Pressure Ulcer Treatment Strategies

A Systematic Comparative Effectiveness Review

Smith ME, Totten A, Hickam DH, Fu R, Wasson N, Rahman B, Motu'apuaka M, Saha S.
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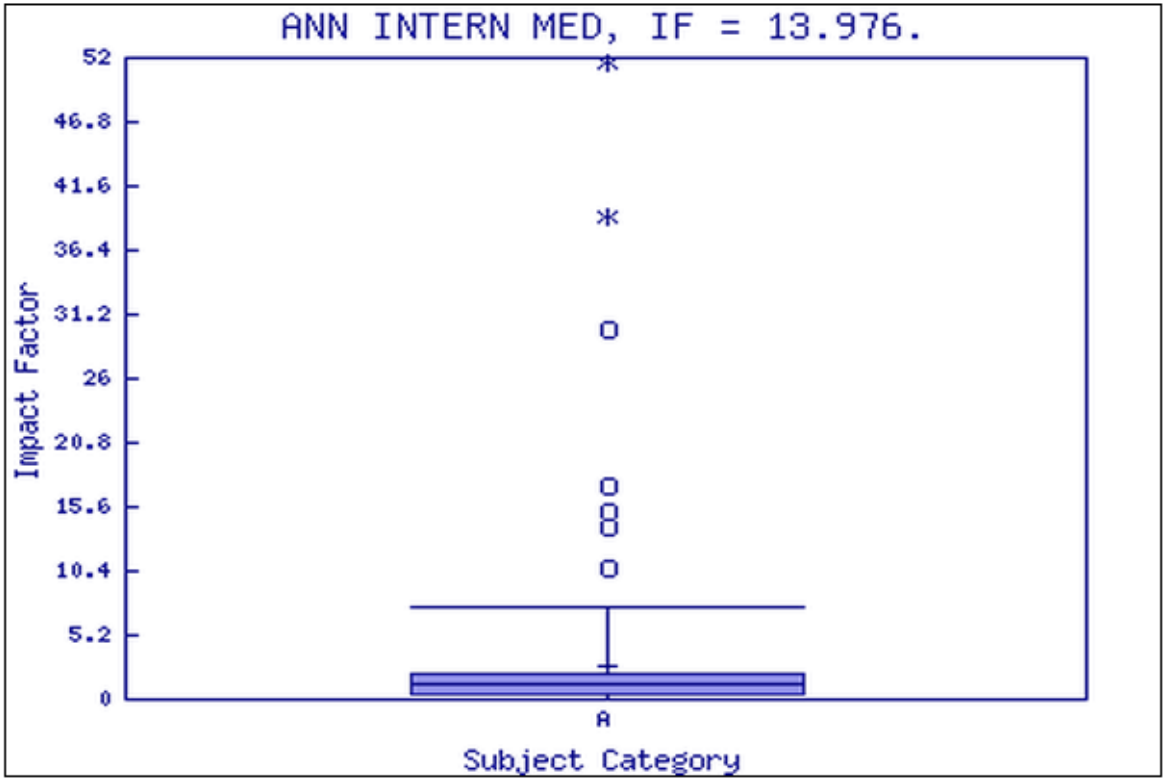
MEDICINE, GENERAL & INTERNAL	155	6	Q1



