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Effect food intake during labor on obstetric outcome: randomised controlled trail

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臨床問題 (待產期間可以進食嗎?)

- 單位常規
  - Vital signs: as ward routine (Qid)
  - On fetal monitor as routine
  - P-P care prn
  - **If Cx os>3cm, call doctor, then:**
    - **NPO**
    - glycerine ball 2# for enema
    - IVF: Lactated Ringer run 60 mL/hr

- 禁食，優點:因應緊急剖腹產，減少食物逆流之危險
  缺點:飢餓難耐
- 進食，優點:增加體力，減少飢餓
  缺點:易有嘔吐情形

前言

- 美國麻醉醫師學會(2007)建議，分娩期間若無特殊併發症，可進食液體，如水、茶、黑咖啡和運動飲料。避免進食固體食物，以降低母親併發症。
- 禁食的住要目的：避免全身麻醉時肺吸入之合病症。
- 長時間空腹，病沒有實證顯示，會減少肺吸入發生率。
- 禁止進食，有害於母親、胎兒及產程進展，進食可能影響正常生產的能力，因產程及新生兒出生時間是無法預知的。

- 荷蘭：79%准許待產婦女進食
- 英國：32%准許取液體和食物
- 美國：限制以液體食物為主

步驟 1：研究探討的問題為何？

P	Primi gravid women (>18歲，尚未生產，妊娠>36週，無糖尿病，頭位，子宮頸<6 cm，包括催生或藥物增強宮縮)
I	Eating (low fat, low residue diet) bread, biscuits, vegetables, fruits, low fat yoghurt, soup, isotonic drinks, and fruit juice.
C	Water (Ice chips and water only)
O	**Maternal outcomes** • Rate of spontaneous vaginal delivery • Duration of labor **Neonatal outcomes** • 第1, 5分鐘 Apgar score • Fetal weight • admission to the neonatal intensive care unit or special care baby unit

步驟 2：研究的品質有多好(內在效度)？

招募(Recruitment) - 受試者是否具有代表性？

我們是否知道病人族群為何(收案場所、納入 / 排除條件)？在理想情況下，納入本研究之受試者應具有連續性(有時為隨機取樣)，了解符合收案條件的對象且簽署同意書。

- We did the trial at Guy’ s and St Thomas’ Hospital in London between June 2001 and April 2006.
- **納入條件**：
  - ✓ >18歲，尚未生產，妊娠>36週，無糖尿病，頭位，子宮頸擴張小於6 cm，包括催生或藥物增強宮縮
- **排除條件**：
  - ✓ 經產婦，已知的產科或醫療併發症，可能增加手術的可能性，嚴重疼痛，待產中打算用注射鴉片類藥物止痛，無法理解英語（沒有翻譯）。
- 簽妥書面同意書

評讀結果：■是 □否 □不清楚 [p2 Selection of patients]

步驟 2：研究的品質有多好(內在效度)？

分派(Allocation) - 分派方式是否隨機且具隱匿性...？

最理想的方式是以中央電腦進行隨機分配，此方式常用於多中心試驗，而較小型的試驗可由獨立人員(如醫院藥師)「監督」隨機分配的過程。

- Midwife randomised them either into the “eating” or the “water only” group.。
- Entry of a woman’sinitials, hospital number, and date of birth on to a dedicated computer on the labour ward automatically generated the allocation group together with a study number, which was then recorded on the outcome sheet.
- These data could, if necessary, be verified against the computer randomisation at a later time.

