



澳門健康管理及促進學會 - 2018 健康講座系列(六):

【新生兒黃疸的診斷、治療和新趨勢】暨

【醫療器械發展及市場需求】

2018 年 10 月 27 日(星期六：上午十時半至十二時半)

地點：澳門何鴻燊博士醫療拓展基金會（地址：澳門置地廣場工銀中心九樓）

人數：名額 200 名（必需預先報名）

內容：醫療講座 & 簡單身體檢查（包括計算心跳、量血壓及量度身高體重比例）

新生兒黃疸的診斷、

治療和新趨勢



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新生兒黃疸的

光治療醫療器械發展及市場需求

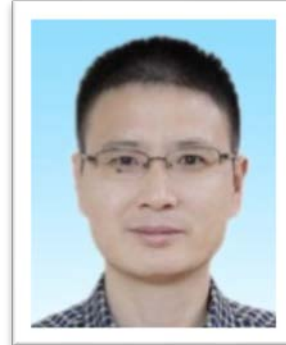


黃駿豪博士

鎧耀光電(香港)有限公司

鎧耀生物醫學科技(深圳)有限公司

副總經理



張長青先生

永勝醫療控股有限公司

國內市場負責人

歡迎各界人士參加

(費用全免，敬請預約留位！)

-是次活動承蒙澳門基金會資助部份經費-

報名方法：

填妥以下表格，並於 10 月 25 日(星期四)前傳真或電郵至秘書處。(853 2855 6207，
aizza.event.nchan@gmail.com) 如有疑問，請致電：853 2855 6207 查詢。

中文姓名		工作機構	
聯絡電話		參加人數	



Management of Neonatal Jaundice – An update

~ 1 million of babies estimated to develop severe NNJ worldwide every year
(> 428 micromol/L or > 25mg/dl)

At risk of developing BIND –

Bilirubin-induced neurologic dysfunction
(long-term sequelae - kernicterus)

Kernicterus

Report from the Pilot Kernicterus Registry

61 newborns readmitted for hyperbilirubinemia, the following diagnoses were the major contributing causes of hyperbilirubinemia that resulted in kernicterus :

No etiology identified – 20 patients

- *Glucose-6-phosphate dehydrogenase (G6PD) deficiency – 20 patients*
- Hemolysis – 9 patients
- Bruising from birth trauma – 6 patients
- Infection – 4 patients
- Crigler-Najjar Syndrome or galactosemia – 3 patients
- All but one of the infants were breastfed
- *16 infants had lost >10 percent of their BW at the time of hospital readmission.*

Jaundice Treatment

- Goal of NNJ treatment
 - quickly and safely reduce the level of bilirubin
- Infants with mild jaundice may need no treatment – *Encourage feeding & ensure good hydration*
- Infants with higher bilirubin levels or hyperbilirubinemia will require treatment –
- *PT* (Phototherapy)
- *ET* (exchange transfusion)
- Jaundice is common in premature infants (those born before 38 weeks of gestation).
- Premature infants are more vulnerable to hyperbilirubinemia because brain toxicity occurs at lower levels of bilirubin than in term infants
- As a result, premature infants are treated at lower levels of bilirubin (See AAP 2004 curves for treatment of Jaundice)

The history of phototherapy

- ❖ Treatment for jaundice in the newborn that involves the exposure of an infant's bare skin to intense fluorescent lights
- ❖ Requires the removal of all clothing and an eye shield

Phototherapy

- Phototherapy — Phototherapy ("light" therapy) is the most common medical treatment for jaundice in newborns
- It consists of exposing an infant's skin to blue light, which breaks bilirubin down into parts that are easier to eliminate in the stool and urine.

Jaundice newborn



A) Physiologic jaundice. B) Pressing the color from the skin allows better recognition of the yellow of jaundice. Infant with bilirubin level of 13 mg/dL. C) Infant with no appreciable jaundice at chest level.
A) Reproduced with permission from: O'Doherty R, *Rites of the Newborn*, JB Lippincott, Philadelphia 1979. Copyright © 1979 Lippincott Williams & Wilkins. B and C) Reproduced with permission from: Fletcher M, *Physical Diagnosis in Neonatology*, Lippincott-Raven Publishers, Philadelphia 1998. Copyright © 1998 Lippincott Williams & Wilkins.

