



臨床情境

■一位懷孕八週婦女因急性腹痛到急診室求診,理學及超音波檢查無特殊發現。臨床醫師解釋腹部電腦斷層檢查也可提供其它資訊以幫忙確診,但病人擔心輻射線對胎兒會有不良影響,甚至造成畸形。請您提供病人意見,若接受腹部電腦斷層輻射線會不會導致畸胎?



記載車品外~ ^{原子能委員會} http://www.aec.gov.tw/



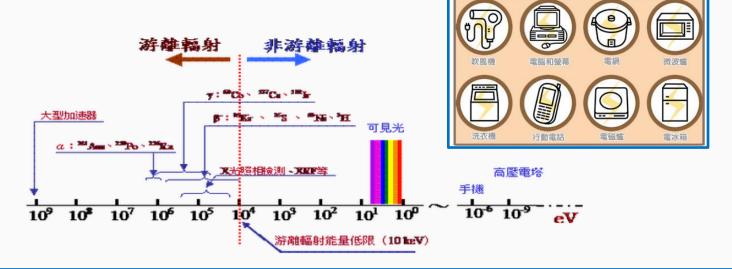
01.什麼是輻射?

輻射是一種具有能量的波或粒子。從字面上解釋,「輻射」含有能量從某個源(輻射源)向四面八方放射出去的意思。一般來說,我們將具有這種特性的電磁波(如無線電波、微波、可見光、X射線、加馬射線等)、超音波,以及從放射性物質發射出來的微小粒子(如阿伐粒子、其他粒子、中子等)都稱之為輻射。

我們依電磁波能量的高低分成游離輻射和非游離輻射兩類。其中游離輻射所具有的能量較高,如X射線與加馬射線。相反地,能量較低屬非游離輻射,如無線電波、微波、可見光、超音波等。

電子伏特(eV)是我們用於表示輻射能量的單位,以電磁波為例,量超過10⁴ eV以上的稱為游離輻射。例如牙科X光照相的X光能量約6×10⁴ eV,胸部X光檢查能量約在8×10⁴ eV, 都屬游離輻射。而能量低的屬於非游離輻射,例如我們常說的彩虹有7種色光,能量最低的是紅光,約有1.8 eV,能量最高的是紫光,約為4 eV。至於基地台或手機通訊電波,

以及高壓電塔或變電箱所釋出的電磁輻射,能量非常非常的低。我們可以下圖表示其能量大小關係。





天然輻射

天然游離輻射產生於外太空,例如宇宙射線,也產生於周圍環境,例如包含於土壤、空氣、水和食物中,甚至於人體中都有的放射性核種。天然游離輻射的主要類型有γ射線,也有α粒子、β粒子、中子以及μ介子等。

外太空中充滿各種能量的游離輻射,有電磁波也有粒子,對於生活在地球表面上的生物,由於受到大氣層以及地球磁場的保護,會減少宇宙射線曝露與影響。但對於太空旅行或 搭國際航班的乘客,將會受到比地表一般民眾較多的宇宙射線的照射。

地表環境的諸多放射性核種中,若從對人類所造成爆露劑量的百分比來看,我們主要關心的核種有⁴⁰K以及²³²Th和²³⁸U衰變系列的子核種。⁴⁰K會隨食物進入人體,也會藉由 人體的代謝自動調節平衡,一個60公斤的成年人,約有4000貝克的⁴⁰K含量。而²³²Th和²³⁸U則存於地殼土壤中,其衰變所產生的子核種中最受到關注的就是氢氣了。氡是一種 放射性元素,目前全世界越來越注意氡的輻射防護與流行病學的研究。室內氡氣來源主要來自於土壤與建材中²³²Th和²³⁸U的一系列衰變,所以地質條件以及建材的選擇與使用

方式的差異,都會影響室內氡氣的濃度。

人造輻射

入造游翻輻射的發現與發展雖只是近一百年間的事,但由於<mark>在醫療、工業、研究、國家安全以及環境保護方面,游離輻射提供了強大的助益,</mark>人造游離輻射的應用非常普遍。不 管你熱悉或不熟悉,聽過或沒聽過,人造游離輻射與現代生活已經息息相關。