評讀結果：□是 □否 ■不清楚[p2 Study design]

步驟 2：研究的品質有多好(內在效度)？

每個組別，在研究開始時的情況是否相同？ (續)

若隨機分配順利，各組研究對象的條件應是相近、可互相比較的。每組研究對象的基本條件越相近越好。應有指標可確認各組研究對象之間的差異是否達到統計上顯著的差異(如 p值)。

評讀結果：■是

說明：[pp3 Result]

研究對象特性

- 年齡
- 種族
- 食物攝取
- 引產方式
- 麻醉
- 嬰兒體重

Table 1 | Baseline characteristics. Values are numbers (percentages) unless stated otherwise

Characteristic	Eating (n=1219)	Water (n=1207)
Age:		
Mean (SD)	29 (6)	29 (6)
Range	18-44	18-47
Ethnic group:		
White	751 (62)	741 (61)
African or Caribbean	285 (23)	281 (23)
Other	183 (15)	185 (15)
Pre-labour food intake:		
Large meal	79 (6)	61 (5)
Light meal	438 (36)	434 (36)
Snack	441 (36)	395 (33)
No food	261 (21)	317 (26)
Labour induction:		
Prostaglandin only	117 (10)	92 (8)
Prostaglandin plus oxytocin	212 (17)	233 (19)
Epidural analgesia	804 (66)	813 (67)
Mean (SD) baby's birth weight (g)	3421 (472)	3428 (520)

- ✓ The two randomised groups were comparable with respect to age, ethnic group, pre-labour food intake, need for intravenous fluids, and use of prostaglandin and oxytocin.
- ✓ The birth weights of the neonates were similar in both groups (table 1)

步驟 2：研究的品質有多好(內在效度)？

維持(Maintenance) - 各組是否給予相同的治療？

各研究組別之間，除了對病人的介入之外，其餘的治療應完全相同(即為了執行本研究所增加的治療、檢驗或評估應相同)。

Obstetric management

The attending obstetricians and midwives made all the relevant decisions about the woman's obstetric management but obviously could not be blinded to trial allocation. The people deciding on obstetric interventions were generally unaware of the trial intervention allocation and had no vested interest in the study. Vaginal dilatation was assessed at four hourly intervals. Continuous external fetal heart rate monitoring and tocodynamometry were used as indicated. Oxytocin infusion, when indicated, was administered according to the hospital protocol. No routine antacid was administered. The decision to proceed to an operative delivery was made by the duty obstetrician. The attending midwife recorded the Apgar scores at delivery.

Dietary advice

After randomisation, women in the eating group were advised to consume a low fat, low residue diet at will during their labour. The emphasis was on small regular amounts of food rather than eating set regular meals. Suggested foods included bread, biscuits, vegetables, fruits, low fat yoghurt, soup, isotonic drinks, and fruit juice. All women had free access to water. Women in the water only group were advised to have ice chips and water only. Women were told that eating was not recommended in labour (as was the policy in the hospital at the time), but they were actively encouraged to do so if randomised to the feeding arm. Women were made aware that this is increasingly practised in many units. Women in the water only group were encouraged not to eat if they requested to do so. Light food was made available on the labour ward, or women could bring in their own food.

評讀結果：■是 □否 □不清楚 說明：[pp2 Obstetric management]

步驟 2：研究的品質有多好(內在效度)？

是否有足夠的追蹤(Follow up)？

研究中流失(無法繼續追蹤)的病人，最好少於 20%。病人應依照隨機分配的組別進行統計分析(即「治療意向分析法」Intention –to-treat , ITT analysis)。

