快速評讀 [臨床隨機試驗 RCT] 結果

討論文獻：

Effect of manual lymph drainage in addition to guidelines and exercise therapy on arm lymphoedema related to breast cancer: randomised controlled trial.

- Devoogdt N, Christiaens MR, Geraerts I, Truijen S, Smeets A, Leunen K, Neven P, Van Kampen M.
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- doi: 10.1136/bmj.d5326.
- PMID: 21885537

步驟 1：研究探討的問題為何？

- **研究族群 / 問題 (Population/ Problem)：**
  consecutive patients with breast cancer and unilateral axillary lymphnode dissection.
- **介入措施 (Intervention)：**
  a treatment programme consisting of guidelines, exercise therapy, and manual lymph drainage
- **比較 (Comparison)：**
  the same programme without manual lymph drainage
- **結果 (Outcomes)：**
  1. The primary outcome was incidence rate for arm lymphedema (increase of 200 mL or more), and time to develop arm lymphedema .
  2. Secondary outcome were at 3, 6, and 12 months after surgery, the cumulative incidence rate for arm lymphoedema and time to develop arm lymphedema , mental and physical health related quality of life.

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？

評讀結果：■是 □否 □不清楚 說明：[P 2 , P11 Fig 1]

1. Between October 2007 and February 2009, all patients with operable breast cancer and scheduled for unilateral surgery at the multidisciplinary breast centre of the University Hospitals in Leuven were assessed before surgery.
2. After surgery, patients with an axillary lymph node dissection were asked to participate in the study (n=337), and 160 (48%) agreed to participate.
3. All included patients gave written informed consent.

分派(Allocation) - 分派方式是否隨機且具隱匿性…？

評讀結果：■是 □否 □不清楚 說明：[P 2]

1. Randomisation occurred after we had information about the adjuvant treatment decided on at the multidisciplinary oncological consultation (three weeks after surgery).
2. Randomisation was performed within each stratum by using permuted blocks (size=4).
3. Strata were body mass index (BMI; ≤25 *v* >25) and postoperative axillary irradiation (yes/no) because these factors are the two most important risk factors for development of arm lymphoedema after axillary dissection.

...每個組別，在研究開始時的情況是否相同？

評讀結果：■是 □否 □不清楚 說明：[P. 3 , P. 8 table 3]

1. All characteristics of the two groups were comparable (table 3⇓).
2. Equal baseline demographics and clinical characteristics of patients (Table 3)

Table 3| **Characteristics of patients according to treatments to prevent development of lymphoedema related to breast cancer. Figures are numbers (percentage) of patients unless specified otherwise**

	Intervention (guidelines, exercise, manual drainage; n=77)	Control (guidelines, exercise; n=81)
Men	1 (1)	1 (1)
Women	78 (99)	80 (99)
Mean (SD) age (years)	55.8 (12.5)	54.5 (11.1)
Mean (SD) BMI	26.6 (5.4)	26.2 (5.4)
Median (IQR) increase in arm volume before start of allocated treatment (mL)	8 (−34-56)	8 (−16-64)
Mean (SD) interval between surgery and start of allocated treatment (days)	40 (8)	34 (12)
Mean (SD) No of sessions:		
Exercise therapy	28 (6)	28 (8)
Manual lymph drainage	34 (7)	0
Mean (SD) No of lymph nodes	19 (6)	18 (6)
Type of breast surgery:		
Mastectomy	52 (66)	56 (69)
Breast conserving	27 (34)	25 (31)
Surgery on dominant side	47 (60)	44 (54)
Level of axillary surgery:		
I	2 (3)	0 (0)
I-II	43 (54)	54 (67)
I-III	34 (43)	27 (33)
Tumour size :		
pT0	1 (1)	0 (0)
pT1	21 (27)	26 (32)
pT2	38 (48)	39 (48)
pT3	13 (17)	12 (15)
pT4	6 (8)	4 (5)
Lymph node stage:		
pN0	23 (29)	25 (31)
pN1	36 (46)	39 (48)
pN2	11 (14)	9 (11)
pN3	9 (11)	8 (10)
Radiotherapy, IMC and medial supraclavicular	69 (87)	67 (83)
Radiotherapy, axilla	8 (10)	5 (6)
Chemotherapy	50 (63)	58 (72)
Neo-adjuvant chemotherapy	14 (18)	14 (17)
Trastuzumab	14 (18)	7 (9)
Endocrine treatment	55 (70)	66 (82)

BMI=body mass index; IQR=interquartile range; IMC=internal mammary chain.