用於醫療方面,例如診斷用的X光攝影、電腦斷層掃描儀(CT)以及正子放射攝影(PET),治療用的X刀、γ刀、電腦斷層治療機以及建造中的質子癌症治療機;用於食品異物檢出或飲料業的液位計,工業界的輻射照射以及厚度計;科學園區用於檢驗用的X光機、X光繞射分析儀、離子佈植機及靜電消除器;在機場海關或重要設施用於安全檢查或查緝走私的X光安全檢查,環保方面用於污染源的遷移追蹤研究等,我們可以說現代生活時等都在利用輻射。





07.游離輻射對健康的影響

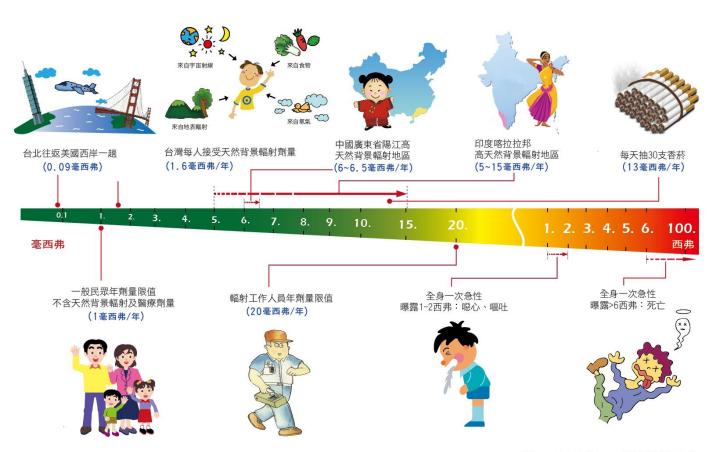
游離輻射對人體健康的傷害分為機率效應與確定效應。確定效應到接受過量輻射照射,造成造成有害的組織反應,若接受的劑量增加,造成的傷害就會更嚴重。確定效應的實例有:睪丸與卵巢因輻射誘發的不孕,造血功能降低與血球細胞減少,皮膚紅斑脫皮等損傷,誘發水晶體混濁與視力減退或器官的發炎。當然劑量若過高,有可能使體內器官嚴重發炎而死亡。根據國際輻射防護委員會ICRP 103號報告指出,100毫西弗以下的劑量(包括一次或多次)不會造成臨床上的功能損害。

另一輻射效應為機率性效應 可能會誘發細胞的突變導致癌症的發生,因為癌症的發生是機率性的,所以這種效應稱為機率效應。癌症發生的機率 與劑量有關,機率隨劑量的增加而提高,例如,受到高劑量輻射可能會引起白血症、肺癌、肝癌、卵巢癌與直腸癌等等。

另一個機率較低的效應是遺傳方面的效應,如果輻射曝露損傷發生在生殖細胞上,則輻射的效應將發生在受曝露人員的後代,也就是遺傳的效應。 國際輻射防護委員會ICRP 103號報告建議,整體的致命風險機率為每西弗(1000毫西弗)百分之五。輻射造成的癌症,可能與人體自然發生或因 其他化學致癌物(如吸菸、飲酒及飲食等等)引起的癌症無法清楚的分辨。此外,由於細胞具有自我修復的功能,根據研究顯示,低劑量輻射(小 於100毫西弗)發生癌症的機率微乎其微,一般民眾亦不致接受到100毫西弗的劑量,因此對於機率性效應,民眾不必擔憂。