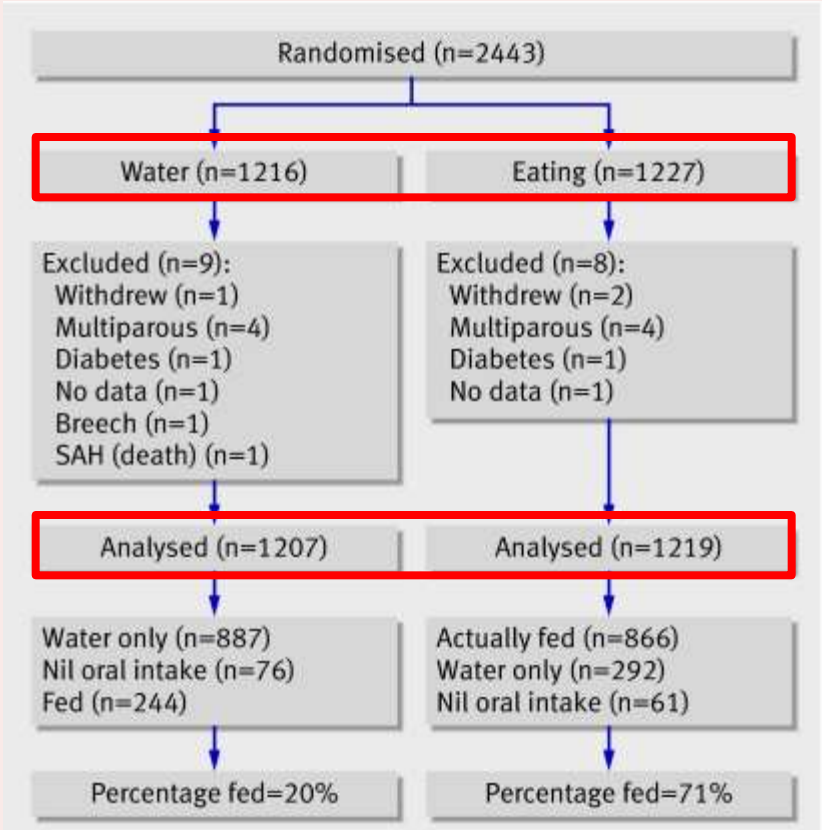
■追蹤率：99.3%

■但，並非治療意向分析法(ITT)

- 所有接受隨機分派的受試者都應該納入分析

評讀結果：■是 □否 □不清楚

說明：[pp3]



Flow of participants through study. PET=pre-eclamptic toxaemia; SAH=subarachnoid haemorrhage

步驟 2：研究的品質有多好(內在效度)？

評估(Measurement) - 受試者與評估者是否對治療方式及(或)評估目的維持盲法(blind)？

最好的狀況是？ 在客觀結果(如：死亡)方面，盲法的重要性較低，但在主觀結果(如：症狀或功能)方面，評估者維持盲法非常重要。

- blind-

1. The attending obstetricians and midwives made all the relevant decisions about the woman’ s obstetric management but obviously could not be blinded to trial allocation.
2. The people deciding on obstetric interventions were generally unaware of the trial intervention allocation and had no vested interest in the study.
3. The trial coordinator was responsible for training midwives on the study protocol and adherence to the protocol and for the daily collection of data sheets.
4. The decision to proceed to an operative delivery was made by the duty obstetrician.
5. The attending midwife recorded the Apgar scores at delivery.

評讀結果： □是 ■否 □不清楚 [pp2 Obstetric management]

步驟 3：研究結果及討論

使用何種評估方式，療效有多大？

Table 2 | Primary and pre-defined secondary maternal outcomes. Values are numbers (percentages) unless stated otherwise

Outcome	Eating (n=1219)	Water (n=1207	P value	Comparison (95% CI)
Normal vaginal delivery*	533 (44)	534 (44)	0.77	0.99† (0.91 to 1.09)
Instrumental delivery	324 (27)	310 (26)	0.64	1.04† (0.91 to 1.19)
Caesarean section	362 (30)	363 (30)	0.86	0.987† (0.87 to 1.12)
Vomited	430 (35)	406 (34)	0.41	1.05† (0.94 to 1.17)
Oxytocin for augmentation	647 (53)	673 (56)	0.19	0.95† (0.88 to 1.02)
Intravenous fluid >500 ml	820 (67)	838 (69)	0.25	0.969† (0.92 to 1.02)
Length of labour (min):				
Geometric mean	597	612	–	0.975‡ (0.927 to 1.025)
Median (interquartile range)	669 (437-929)	658 (432-905)	–	

*Primary outcome.
†Risk ratio.
‡Ratio of geometric means.

Results are presented as estimates with 95% confidence intervals, to facilitate determination of clinical equivalence.