維持(Maintenance) - 各組是否給予相同的治療？

評讀結果：■是 □否 □不清楚 說明：[P. 2]

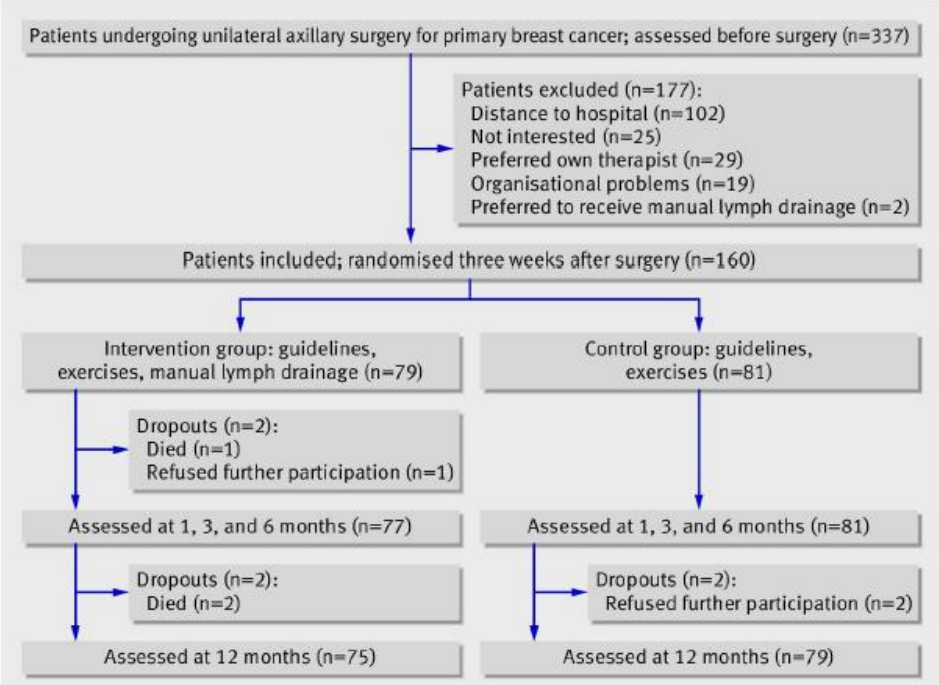
1. Patients received guidelines about the prevention of lymphoedema and exercise therapy as soon as possible after surgery.
2. Manual lymph drainage (in the intervention group) or no lymph drainage (control group) was started one week after removal of the axillary drains, so five weeks after the surgery on average, and was applied over 20 weeks.

...是否有足夠的追蹤(Follow up)？

評讀結果：■是 □否 □不清楚 說明：[P. 2]

1. All patients were measured before and 1, 3, 6, and 12 months after axillary

surgery in the department of physiotherapy.



2. Over all Follow up rate more than 90%

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)？

評讀結果：■是 □否 □不清楚 說明：[P.1 , P.2]