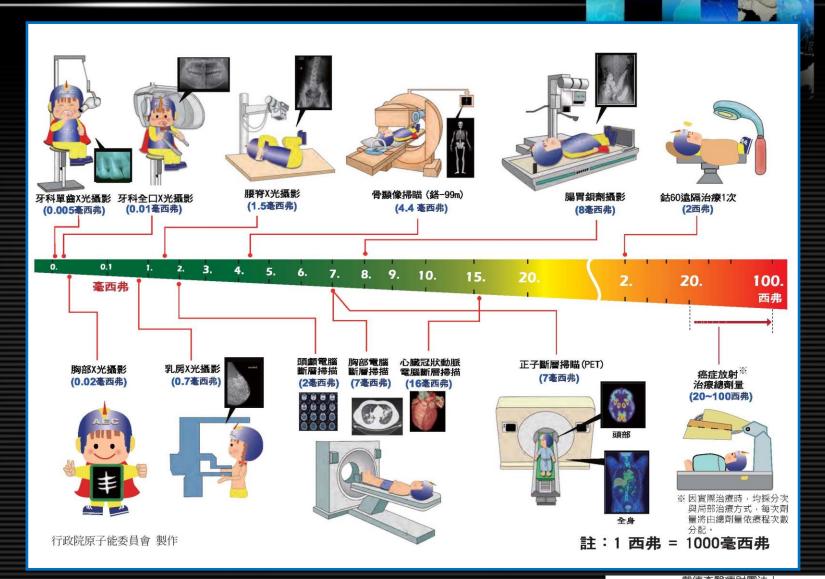
一般游離輻射劑量比較圖



註:1 西弗 = 1000毫西弗



行政院原子能委員會 製作



EBM 五大步驟 (5A)

Asking 問問題(可以回答的問題)

Accessing 找資料(可獲得最好的證據資訊)

Appraising 分析判斷(文獻效度與重要性)

Applying 臨床應用(整合四大層面)

Auditing 評估成果(執行EBM的效率)



前景問題 (Foreground questions)

■ 一位**懷孕八週婦女**因急性腹痛到急診室求診,理學及超音波檢查無特殊發現。臨床醫師解釋腹部電腦斷層檢查也可提供其它資訊以幫忙確診,但病人擔心**輻射線**對**胎**免會有不良影響,甚至造成畸形。請您提供病人意見,若接受**腹部電腦斷層輻射線**會不會導致**畸胎**?

| | 中文 | 英文 | |
|---|----------------------------------------|--------------------------------------------|--|
| Р | 懷孕八週婦女、胎兒 | (early) pregnant \ fetus | |
| I | 腹部電腦斷層檢查 | Abdomen CT · radiation | |
| С | | background radiation | |
| O | 畸胎 一般原則是 先放「P」與「I」, 「C」與「O」視搜 | teratogenesis \ teratogen \ teratogenicity | |