Key

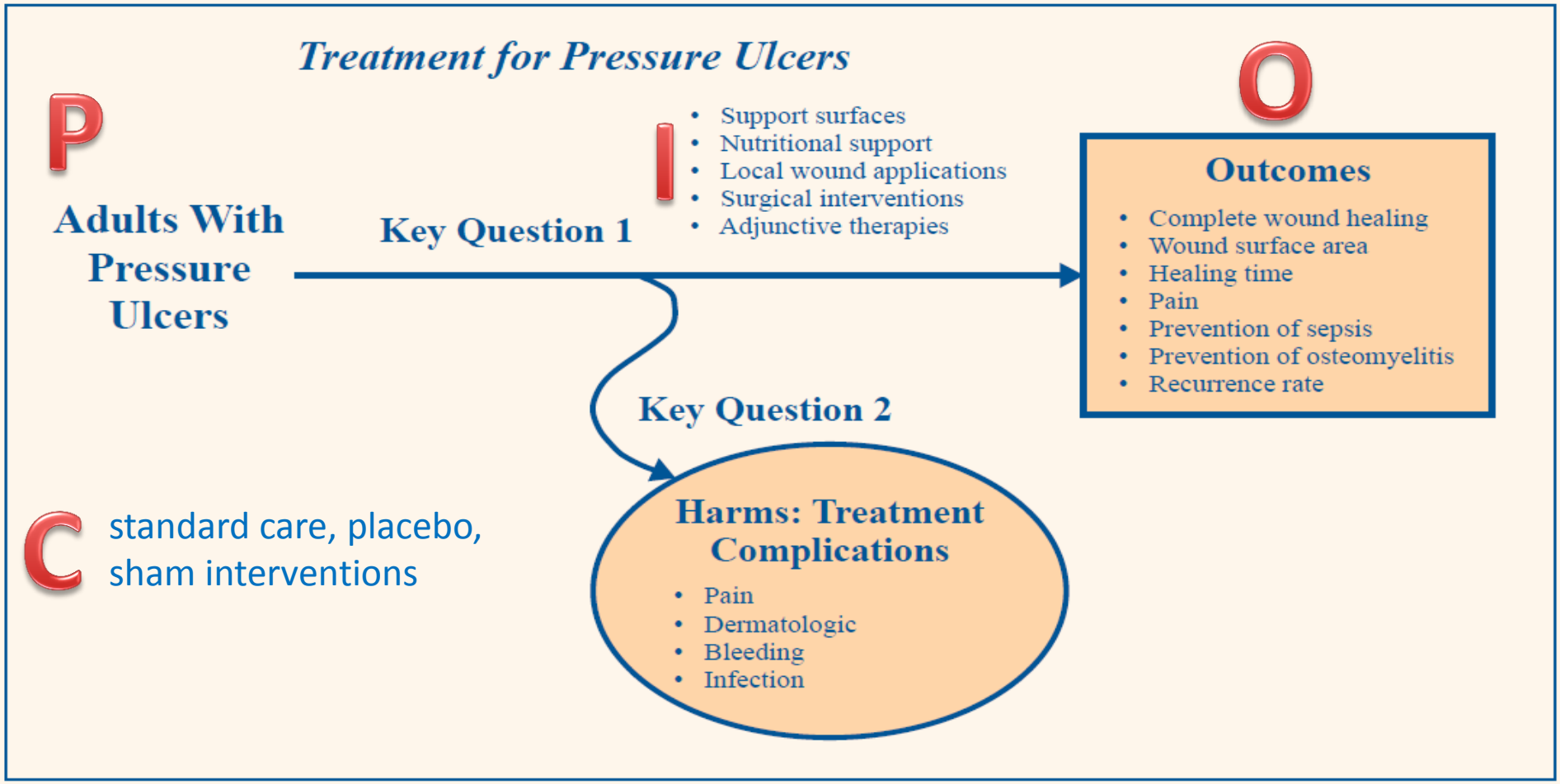
A - MEDICINE, GENERAL & INTERNAL

緣起

- Pressure Ulcer

步驟 1：系統性文獻回顧探討的問題為何？

Figure C. Analytic framework: pressure ulcer treatment strategies



Key Question 1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes

Key Question 2. What are the harms of treatments for pressure ulcers?

步驟 2：系統性文獻回顧的品質如何？(FAITH)

F - 研究是否找到 (Find) 所有的相關證據？

最好的狀況是？
良好的文獻搜尋至少應包括二個主要的資料庫(如：Medline, Cochrane考科藍實證醫學資料庫, EMBASE 等)，並且加上文獻引用檢索(參考文獻中相關研究、Web of Science, Scopus或 Google Scholar)、試驗登錄資料等。文獻搜尋應不只限於英文，並且應同時使用 MeSH字串及一般檢索詞彙(text words)。

Data Sources and Searches →P40
We searched for relevant English- and foreign-language studies and systematic reviews in MEDLINE,EMBASE, CINAHL, Evidence-Based Medicine Reviews, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Health Technology Assessment Database, gray literature, scientific information packets, and reference lists. Given the technological advancement in treatment interventions, we restricted our search to January 1985 to October 2012 to find studies of current relevance.