UpToDate

Decreased risk (these factors are associated with decreased risk of significant jaundice, listed in order of decreasing importance)
TB or TB level in the low-risk zone
Gestational age ≥41 weeks
Exclusive bottle feeding
Black race*
Discharge from hospital after 72 hours

TB: total serum or plasma bilirubin; TB: transcutaneous bilirubin; G6PD: glucose-6-phosphate dehydrogenase; ETCD: end tidal carbon monoxide concentration.

* Race as defined by mother's description.

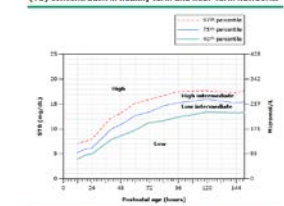
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UpToDate

Risk factors for development of severe hyperbilirubinemia in infants of 35 or more weeks gestation (in approximate order of importance)

Major risk factors
Pre-discharge TB or TB level in the high-risk zone
Jaundice observed in the first 24 hours
Blood group incompatibility with positive direct antiglobulin test, other known hemolytic disease, G6PD deficiency, elevated ETCD
Gestational age ≤35 weeks
Previous sibling received phototherapy
Cephalohematoma or significant bruising
Exclusive breastfeeding, particularly if nursing is not going well and weight loss is excessive
East Asian race*
Minor risk factors
Pre-discharge TB or TB level in the high-intermediate-risk zone
Gestational age 27 to 35 weeks
Jaundice observed before discharge
Previous sibling with jaundice
Macrosomic infant of a diabetic mother
Maternal age <20 years
Male gender

Nomogram of hour-specific serum or plasma total bilirubin (TB) concentration in healthy term and near-term newborns



Risk zones are designated according to percentile: high (10-20%), high intermediate (50-70-20%), low intermediate (20-30-20%), and low (10-20%). Infants with values in the high-risk zone are at increased risk for the development of clinically significant hyperbilirubinemia requiring intervention.

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UpToDate

- Treatment with phototherapy involves using special blue lights, such as blue light-emitting diodes (LEDs), and is successful for almost all infants.
- Phototherapy is usually done in the hospital, but in certain cases, it can be done at home if the baby is healthy and at low risk for complications.

Prevention of Severe NNJ

- Screen
- Monitor
- Treat Promptly

Guidelines

American Academy of Paediatrics (AAP) 2004 – Main reference: American Academy of Pediatrics Clinical Practice Guideline. Subcommittee on hyperbilirubinemia. *Management of unconjugated hyperbilirubinemia in newborn infants 35 or more weeks of gestation. Pediatr 2004; 114: 297*

- AAP 2011
- Local HK Guidelines in Public Hospital 2015
- Nice Guidelines 2014
- Chinese Expert Guidelines 2014

Guidelines for Intensive Phototherapy

- American Academy of Pediatrics (AAP)
- “Intensive phototherapy” implies irradiance in the blue-green spectrum (wavelengths of approximately 430–490 nm) of at least 30 $\mu\text{W}/\text{cm}^2/\text{nm}$
- Intensive phototherapy which should be used when the TSB exceeds the line indicated for each category

Spectrum (430–490 nm) (most effective 460nm – 490nm)

- Heat produced from light panels
- Need to protect eyes

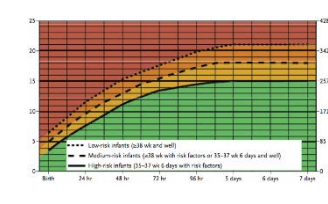
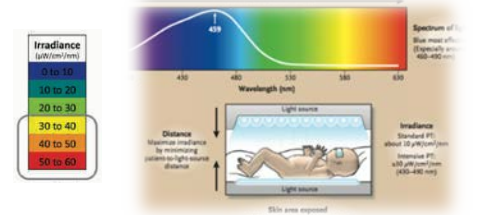
- Updated *evidence-based* clinical practice adopted by hospitals, and allows them to provide guidance and advice on referral (MCHC) aligning with our current recommendation to parents of these jaundice babies seen by them.

- To reduce *unnecessary* admission to hospital, workup and unwarranted treatment.

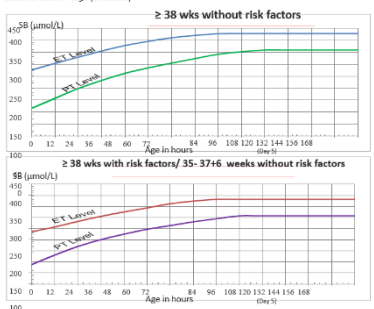
- Building a baby-friendly hospital-community health service partnership

- To adopt in principle the American Academy of Pediatrics (AAP) 2004 *Clinical Practice Guideline: Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation**.