步驟 3：研究結果及討論

使用何種評估方式，療效有多大？

Table 3 | Pre-defined secondary neonatal outcomes. Values are numbers (percentages) unless stated otherwise

Outcome	Eating (n=1219)	Water only (n=1207)	P value	Risk ratio (95%CI)
Apgar score 5 min ≤7	16 (1.3)	22 (1.8)	0.33	0.72 (0.38 to 1.36)
Apgar score 5 min ≤4	4 (0.33)	9 (0.75)	0.18	0.44 (0.14 to 1.42)
Admission to SCBU/ICU	61 (5.0)	62 (5.2)	0.81	0.96 (0.68 to 1.35)

ICU=intensive care unit; SCBU=special care baby unit.

Results are presented as estimates with 95% confidence intervals, to facilitate determination of clinical equivalence.

步驟 3：研究結果

WHAT IS ALREADY KNOWN ON THIS TOPIC

The practice of fasting women during labour was intended to protect them from pulmonary aspiration should general anaesthesia be needed for an emergency operative delivery

Prolonged fasting in labour has never been proved to influence the incidence of pulmonary aspiration

Some clinicians and midwives argue that preventing food intake during labour can be detrimental to the mother, her baby, and the progress of labour

WHAT THIS STUDY ADDS

Eating did not influence obstetric (mode of delivery or duration of labour) or neonatal outcomes

No evidence of harm was found, but the power was insufficient to imply safety owing to the current extremely low incidence of acid pulmonary aspiration in obstetrics

If low risk women are offered a light, easily digestible diet during labour they should be advised that this will not improve their obstetric and neonatal outcome

Restricting oral fluid and food intake during labour (Review) 2010

Cochrane Database of Systematic Reviews

文獻摘要(1)

- **Objectives**
  - To determine the benefits and harms of oral fluid or food restriction during labour.
- **Search methods**
  - We searched the Cochrane Pregnancy and Childbirth Group’ s Trials Register (April 2009).
- **Selection criteria**
  - Randomised controlled trials (RCTs) and quasi-RCTs of restricting fluids and food for women in labour compared with women free to eat and drink.
- **Data collection and analysis**
  - Two authors independently assessed the studies for inclusion, assessed risk of bias and carried out data extraction.

文獻摘要(2)

- Results
  - ✓We identified five studies (3130 women).
  - ✓All studies looked at women in active labour and at low risk of potentially requiring a general anaesthetic.
    - One study looked at complete restriction versus giving women the freedom to eat and drink at will;
    - two studies looked at water only versus giving women specific fluids and foods
    - two studies looked at water only versus giving women carbohydrate drinks.

Selected Results (1)