評讀結果：v 是 □否 □不清楚

步驟 2：系統性文獻回顧的品質如何？(FAITH)

A - 文獻是否經過嚴格評讀 (Appraisal)？

最好的狀況是？

應根據不同臨床問題的文章類型，選擇適合的評讀工具，並說明每篇研究的品質(如針對治療型的臨床問題，選用隨機分配、盲法、及完整追蹤的研究類型)。

Data Extraction and Quality Assessment

- We used an approach adapted from the Agency for Healthcare Research and Quality (AHRQ) *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* (9) for determining the strength of evidence as "high," "moderate," "low," or "insufficient" on the *basis of the design, quantity, size, and quality (risk of bias) of studies, consistency across studies, precision of estimates and directness of evidence*

步驟 2：系統性文獻回顧的品質如何(FAITH)[2]

Table. Summary of Evidence of Benefits and Harms of Pressure Ulcer Treatment Strategies*

Intervention	Strength of Evidence† and Summary of Results for Wound Healing	Studies, Participants, and Study Duration for Wound Healing Analysis	Strength of Evidence for Harms‡	Studies and Participants for Harms Analysis
Support surface				
AF beds vs. other surfaces§ (ulcer stage II, III, or IV and unstageable)	Moderate Reduction in wound size: superior	5 studies (n = 908) Duration: 4 d–36 wk	Insufficient Unclear harms for AF beds (rare or minor harms reported)	7 studies (for all support interventions) (n = 526)
AP beds comparison of brands/ forms (ulcer stage II, III, or IV)	Moderate Complete wound healing: similar Reduction in wound size: similar	4 studies (n = 369) Duration: 4 wk–discharge, healing, or death	Insufficient Unclear harms for AP beds, comparison of brands (rare or minor harms reported)	
AP beds vs. other surfaces (ulcer stage I, II, III, or IV)	Low Reduction in wound size: similar	4 studies (n = 368) Duration: 2 wk–3 mo	Insufficient Unclear harms for AP beds vs. other surfaces (rare or minor harms reported)	
LAL beds vs. other surfaces (ulcer stage I, II, III, or IV)	Low Reduction in wound size: similar	5 studies (n = 329) Duration: 1 wk–discharge, healing, or death	Insufficient Unclear harms for LAL beds (rare or minor harms reported)	

評讀結果：v 是 □否 □不清楚

步驟 2：系統性文獻回顧的品質如何(FAITH)

I - 是否只納入 (included) 具良好效度的文章？

最好的狀況是？
僅進行文獻判讀是不足夠，系統性文獻回顧只納入至少要有一項研究結果是極小偏誤的試驗。

Study Selection →P40

- We included randomized trials and comparative observational studies of treatments for pressure ulcers in adults.
- We included noncomparative intervention series (*n* > 50) for surgical interventions and evaluation of harms.
- Exclusion criteria were wrong population (children; adolescents; and patients with non–pressure-related ulcers, including but not limited to venous ulcers and diabetic foot ulcers), studies of interventions without comparators, hospice care settings unless complete wound healing was an outcome measured, and case reports.
- At least *2 investigators* independently evaluated each study to determine inclusion eligibility. Disagreement was settled by consensus or adjudication by a senior investigator when consensus could not be reached.

評讀結果：v 是 □否 □不清楚

步驟 2：系統性文獻回顧的品質如何(FAITH)

T - 作者是否以表格和圖表「總結」(total up) 試驗結果？

最好的狀況是？應該用**至少 1 個摘要表格**呈現所納入的試驗結果。若結果相近，可針對結果進行統合分析(meta-analysis)，並以「森林圖」(forest plot)呈現研究結果，最好再加上異質性分析。