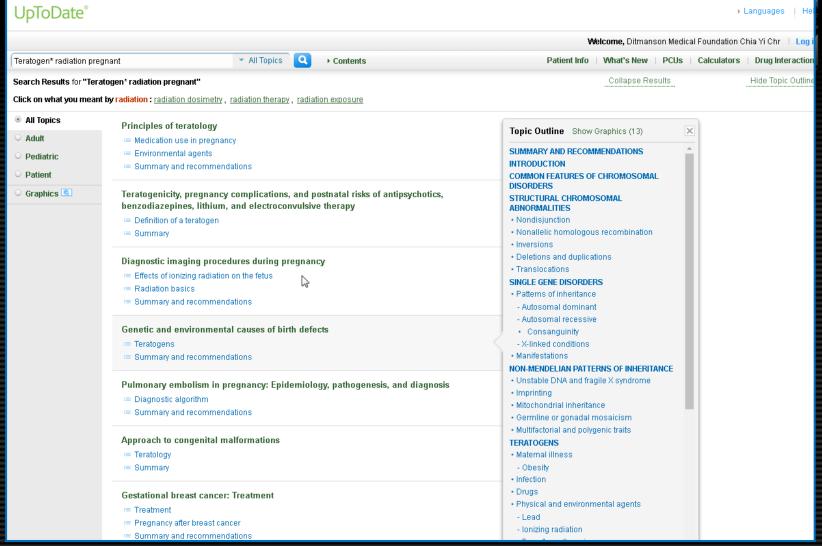
尋結果決定





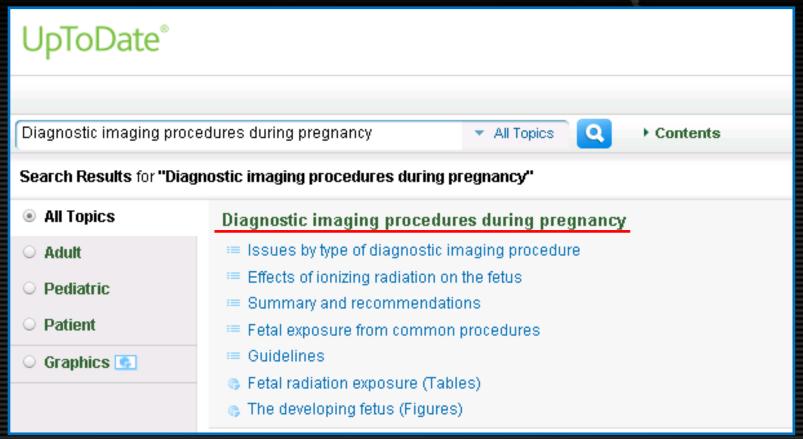
■ 由3,000多位專業醫師執筆撰寫,資料涵蓋 6,000多個內科及次專門科主題評論,並涉 及家醫科、小兒科及婦產科,提供up-todate實證醫學及臨床醫療資訊,以協助醫 師進行診療上的快速判斷與決策,內容也 包含160,000筆醫學摘要、Lexi-Comp 藥 物資料庫,以及病人宣傳手冊。















EFFECTS OF IONIZING RADIATION ON THE FETUS

Overview — There are no studies in humans from which to derive data on risks of ionizing radiation; most of our information is based upon case reports and extrapolation of data from investigations of survivors of the atomic bomb in Japan and the Chernobyl accident [9-15]. Based on these data, the potential deleterious consequences of ionizing radiation can be divided into four categories [16,17]:

- Pregnancy loss (miscarriage, stillbirth)
- Malformation
- Disturbances of growth or development
- Mutagenic and carcinogenic effects

Exposure less than 0.05 Gy (5 rads) — Diagnostic imaging procedures typically expose the fetus to this level of radiation (table 1). There is NO evidence of an increased risk of fetal anomalies, intellectual disability, growth restriction, or pregnancy loss from ionizing radiation at doses less than 0.05 Gy [18-20]. The margin of safety is augmented by the fact that most human exposure from diagnostic imaging will be fractionated over a period of time; this type of exposure is less harmful than acute exposure [18].

Exposure 0.05 to 0.50 Gy (5 to 50 rads) — The threshold at which an increased risk of congenital malformations is observed in radiation exposed embryos/fetuses has not been definitively determined. The evidence suggests the risk of malformations is increased at doses above 0.10 Gy, whereas the risk between 0.05 and 0.10 Gy is less clear [24]. It is important to note that even those diagnostic imaging procedures associated with high fetal radiation exposure (eg, abdominal or pelvic CT, <u>barium</u> enema, cystourethrogram) almost never expose the fetus to this level of radiation (table 1).

First 14 days after conception — The developing human is most sensitive to the lethal effects of ionizing radiation during the first 14 days after conception. During this period, the radiation-exposed "embryo" either survives undamaged or is resorbed (termed the "all or none" phenomenon) [25]. Radiation-induced teratogenesis, growth restriction, or carcinogenesis are not observed during this stage of development [18], presumably because of the pluripotent nature of each cell of the very early embryo.

For human exposure, a conservative estimate of the threshold for death at this stage is more than 0.1 Gy rads (10 rads) [19]. A fetal dose of 1 Gy (100 rads) will likely kill 50 percent of embryos; the dose necessary to kill 100 percent of human embryos or fetuses before 18 weeks of gestation is about 5 Gy (500 rads).

After the first 14 days — During the period of organogenesis (approximately 2 to 8 weeks after fertilization or 4 to 10 weeks after the last menstrual period), the embryo may be damaged as a result of radiation-induced cell death, disturbances in cell migration and proliferation, or mitotic delay [26]. Lethality is rare.

The major sequelae of radiation damage at this stage are fetal growth restriction and congenital malformations, particularly of the central nervous system (eg, microcephaly, intellectual disability, gross eye abnormalities). Microcephaly is the most frequently cited manifestation of radiation injury in utero [27]. In the absence of any of these findings, the presence of other types of malformations in humans should not be attributed to radiation exposure [18].

