work of screening and management, coordinated data collection and approved the final manuscript as submitted. All authors approved the final manuscript as submitted and agreed to be accountable for all aspects of the work.

Funding This work was supported by the Special Scientific Research Fund of the Ministry of Health, China (grant number: 201002006), the Shanghai Public Health Three-Year Action Plan (2015–2017) sponsored by the Shanghai Municipal Government (grant number: GWIV14.2), and the Chronic Disease Prevention and Control Project sponsored by the Shanghai Hospital Developmental Center (grant number: SHDC12015301).

Competing interests None declared.

Patient consent Parental/guardian consent obtained.

Ethics approval The study was approved by the Research Ethical Committee of Children's Hospital of Fudan University.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

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