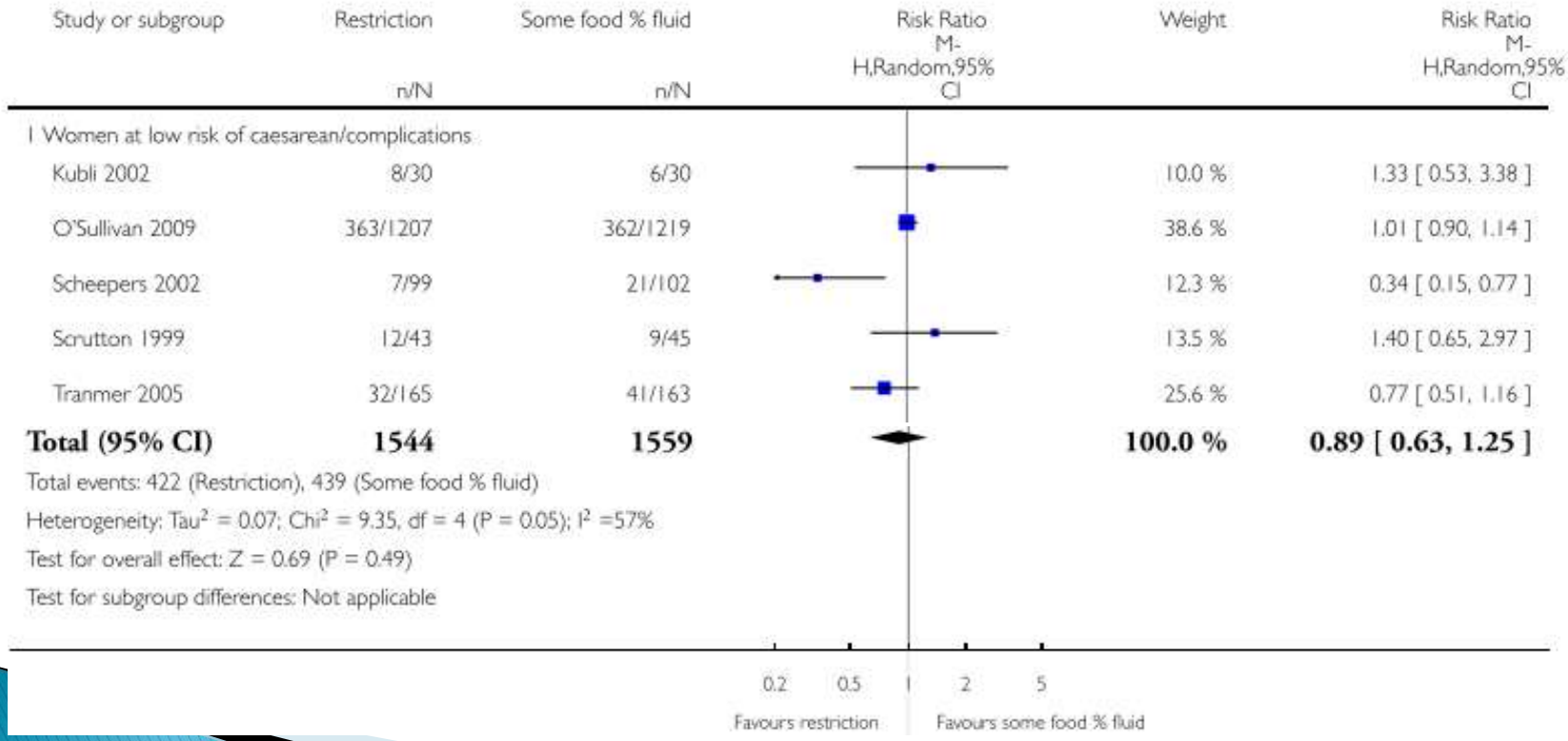
Analysis 1.1. Comparison 1 Any restriction of oral fluid and food versus some fluid and food, Outcome 1 Caesarean section.

Review: Restricting oral fluid and food intake during labour

Comparison: 1 Any restriction of oral fluid and food versus some fluid and food

Outcome: 1 Caesarean section

- 5 studies, 3103 women
- average RR 0.89, 95% CI 0.63 to 1.25
- $T^2 = 0.07$, Chi^2 P = 0.05, $I^2 = 57$ %



Selected Results (2)

Analysis 1.2. Comparison 1 Any restriction of oral fluid and food versus some fluid and food, Outcome 2 Operative vaginal birth.

Review: Restricting oral fluid and food intake during labour

Comparison: 1 Any restriction of oral fluid and food versus some fluid and food

Outcome: 2 Operative vaginal birth

- 5 studies, 3103 women
- average RR 0.98, 95% CI 0.88 - 1.10
- $T^2 = 0.00$, Chi^2 P = 0.67, I^2 =0%

Study or subgroup	Restriction n/N	Some food % fluid n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Women at low risk of caesarean/complications					
Kubli 2002	4/30	6/30		1.0 %	0.67 [0.21, 2.13]
O'Sullivan 2009	310/1207	324/1219		73.8 %	0.97 [0.85, 1.10]
Scheepers 2002	36/99	29/102		8.1 %	1.28 [0.85, 1.91]
Scrutton 1999	13/43	16/45		3.7 %	0.85 [0.47, 1.55]
Tranmer 2005	53/165	53/163		13.5 %	0.99 [0.72, 1.35]
Total (95% CI)	**1544**	**1559**		**100.0 %**	**0.98 [0.88, 1.10]**

Total events: 416 (Restriction), 428 (Some food % fluid)

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 2.36$, df = 4 (P = 0.67); I^2 =0.0%

Test for overall effect: Z = 0.29 (P = 0.77)

Test for subgroup differences: Not applicable

Selected Results (3)

Analysis 1.10. Comparison 1 Any restriction of oral fluid and food versus some fluid and food, Outcome 10 Duration of labour (hours).