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LAL beds vs. other surfaces (ulcer stage I, II, III, or IV)	Low Reduction in wound size: similar	5 studies (n = 329) Duration: 1 wk–discharge, healing, or death	Insufficient Unclear harms for LAL beds (rare or minor harms reported)	
Nutrition				
Protein-containing nutritional supplements vs. standard diets or placebo (ulcer stage I, II, III, or IV)	Moderate Rate of reduction in wound size: superior	12 studies (n = 562) Duration: 7 d–10 mo	Insufficient Unclear harms of nutritional supplementation	7 studies (n = 448)
Vitamin C vs. placebo (ulcer stage II, III, or IV)	Low Rate of wound healing: similar	1 study (n = 88) Duration: 30 d–12 wk	Insufficient Unclear harms of vitamin C supplementation	2 studies (n = 135)
Local wound applications				
Hydrocolloid dressings vs. conventional care (ulcer stage I, II, III, or IV)	Low Reduction in wound size: superior	10 studies (n = 560) Duration: 3–12 wk	Moderate Hydrocolloid (rate of harms, 0%–16%): skin reactions (inflammation, erythema), maceration, pain, wound deterioration, and overgranulation	4 studies (n = 218)
Hydrocolloid dressings vs. foam dressings (ulcer stage II, III, or IV)	Moderate Complete wound healing: equivalent	8 studies (n = 508) Duration: 2–16 wk	Moderate Foam dressings (rate of harms, 0%–30%): bleeding, overgranulation, wound deterioration, maceration, tissue damage	4 studies (n = 230)
Radiant heat vs. other dressings (ulcer stage III or IV)	Moderate Complete wound healing: similar Rate of reduction in wound size: superior	4 studies (n = 160) Duration: 4–12 wk	Insufficient Unclear harms for radiant heat dressings	1 study (n = 50)
Dextranomer paste vs. wound dressings (ulcer stage I, II, III, or IV)	Low Reduction in wound size: inferior	2 studies (n = 227) Duration: 3–8 wk	Low Dextranomer (rate of harms, 22%): minor infection, bleeding, overgranulation, and skin irritation	1 study (n = 92)
Topical collagen vs. hydrocolloid dressings or standard care (ulcer stage II, III, or IV)	Low Reduction in wound size: similar	3 studies (n = 169) Duration: 2–8 wk	Insufficient Unclear harms for topical collagen	2 studies (n = 145)
PDGF vs. placebo (ulcer stage III or IV)	Low Reduction in wound size: similar	4 studies (n = 209) Duration: 4–16 wk	Insufficient Unclear harms for PDGF	5 studies (n = 322)
Adjunctive therapy				
Electrical stimulation vs. sham (ulcer stage II, III, or IV)	Moderate Complete wound healing: similar Rate of reduction in wound size: superior	6 studies (n = 243) Duration: 4–6 wk 9 studies (n = 397) Duration: 3–16 wk	Low Local skin irritation	3 studies (n = 146)
Electromagnetic therapy vs. sham (ulcer stage II, III, or IV)	Low Rate of reduction in wound size: similar	4 studies (n = 112) Duration: 2–12 wk	Insufficient Unclear harms for electromagnetic therapy	1 study (n = 30)
Therapeutic ultrasound vs. sham or standard care (ulcer stage II, III, or IV)	Low Complete wound healing: similar Reduction in wound size: similar	3 studies (n = 148) Duration: 2–13 wk	Insufficient Unclear harms for therapeutic ultrasound	3 studies (n = 101)
NPWT vs. standard care or topical gel (ulcer stage III or IV)	Low Reduction in wound size: similar	3 studies (n = 138) Duration: 4–6 wk	Insufficient Unclear harms for NPWT	2 studies (n = 77)
Light therapy vs. sham or standard care (ulcer stage II, III, or IV)	Low Complete wound healing: similar	2 studies (n = 317) Duration: 12 wk	Low No clinically important harm reported	4 studies (n = 327)
Light therapy vs. sham or standard care (ulcer stage I, II, III, or IV)	Low Reduction in wound size: superior	5 studies (n = 48 Duration: 2–12 wk	[illegible]	[illegible]
Laser therapy vs. sham or standard care (ulcer stage II, III, or IV)	Low Reduction in wound size: similar	3 studies (n = 13 Duration: 5–6 wk	[illegible]	[illegible]

評讀結果：v 是 □否 □不清楚

步驟 2：系統性文獻回顧的品質如何(FAITH)

H - 試驗的結果是否相近 - 異質性 (Heterogeneity) ?

最好的狀況是？

在理想情況下，各個試驗的結果應相近或具同質性，若具有異質性，作者應評估差異是否顯著(卡方檢定)。根據每篇個別研究中不同的PICO及研究方法，探討造成異質性的原因。

[ex] Local Wound Applications→P44-45

...We found 10 studies (1 good-quality [52], 2 fairquality[53, 54], and 7 poor-quality [55–59, 112, 113])that compared hydrocolloid with gauze dressings and provided low-strength evidence indicating greater reduction in wound size with hydrocolloid dressings. Statistical heterogeneity precluded quantitative pooling of results across these studies. Complete wound healing was equivalent with hydrocolloid and foam dressings (pooled relative risk, 1.12 [95% CI, 0.88 to 1.41]; $I2$ 16.4%; P 0.301) (8 studies; moderate-strength evidence) (72–79). Radiant heat dressings produced more rapid reduction in wound size than other dressings based on moderately consistent results from 2 good-quality and 2 fair-quality trials, but there was no evidence of benefit in terms of complete wound healing(pooled relative risk, 1.23 [CI, 0.70 to 2.14]; $I2$ 0.0%; P 0.916) (83– 86). Evidence about the comparative effectiveness of other dressing types was insufficient.