- The original AAP recommendations, the treatment thresholds for phototherapy and exchange transfusion are decided according to gestation of neonates at birth and the presence of risk factors (*isoimmune haemolysis, G6PD deficiency, asphyxia, significant lethargy, temperature instability, sepsis, acidosis or albumin < 30g/L* (if measured)).



Appendix: Treatment threshold according to gestation + risk factors
Risk factors are: isoimmune haemolysis, G6PD deficiency, asphyxia, significant lethargy, temperature instability, sepsis, acidosis or albumin < 30g/L (if measured)



中华儿科杂志 2014 年 10 月第 53 卷第 10 期 (Chin J Pediatr, October 2014, Vol. 53, No. 10)

- 745 -

标准·方案·指南

新生儿高胆红素血症诊断和治疗专家共识

中华医学会儿科学分会新生儿学组
《中华儿科杂志》编辑委员会

以未结合胆红素增高为主的生后新生儿高胆红素血症是十分常见的临床问题,胆红素脑病在我国也并非罕见^[1]。高胆红素血症的监测、高危因素的评估以及及时的干预对于预防重度高胆红素血症和胆红素脑病具有十分重要的意义。血清总胆红素(TSB)水平对个体的危急性受机体状态和环境等多种因素影响,因此不能简单地用一个固定的界值作为干预标准。中华医学会儿科学分会新生儿学组在 2001 年曾起草制定“新生儿黄疸干预指南”^[2],2009 年又在

功能态恶化等,不易诊断。通常足月儿发生胆红素脑病的 TSB 峰值在 427 $\mu\text{mol}/\text{L}$ (25 mg/dl)以上,但合并高危因素的新生儿在较低胆红素水平也可能发生,低出生体重儿甚至在 171–239 $\mu\text{mol}/\text{L}$ (10–14 mg/dl)即可发生。发生胆红素脑病的高危因素除了高胆红素血症以外还包括合并同族免疫性溶血、葡萄糖-6-磷酸脱氢酶(G6PD)缺乏、窒息、败血症、代谢性酸中毒和贫血等。胆红素脑病的诊断主要依据新生儿高胆红素血症及典型的神经系统临床表现:头颅硬

3. 核黄疸:指出生数周以后出现的胆红素神经毒性作用所引起的慢性、永久性损害及后遗症,包括锥体外系运动障碍、感觉神经性听力丧失、眼球运动障碍和牙釉质发育异常。

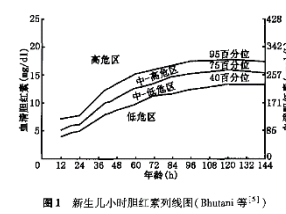
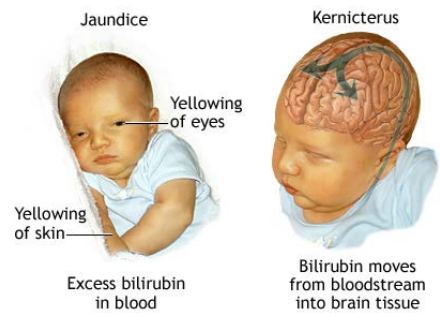


图 1 新生儿小时胆红素曲线图 (Bhutani 等^[3])

