Position Statements and Guidelines

Guidelines on management of congenital hypothyroidism in Sri Lanka

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Introduction

Congenital hypothyroidism (CH) is the commonest preventable cause of mental retardation in children. CH could be prevented by universal screening of newborns with the Dried Blood Spot (DBS) test carried out within the first few days of birth. Developed countries have practised this for more than 40 years. A circular was issued by the Director General of Health Services (DGHS) of Sri Lanka in August 2010 outlining the management of CH. Sri Lanka commenced newborn screening for CH on a regional basis in the Southern Province in September 2010. Later it was expanded to 3 other districts in Sri Lanka. However, currently only 23% of the birth cohort gets screened for CH. The new guidelines have covered several areas not addressed in the circular by DGHS. The Sri Lanka College of Paediatricians (SLCP) appointed a subcommittee to formulate new guidelines on management of CH in Sri Lanka. The subcommittee comprised Professor Shamya de Silva, Dr. Navoda Atapattu, Dr. Padmakanthi Wijesuriya, Dr. Lilanthi de Silva, Dr. Ramya de Silva, Professor Sujeewa Amarasena and Dr. Samantha Waidyanatha.

Neonatal screening for congenital hypothyroidism

- All babies should have a heel prick blood screening test for thyroid stimulating hormone (TSH) before discharge from the institution at which the birth took place.
- Abnormal heel prick results should be notified over the phone to the parents and the relevant paediatrician, as soon as such results are available.
- Parents/Paediatrician should be notified when the TSH level is over 20 mIU/L.
- Preterm neonates, low-birth weight (LBW) and very low-birth weight (VLBW) neonates and ill preterm neonates admitted to neonatal intensive care units should have their screening either before discharge or before 4 weeks of age, whichever comes earlier.
- Neonates treated with dopamine or dobutamine should have their screening test two weeks after stopping dopamine/dobutamine.

If a heel prick screening test has not been done, perform a venous blood TSH from day 3 to day 5 of life.

If cord blood TSH has been done, though not recommended internationally or by SLCP, and TSH is over 20 mIU/L, perform a venous blood free thyroxine (FT4) and TSH from day 3 to day 5 for confirmation.

Biochemical criteria used in the decision to initiate treatment

- If capillary blood TSH concentration on neonatal screening is ≥40 mIU/L, perform TSH and FT4 (thyroid function tests) on venous blood and start treatment. If results can be obtained on the same day, treatment can be withheld till then.
- If capillary TSH concentration is 20-40 mIU/L, repeat venous blood thyroid function tests (TFTs). Treatment can be withheld until the venous blood TFT results are available, provided these will be available on the following day.

Decision to start treatment based on the venous blood TFTs

- If venous FT4 concentration is below the normal range for age, treatment should be started immediately.
- If venous TSH concentration is >20 mIU/L, treatment should be started even if the FT4 concentration is normal.
- If venous TSH concentration is between 6-20 mIU/L in a well-baby with a FT4 concentration in the normal range for age,
  o Repeat TFT in 2 weeks.
  o Perform an ultrasound scan (USS) of the thyroid gland.
  o If a small/ectopic thyroid gland is seen with TSH 6-20 mIU/L, then irrespective of FT4 value, thyroxine therapy should be started.
  o If the thyroid gland is normal on USS with a TSH 6-20 mIU/L and a
normal fT₄, repeat TFT every two weeks till TSH normalizes

Imaging

- **All children with CH should have an USS of the thyroid gland.**
- If facilities are available, radioisotope scanning should be done before starting treatment or within 3 days of starting treatment.
- Initiation of treatment should **never be delayed** pending imaging.

Treatment and monitoring of CH

- Levothyroxine (L-T₄) is the medication of choice.
- L-T₄ should be initiated as soon as possible and during the first 2 weeks after birth or immediately after confirmatory serum test results are available.
- Initial dose of L-T₄ is 10-15µg/kg per day.
- L-T₄ tablet should be crushed and given dissolved in a few millilitres of breast milk or water.
- Thyroxine should be given early morning on an empty stomach and breast milk should be withheld for 30-45 minutes after the medication is administered.
- Parents should be provided with written instructions regarding L-T₄ treatment.

Monitoring of dose and follow-up

- Serum or plasma fT₄ and TSH concentrations should be determined between 8.00-9.00 a.m. before the morning dose of L-T₄.
- At the first follow-up visit 2 weeks after starting L-T₄, the fT₄ level should be checked and the dose adjusted accordingly.
- fT₄ concentration should be maintained in the upper half of the age-specific reference range.
- TSH should be maintained in the age-specific reference range.
- Any reduction of L-T₄ should not be based on a single increase in fT₄ concentration during treatment.
- Once TSH/ fT₄ levels have normalized the suggested follow-up is as follows:-
  - During the first 6 months of life - fT₄ and TSH should be checked every 6 weeks.
  - 6 months to 12 months of life - fT₄ and TSH should be checked every 8 weeks.
  - 1 year to 3 years of life - fT₄ and TSH should be checked every 3 months.
  - After 3 years till growth is completed - fT₄ and TSH should be checked every 6-12 months.

  - Additional evaluations should be carried out 4-6 weeks after any change in L-T₄ dose.
  - Adequate treatment throughout childhood is **essential** for normal growth and development.
  - Over-treatment should be avoided.
  - Anthropometry, including occipitofrontal circumference (OFC) measurements, and developmental assessments should be monitored at each clinic visit.

Thyroid re-evaluation

Thyroid re-evaluation should be considered in the following group of patients:

- Those who had initial TSH >20 mIU/L with normal fT₄ and normal USS.
- All preterm and sick babies who required treatment.
- Those who had normal TSH levels immediately after commencing treatment.

In these patients treatment should be continued till 3 years of age with regular clinical and biochemical monitoring. In general transient hypothyroidism is characterized by a marginally elevated TSH on repeated testing, slightly low or normal fT₄ and a low dose of L-T₄ is required to maintain euthyroid status.

Suggested procedure for re-evaluation is as follows:

- Reduce dose of L-T₄ by 30%.
- Check TSH/ fT₄ after 3 weeks.
- Repeat an USS of the thyroid gland.
- If TSH >10mIU/L, CH is confirmed and lifelong treatment needs to be given.
- If CH is not confirmed, reduce L-T₄ dose gradually with repeat TFTs at 3 weekly intervals and stop treatment thereafter.
- Repeat TFT after 3 months of stopping treatment.