- Malformations For the developing fetus under 16 weeks of gestation, the threshold for possible prenatal radiation effects is approximately 0.10 to 0.20 Gy (10 to 20 rads) [19]. After 16 weeks of gestation, the consensus of most researchers is that this threshold is much higher, at least 0.50 to 0.70 Gy (50 to 70 rads).
- Mental retardation Studies in survivors of the Hiroshima atomic bomb demonstrated that the risk of mental retardation and microcephaly was highest for radiation exposures at 8 to 15 weeks after conception [10]. The abnormalities were attributed to alterations in neuronal development. No cases of severe intellectual disability were identified in the children of atomic bomb survivors who were exposed prior to 8 weeks or after 25 weeks following conception. The risk appeared to be a linear function of dose, with a threshold of 0.12 Gy (12 rads) at 8 to 15 weeks, and 0.21 Gy (21 rads) at 16 to 25 weeks [11-14].

In addition, at 8 to 15 weeks, the average IQ loss was approximately 25 to 31 points per Gy (per 100 rads) above 0.1 Gy (10 rads), and the risk for severe intellectual disability was approximately 40 percent per Gy (per 100 rads) above 0.1 Gy (10 rads). By comparison, at 16 to 25 weeks, the average IQ loss was approximately 13 to 21 points per Gy at doses above 0.7 Gy, and the risk of severe intellectual disability was approximately 9 percent per Gy above 0.7 Gy.

Growth restriction — Atomic bomb survivor data showed a permanent restriction of physical growth with increasing radiation dose, particularly above 1 Gy [19]. This was most pronounced when the exposure occurred in the first trimester. A 3 to 4 percent reduction in height at age 18 occurred when the dose was greater than 1 Gy.





Estimated average fetal radiation exposure from selected imaging studies performed on the mother during pregnancy

| Procedure | Fetal dose (mrad) for an average study |
|------------------------------------------|----------------------------------------|
| Chest radiograph (PA and lateral) | <1 |
| Abdominal plain film | 200 to 300 |
| Intravenous pyelogram | 400 to 900 |
| Barium enema | 700 to 1600 |
| Cervical spine radiograph | <1 |
| Dorsal spine radiograph | <1 |
| Lumbar spine radiograph | 400 to 600 |
| Lumbosacral area | 200 to 600 |
| Upper GI series | 50 to 400 |
| Hip and femur radiograph | 100 to 400 |
| Dental radiograph | 0.01 |
| Mammography | Negligible |
| Cerebral angiography | <10 |
| CT of the chest | 30 |
| CT of the abdomen | 250 |
| Perfusion lung scan with 99Tc | 6 to 12 |
| Ventilation lung scan | 1 to 19 |
| Pulmonary angiography via femoral route | 221 to 374 |
| Pulmonary angiography via brachial route | <50 |

PA: posterior-anterior; GI: gastrointestinal; CT: computed tomography; 99Tc: techniticum-99.

Data from: Bentur Y. Ionizing and nonionizing radiation in pregnancy. In: Maternal-fetal toxicology, 2nd ed, Koren G (Ed), Marcel Dekker, New York, 1994, p.515, and Guidelines on diagnosis and management of acute pulmonary embolism. Task Force on Pulmonary Embolism, European Society of Cardiology. Eur Heart J 2000; 21:1301.





Computed tomography — The fetal radiation dose from a CT scan is affected by several variables, including the number, location, and thickness of slices. When CT imaging is performed in pregnancy, using a narrow collimation and wide pitch (ie, the patient moves through the scanner at a faster rate) results in a slightly reduced image quality, but provides a large reduction in radiation exposure. Scanning protocols should also be modified. As an example, if performing a CT scan with contrast, the number of acquisitions can be reduced by eliminating the precontrast series. (See "Principles of computed tomography of the chest".)

Fetal radiation exposure during CT scans not involving the abdomen or pelvis is minimal. As an example, the radiation exposure from maternal head CT is approximately 2 mGy (200 mrad) for the mother and less than 0.10 mGY (10 mrad) for the fetus if the abdomen is shielded.