Review: Restricting oral fluid and food intake during labour

Comparison: 1 Any restriction of oral fluid and food versus some fluid and food

Outcome: 10 Duration of labour (hours)

- 3 studies, 476 women
- average MD -0.29, 95% CI -1.55 to 0.97
- $T^2 = 0.72$, Chi^2 P = 0.09, $I^2 = 58$ %

Study or subgroup	Restriction N	Restriction Mean(SD)	Some food % fluid N	Some food % fluid Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Women at low risk of caesarean/complications							
Kubli 2002	30	8.9 (2.9)	30	7.95 (2.5)		34.2 %	0.95 [-0.42, 2.32]
Scrutton 1999	43	10.7 (3.75)	45	11.8 (3.7)		30.6 %	-1.10 [-2.66, 0.46]
Tranmer 2005	165	9.5 (5.6)	163	10.3 (6.6)		35.2 %	-0.80 [-2.13, 0.53]
Total (95% CI)	**238**		**238**			**100.0 %**	**-0.29 [-1.55, 0.97]**

Heterogeneity: $Tau^2 = 0.72$; $Chi^2 = 4.75$, df = 2 (P = 0.09); $I^2 = 58\%$

Test for overall effect: Z = 0.46 (P = 0.65)

Test for subgroup differences: Not applicable

Selected Results (4)

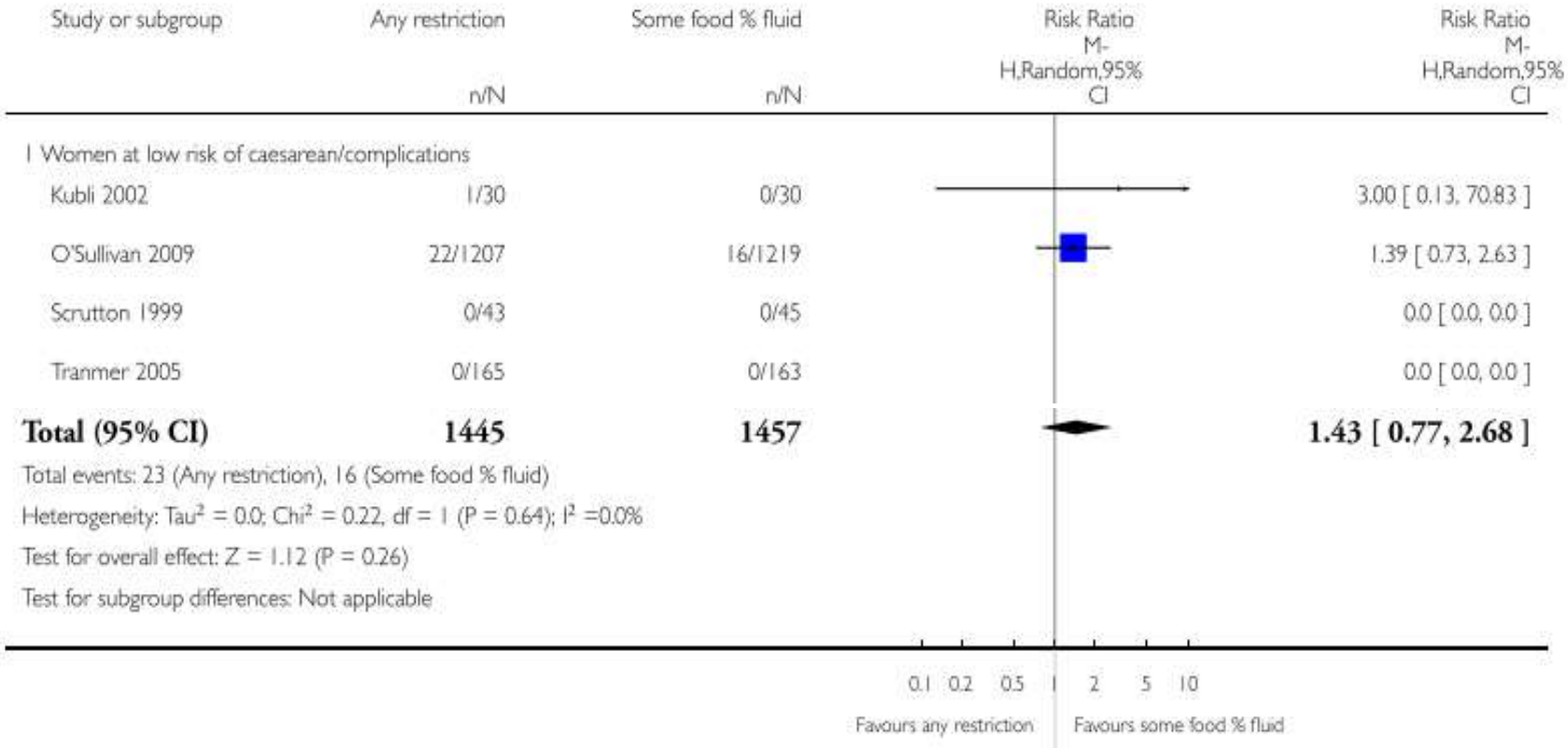
Analysis 1.4. Comparison 1 Any restriction of oral fluid and food versus some fluid and food, Outcome 4 Apgar < 7 at 5 min.