新生兒黃疸的光治療醫療器械發展及市場需求

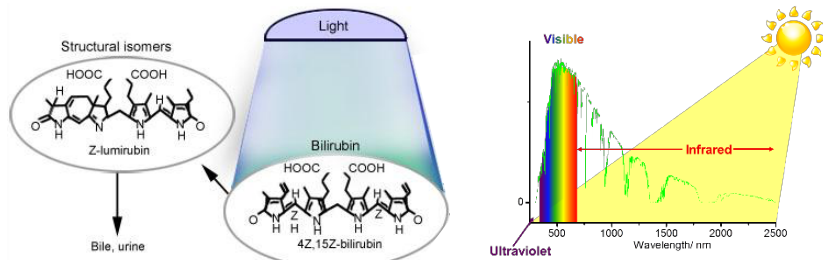
什麼是新生兒黃疸？

- 發生在 60~80% 新生兒
- 不及時處理會引起核黃疸
- 破壞中樞神經系統
- 嚴重核黃疸的後遺症往往是不可逆的



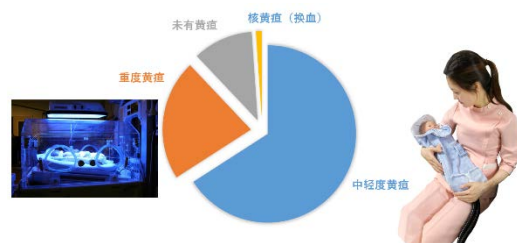
光照療法的原理

- 如何降低及排出膽紅素？
- 膽紅素吸收藍光後便可排出體外
- 藍光強度？
- 其他光源？
- 有害光線：紫外線和紅外線



理想的光療設備

- 視乎黃疸嚴重程度
- 安全、有效；符合美國兒科學院指南（AAP）
- 以袋鼠式護理提供嬰兒所需的溫暖及安全感



香港設計及開發

- 安全、有效；符合美國兒科學院指南（AAP）
- 以袋鼠式護理提供嬰兒所需的溫暖及安全感
- 哺乳期間不需中斷光療
- 適合醫院、兒科診所、月子中心和家庭使用
- 已於 2018 Q1 取得中國 CFDA 註冊證



以母親與孩子為中心的設計理念

- 專用毯子採用棉質布料
- 發光板採用柔軟物料製造
- 所有與皮膚接觸的物料均符合 ISO 10993 要求
- 光照治療時母親與孩子都不需使用眼罩



安全性

- 不會放射有害的紫外線及紅外線
- 發光板不會產生熱能
- 採用生物相容物料（ISO 10993）
- 符合國際標準（IEC 60601-1, IEC 60601-2-50, IEC 60601-1-2）

有效性

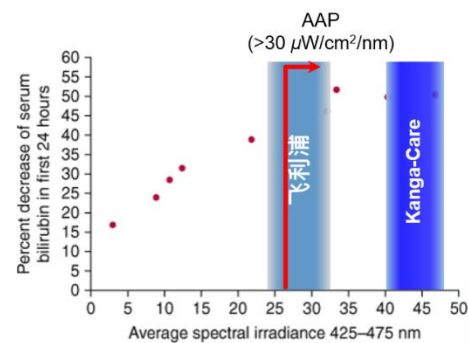
- 附合美國兒科學院指南（AAP）
- 屬於強光治療（ $>30 \mu\text{W}/\text{cm}^2/\text{nm}$ ）
- 純藍光（430–490 nm）
- 嬰兒與發光板零距離接觸
- 光照面積大（ 350cm^2 ）；胸口及背部同時接受光療

其他

- 低噪 (<56 db)
- 有效阻礙和減弱漏出藍光
- 哺乳期間不需中斷光照治療

特點一：高強度藍色冷光的雙面光療

- 高強度藍色冷光 (45 $\mu\text{W}/\text{cm}^2/\text{nm}$)
- 滿足 AAP 指南要求 (> 30 $\mu\text{W}/\text{cm}^2/\text{nm}$)
- 比飛利浦 BiliTx 強 2 倍
- 大面積雙面光療 (背部和胸部同時光照；350 cm^2)



Tan, K. L. *Pediatr. Res.* 1982, 16, 670-674.

特點二：節省空間的可攜式醫療器械

- 小巧輕便和節省空間的可攜式設備
- 適用於醫院、門診、月子中心和家庭使用
- 袋鼠式護理：不需因光療而母嬰分離
- 光療同時可以母乳餵養



特點三：高度舒適的光治療

- 專為新生兒設計的專用毯子讓新生兒安全和舒適地接受光療
- 光療期間，新生兒不需帶眼罩
- 雙發光板設計：舒適地提供最大的光照區域



中國黃疸治療現況

- 新生兒出生人數增加
- 產床、治療儀數量不足
- 醫護人員人數不足
- 各醫院產科工作負荷增加

- 妊娠合併症的發病率增加
- 大大增加醫療風險
- 由於國家放開二胎政策，產婦年齡偏大 (38-42 歲)

迫切醫療需求

- 適合醫院、兒科診所、月子中心和家庭使用
- 獨特的便攜帶式設計
- 以袋鼠式護理提供嬰兒所需的溫暖及安全感
- 哺乳期間不需中斷光療，新生兒也不需帶眼罩



臨床使用情況

- 積極為前線人員提供培訓
- 已推廣到 23 家公立綜合三甲醫院及地市級婦幼保健院
- 重慶醫科大學附屬兒童醫院
- 另有 11 家民營醫療機構在採購及臨床試用