SUMMARY AND RECOMMENDATIONS

- Ideally, semi-elective radiologic procedures are scheduled during the first 10 days (follicular phase) of the menstrual cycle. All women of childbearing potential should be asked if they could be pregnant at the time of a radiologic examination. If any doubt exists, a pregnancy test should be obtained prior to the diagnostic procedure. The perceived risk of radiation exposure is much greater than the actual risk, but a full explanation of these risks to the woman and her family is best given prior to, rather than after, the exposure. (See "Introduction" above.)
- During pregnancy, ultrasound examination and magnetic resonance (MR) imaging are generally preferred to imaging modalities that involve ionizing
- However, concern about the possible effects of ionizing radiation should not prevent medically indicated diagnostic procedures using the best avatechniques can be employed to minimize the radiation dose. (See <u>'Effects of ionizing radiation on the fetus'</u> above and <u>'Issues by type of diagnos</u>
- Radiation risks should be discussed with the pregnant patient, including an explanation of the background population risk for miscarriage, conge
 well as the risk of developmental disorders. Consultation with a radiologist should be obtained to plan the optimum study using the least amount
 the pregnancy. (See <u>Effects of ionizing radiation on the fetus'</u> above and <u>Fetal exposure from common procedures'</u> above.)
- At doses less than 0.05 Gy, there is no evidence of an increased risk of fetal anomalies, intellectual disability, growth restriction, or pregnancy to 3000 background rate. (See Exposure less than 0.05 Gy (5 rads) above.)
- During the first 14 days after fertilization, intact survival or death are the most likely outcomes of radiation exposure above 0.05 Gy (5 rads). A conception above.)
- After the first 14 days, radiation exposure over 0.5 Gy may be associated with an increased risk of congenital malformations, growth restriction,

懷孕初期(1~3個月)

胚胎發育期

懷孕中期(4~6個月)

大腦成長期

懷孕後期〔7~10個月〕

器官發育期

胎兒處在胚胎發育期,胎盤、胎膜尚在形成之中,電磁波輻射會使胚胎細胞的DNA(脱氧核糖核酸)受損、受精卵異常、基因和染色體發生突變,可能會導致流產或胎兒畸形的情況。

胎兒處在大腦成長期,也是胎兒發展最重要的 時期,電磁波輻射會影響胎兒的甲狀腺機能, 並使得血液中的鐵質被磁化而導致血量减少, 進而引起營養缺乏、智力下降、低能或癡呆的 情況。

胎兒處在器官發育期,電磁波輻射會影響胎兒 的血液而使得各項器官細胞發育異常,並且破 壞生物?活性,影響胎兒免疫系統,造成胎兒出 生後容易體弱多病。

GO

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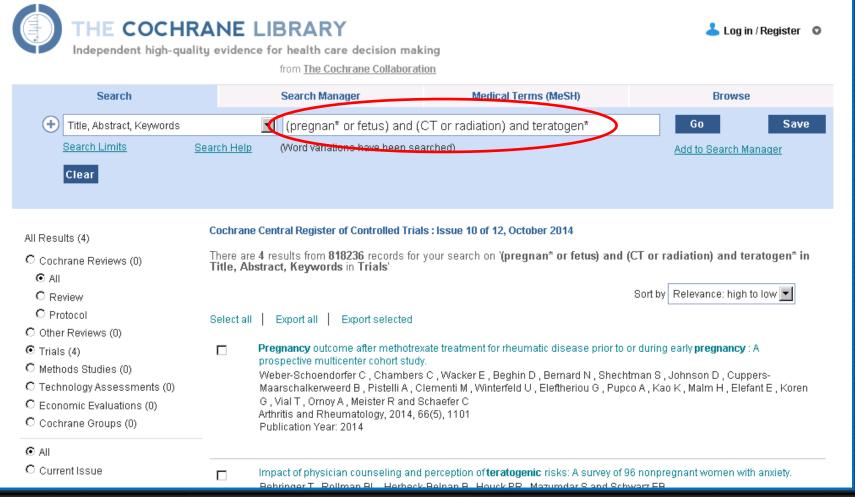