Review: Restricting oral fluid and food intake during labour

Comparison: 1 Any restriction of oral fluid and food versus some fluid and food

Outcome: 4 Apgar < 7 at 5 min

- 4 studies, 2902 infants
- average RR 1.43, 95% CI 0.77 to 2.68
- T^2 =0.00, Chi^2 P = 0.64, I^2 = 0%



Main results & Authors' conclusions

- There were no statistically significant differences identified in:
  - ✓Caesarean section
  - ✓Operative vaginal births
  - ✓Apgar scores <=7 (5')
  - ✓Nor in any of the other outcomes assessed
  - ✓Women's views were not assessed

- 目前沒有任何證據支持，對於低妊娠風險的婦女，在待產期間限制液體和食物的攝取，有任何益處。
  - ✓ 只有一篇比較報告指出，待產期間食用碳水化合物的婦女，比只喝水的婦女，有較高的剖腹產率，但因樣本量較小，結果應謹慎解釋 (Scheepers, 2002)

討論(1)~ 其他醫院的作法

	喝飲料	吃東西	禁食
本院			
A醫院			
B醫院			
C醫院			
D醫院			
E醫院			
F醫院			

討論(2)

- 麻醉科戴主任
  - ✓常規剖腹生產，應以常規禁食八小時，但若緊急剖腹產，則尊重婦產科醫師對禁食之考量，不需限制禁食時間。
  - ✓全身麻醉會發生肺吸入之狀況非常少，通常在插管的三分鐘內就會決定是否有此狀況，且可作好預防措施。
- 高副院長
  - ✓此篇研究在新生兒的結果方面: Apger score、baby weight與生產期間之outcome variables，與待產期間是否進食沒有太大關係，重要指標應是”吸入性肺炎 “。
- 婦產科祝醫師
  - ✓目前以人性化待產為主，鼓勵適度進食，尊重其決定，除非產婦或胎兒有醫療上的特殊狀況。

討論(3)

- 待產期間是否可以進食(low fat, low residue diet) 或喝水嗎?
  - 同意20人
  - 懷疑1人
  - 不同意0人

Thank You