評讀結果： v是 □否 □不清楚

OUTCOME-benefit (1)

		Support
Air-fluidized beds	Moderate	Air-fluidized beds produced better healing in terms of reduction in ulcer size compared with other surfaces (5 studies conducted in the late 1980s and 1990s).
Alternating pressure beds	Moderate	Complete wound healing and reduction in ulcer size were similar across different brands and types of alternating pressure beds (4 studies).
Alternating pressure beds compared with other surfaces	Low	Wound improvement was similar for alternating pressure beds when compared with air, fluid, or standard beds (4 studies).
Alternating pressure chair cushions	Insufficient	Evidence about alternating pressure chair cushions did not permit conclusions due to differences in the patient populations studied (2 studies).
Low-air-loss beds	Low	Wound improvement was similar for low-air-loss beds compared with foam surfaces (4 studies) and for low-air-loss beds compared with low-air-loss bed overlays (1 study).

OUTCOME-benefit (2)

Nutrition		
Protein-containing nutritional supplements	Moderate	When used in addition to other measures for treating pressure ulcers, protein-containing nutritional supplementation resulted in wound improvement (12 studies).
Vitamin C	Low	Vitamin C used as a single nutritional supplement did not result in wound improvement (1 study).
Zinc	Insufficient	The evidence did not allow conclusions as to whether zinc supplementation improves pressure ulcer healing (1 study).

OUTCOME-benefit (3)

Local Wound Applications		
Hydrocolloid dressings compared with conventional care	Low	Wound improvement was superior with hydrocolloid compared with gauze dressings (10 studies).
Hydrocolloid compared with foam	Moderate	Wound improvement was equivalent with hydrocolloid and foam dressings (8 studies).
Comparisons of different wound dressings	Insufficient	Evidence regarding the comparative effectiveness of hydrogel (compared with standard care or other dressing types; 7 studies), transparent film (4 studies), silicone (2 studies), and alginate dressings (1 study) was inconclusive due to limitations in the number, size, and quality of studies.
Radiant heat compared with other dressings (healing rate)	Moderate	Radiant heat dressings produced more rapid wound healing rates than other dressings for stage III and IV ulcers (4 studies).
Radiant heat compared with other dressings (complete wound healing)	Moderate	Radiant heat dressings were similar to other dressings in terms of complete wound healing of stage III and IV ulcers (4 studies).
Debriding enzymes compared with dressings or other topical therapies	Insufficient	Evidence about the effectiveness of collagenase and other debriding enzymes was inconclusive due to differences in the enzymes studied and outcomes measured (5 studies).
Dextranomer paste compared with wound dressings	Low	Dextranomer paste was inferior to wound dressings (alginate, hydrogel) in promoting wound area reduction (2 studies).
Topical collagen compared with hydrocolloid dressings or standard care	Low	Wound improvement was similar with topical collagen applications compared with hydrocolloid dressings or standard care (3 studies).
Topical phenytoin	Insufficient	Three studies of the effectiveness of topical phenytoin used different comparators and produced inconsistent results.
Maggot therapy	Insufficient	Evidence about the effectiveness of maggot therapy was inconclusive due to poor study quality (3 studies).

OUTCOME-benefit (4)

Local Wound Applications		
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Topical phenytoin	Insufficient	Three studies of the effectiveness of topical phenytoin used different comparators and produced inconsistent results.
Maggot therapy	Insufficient	Evidence about the effectiveness of maggot therapy was inconclusive due to poor study quality (3 studies).

OUTCOME-benefit (5)

Surgery		
Surgical techniques	Insufficient	Evidence was inconclusive as to whether one approach to closure of stage III to IV pressure ulcers was superior to others due to poor-quality studies and heterogeneity in patient populations and surgical procedures (4 studies).