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| #7 | #5 and #6 | 4 |
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| #5 | (#1 or #2) and (#3 or #4) | 1001 |
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| #3 | radiation [ti,ab,kw] | 9874 |
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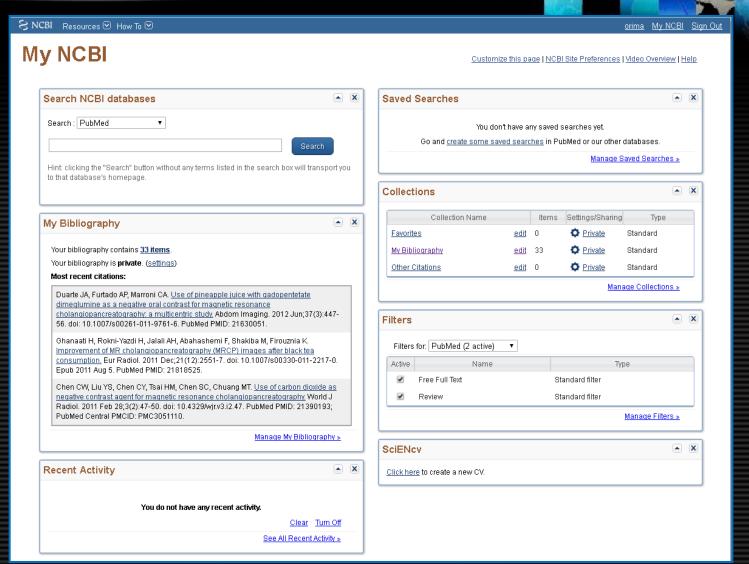
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| #2 | #1 and Teratogen* | 572 | |
| #1 | (Pregnan* or fetus) and (radiation or CT) | 17704 | |



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決定問題的型態

- 治療或預防
 - 服用阿斯匹林是否可以預防中風?
- 傷害或病因
 - 停經婦女使用荷爾蒙治療是否會增加乳癌的機率?
- 診斷
 - McBurney 's sign診斷急性盲腸炎的敏感性 及特異性為何?
- 預後
 - 利用 Ranson 's criteria 預測急性胰臟炎死亡 率為何?

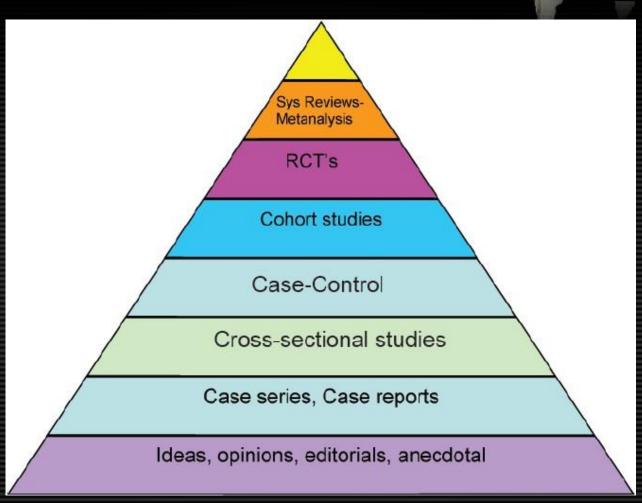
依問題的型態決定研究設計



| Type of question | Suggested best type of study |
|------------------|-------------------------------------------------|
| Therapy | RCT > Cohort > Case Control > Case Series |
| Diagnosis | Prospective, blind comparison to gold standard |
| Etiology/Harm | RCT > Cohort > Case Control > Case Series |
| Prognosis | Cohort Study > Case Control > Case Series |
| Prevention | RCT > Cohort Study > Case Control > Case Series |
| Clinical Exam | Prospective, blind comparison to gold standard |
| Cost analysis | economic analysis |



證據等級高低





Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

| Question | Step 1 | | Step 3 | | | Step 5 (Level 5) |
|-------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|-------------------------------------------------|------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|------------------------------|
| | (Level 1*) | (Level 2*) | (Level 3*) | | (Level 4*) | |
| How common is the problem? | Local and current random sample surveys (or censuses) | Systematic review of surveys that allow matching to local circumstances** | Local non-random samp | ole** | Case-series** | n/a |
| Is this diagnostic or monitoring test accurate? (Diagnosis) | Systematic review of cross sectional studies with consistently applied reference standard and blinding | 1 | Non-consecutive studie consistently applied ref | • | Case-control studies, or "poor or non-independent reference standard** | Mechanism-base reasoning |
| What will happen if | of incontion schoot studios | Inception cohort studies | , | arm of randomized trial* | Case-series or case- control studies, or poor quality prognostic cohort study** | n/a |
| wna | at are t | ne KA | KE | led cohort/follow-up | studies, or historically controlled studies** | Mechanism-based reasoning |
| harr | ns? | | | led cohort/follow-up urveillance) provided bers to rule out a 3-term harms the 1st be sufficient.)** | Case-series, case-control, or historically controlled studies** | Mechanism-based reasoning |
| (Treatment Harms) | | | | | | |
| | | | | lled cohort/follow-up | Case-series, case-control, or historically controlled studies** | Mechanism-based reasoning |
| | | | | † | | |

^{*} Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect size.