OUTCOME-benefit (6)

Adjunctive		
Electrical stimulation	Moderate	Electrical stimulation was beneficial in accelerating the rate of healing of stage II, III, and IV pressure ulcers (9 studies).
Electromagnetic therapy	Low	Wound improvement of stage II, III, or IV pressure ulcers was similar with electromagnetic therapy compared with sham treatment (4 studies).
Therapeutic ultrasound	Low	Wound improvement was similar with ultrasound compared with standard care or sham treatment (3 studies).
Negative pressure wound therapy	Low	Wound improvement was similar with negative pressure wound therapy compared with standard care (3 studies).
Hydrotherapy	Insufficient	Evidence on the effectiveness of hydrotherapy was insufficient based on 2 randomized trials evaluating different treatment modalities (1 of whirlpool therapy and 1 of pulsatile lavage).
Light therapy (complete wound healing)	Low	Light therapy was similar to sham light therapy in producing complete wound healing based on 2 randomized trials.
Light therapy (wound surface area reduction)	Low	Light therapy reduced wound surface area over time compared with standard care or sham light therapy (5 studies).
Laser therapy	Low	Wound improvement was similar with laser therapy compared with sham treatment or standard care (4 studies).

OUTCOME-harms

Key Question 2. What are the harms of treatments for pressure ulcers?		
Harms: Support		
Support, all strategies	Insufficient	Few of the identified studies (7 out of 24) explicitly addressed harms attributable to support surfaces. In those where harms were mentioned, most reported no significant differences in harms across the different support surfaces. However, as the harms studied were different and were associated with different support surfaces, we were unable to summarize across studies.
Harms: Nutrition		
Nutrition, all strategies	Insufficient	Harms or adverse events were reported in about half of the studies (8 of 16), but the studies reported different harms, did not describe the harm, or did not specify if it was related to treatment.
Harms: Local Wound Applications		
Dressings and topical therapies	Moderate	Harms reported with dressings and topical therapies for pressure ulcers most commonly included skin irritation and inflammation and tissue damage and maceration. Variability in study populations, interventions, adverse event measurement, and reporting precluded an estimate of adverse event rates for dressings and topical therapies (30 studies).
Dressings and topical therapies	Insufficient	Evidence was inconclusive as to whether specific dressing types or topical therapies were associated with fewer harms than others due to poor study quality and differential reporting of harms across studies (7 studies).
Biological agents	Insufficient	Few harms were reported with biological agents, but evidence did not permit determination of the incidence of harms due to lack of precision across studies (5 studies).
Harms: Surgery		
Recurrence or flap failure	Low	Reoperation due to recurrence or flap failure ranged from 12 to 24 percent (2 studies).
Adjunctive		
Electrical stimulation	Low	The most common adverse effect of electrical stimulation was local skin irritation (3 studies).
Electromagnetic therapy Therapeutic ultrasound Negative pressure wound therapy	Insufficient	Due to a lack of reporting, evidence did not permit conclusions about the harms of electromagnetic therapy (1 study), ultrasound (3 studies), or negative pressure wound therapy (2 studies).
Light therapy	Low	Light therapy caused no significant adverse events based on 4 randomized studies (4 studies).
Laser therapy	Low	Short-term use of laser therapy caused no significant adverse events based on 3 randomized studies (4 studies in all).

討論

- Air-fluidized beds
  - 臨床經驗分享：使用氣墊床，確實有助於壓瘡預防及改善
  - 天津第一人民醫院 ICU，每床均配備氣墊床
- Protein supplementation
  - 營養狀況不佳的病人，因為非常瘦弱，容易產生pressure sore，一旦產生，不易癒合
  - 目前入院評估中，有幾項建議會診營養師的criteria，可考慮將有pressure sore或難以癒合傷口的病人納入，及早啟動營養會診機制
- Local Wound Applications
  - 傷口護理師建議:依傷口復原狀況，選用適當的敷料
    - 乾性傷口：使用水膠性敷料，濕性傷口：使用Aq-cell及foam吸水性強，生長肉芽組織之傷口：使用人工皮，效果較佳
- 其他
  - 建議注意空調及濕度(傷口狀況評估、皮膚是否容易出汗...)
  - 避免使用手套裝水製成之水球當作緩衝物(沒有實證依據、且容易漏水、增加照護困難)
  - 可與感染科、整型外科、營養室進行跨團隊討論，及早處理

探討

- 建議使用氣墊床?
  - 同意24, 懷疑4

- 已產生壓瘡病人，及早會診營養師，提供 protein supplementation?
  - 同意26, 懷疑2

- 依據傷口復原進展及狀況，選用合適的Local Wound Applications?
  - 同意27, 懷疑1


Thanks!
氣球城堡