How to cite the Levels of Evidence Table

OCEBM Levels of Evidence Working Group*. "The Oxford 2011 Levels of Evidence".

Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653

^{**} As always, a systematic review is generally better than an individual study.

^{*} OCEBM Table of Evidence Working Group = Jeremy Howick, Iain Chalmers (James Lind Library), Paul Glasziou, Trish Greenhalgh, Carl Heneghan, Alessandro Liberati, Ivan Moschetti, Bob Phillips, Hazel Thornton, Olive Goddard and Mary Hodgkinson

不要忘記研究倫理道德

- 此研究問題不適合用前瞻性的研究設計,較適合用回溯性的研究設計。
 - Case control, case series, case report



回溯性的文獻:以此篇為例



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SMALL HEAD SIZE AFTER IN-UTERO EXPOSURE TO ATOMIC RADIATION

RobertW. Miller, WilliamT. Blot 1

Abstract

For the first time, dose estimates have been related to small head circumference induced by exposure in utero to the atomic bomb. There was a progressive increase with dose in the frequency of the abnormality among persons whose mothers were exposed before the eighteenth week of pregnancy. In Hiroshima the minimum dose-producing effect was 10-19 rad, but in Nagasaki no effect was observed under 150 rad. At maternal doses of 150 rad or more in both cities, small head circumference was often accompanied by mental retardation. The observations at low doses in Hiroshima are not directly applicable to medical radiology because of the possible influence of neutrons (nil in Nagasaki) and perhaps to interactions with other environmental disturbances, more widespread in Hiroshima than in Nagasaki.

Summary

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^{悪森}醫療財團法人 **〒 ★ まままま ホヌ ギケ** (

新我举首纵置阮 Ditmanson Medical Foundation Chia-Yi Christian Hospita

 $[\]underline{a}$ Epidemiology Branch, National Cancer Institute, Bethesda, Maryland, U.S.A..

 $[\]underline{b}$ and Atomic Bomb Casualty Commission, Hiroshima, Japan

其摘要 (1)

- For the first time, dose estimates have been related to small head circumference induced by exposure in utero to the atomic bomb.
- There was a progressive increase with dose in the frequency of the abnormality among persons whose mothers were exposed before the eighteenth week of pregnancy.



其摘要 (2)

- In Hiroshima the minimum dose-producing effect was 10-19 rad, but in Nagasaki no effect was observed under 150 rad.
- At maternal doses of 150 rad or more in both cities, small head circumference was often accompanied by mental retardation.
- The observations at low doses in Hiroshima are not directly applicable to medical radiology because of the possible influence of neutrons (nil in Nagasaki) and perhaps to interactions with other environmental disturbances, more widespread in Hiroshima than in Nagasaki.



結論

- 含輻射線之診斷檢查需依ALARA (As Low As Reasonably Achievable)的原則。
- 游離輻射效應分為stochastic effect及 deterministic effect。
- 容易因游離輻射產生畸胎的孕期約為2-20週,懷 孕8週是位於游離輻射易感期內。
- 標準的腹部電腦斷層檢查對胎兒的劑量約為1-4.6
 rad,以 deterministic effect來說,未達致畸胎 關值(5 rad)。以stochastic effect來說,雖然機 率很低,仍無法完全排除致畸胎可能。



結論

- 在理學檢查或超音波仍無法對腹部急症的懷孕婦女有初步的診斷或排除嚴重或致死性疾病時,電腦斷層檢查對媽媽來說,還是一個必須要考慮的選項。
- 因為倫理道德考量,不應該做有關游離輻射效應的人體試驗和研究。因此搜尋後所找到的文獻,其證據等級不會太高。在研究方法的限制之下,只能根據目前有限的證據和強度,對病患和家屬據買以告,協助他們做最適合的決定。