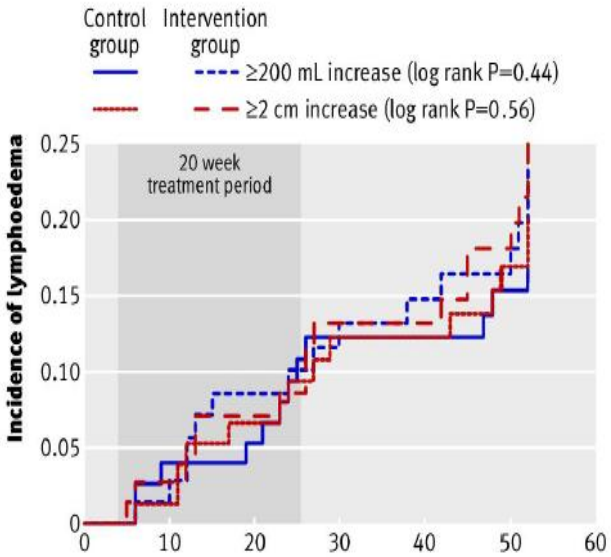
1. Patients with a subjective feeling of arm lymphoedema received an extra measurement of the arm.
2. Two blinded and well trained assessors (different from the therapists) performed the measurements.

步驟 3：研究結果

1. A six month treatment programme consisting of guidelines, exercise therapy, and manual lymph drainage applied after axillary lymph node dissection for breast cancer ***had no medium to large effect*** on the prevention of arm lymphoedema than the same treatment programme without manual lymph drainage.
   (1) Primary outcomes: the cumulative incidence of arm lymphoedema and time to develop arm lymphedema were comparable between both groups, during, immediately after, and six months after the treatment sessions.

(2) Secondary outcomes: comparable between both groups.

2. The results show that manual lymph drainage applied after axillary lymph node dissection for breast cancer and additional to guidelines and exercise therapy is unlikely to have a medium to large effect on the prevention of arm lymphoedema in the short term.
3. Time to develop lymphoedema after axillary lymph node dissection for breast cancer in 160 patients for two definitions of lymphoedema: increase ≥200 mL in volume or increase ≥2 cm in circumference at two adjacent points (**Fig 2**).



4. 討論(本研究是否可用於臨床?)

1. 乳癌病人預防淋巴水腫，是否建議病人接受淋巴引流按摩?

討論：

(1) 本篇文章研究結果顯示，接受淋巴引流按摩對於預防乳癌病人淋巴水腫之效果不彰，故不建議列入常規護理中。

(2) 本研究為考量病人狀況，若病人非常虛弱，無法主動執行復健運動，或許研究結果不同。

2. 因研究組及對照組均有給予一般的衛教措施、以及教導病人執行復健運動，本研究建議之復健運動是否可融入目前的護理常規?

目前本院乳癌病人術後護理重點：

一、術後護理常規：

1. 減少干擾淋巴液回流的因子

(1)避免患肢長期處於下垂狀態，若方便時可將患肢抬高。

(2)避免於患肢穿戴緊身衣物、手錶或手飾。

(3)胸罩鬆緊適度，不要有綱絲。

(4)不要用患側的肩膀背皮包。

(5)避免於患肢測量血壓。

(6)常作輕鬆的患肢治療性運動，或水中運動。

2. 限制淋巴液的產生

(1)避免使用患肢做勞累的工作，如提重物、推重物、練習舉重等。

(2)使用患肢做輕微的工作時，中途應多休息。

(3)由於溫度增加會使血管擴張，可能會增加淋巴液的產生，因此宜避免曝曬於炎陽下或使用蒸汽浴，也不建議在患肢熱敷。

(4)深部按摩也會使血液擴張，增加淋巴的產生，宜避免之。

(5)在高山上空飛行時，因氣壓較低易使水腫增加，宜穿戴壓力手套或用繃帶纏繞壓迫。

(6)保持適當體重及均衡的飲食(低鹽、高纖)。

3. 保護皮膚，避免皮膚有傷口及感染。

(1)避免於患肢抽血、注射、打點滴、針灸、或放血。

(2)保護患肢皮膚，避免針刺、刮傷、燒燙傷、或蟲叮咬等外傷。

(3)在廚房或花園工作時應戴保護性手套。

(4)剪指甲時要小心。

(5)如果有香港手、腳等黴菌感染時，請看皮膚科醫師。

(6)有患肢皮膚上塗抹水溶性乳液，避免皮膚乾燥。

(7)皮表的傷口應使用優碘消毒，再塗上抗生素藥膏，並以紗布覆蓋於上。

(8)看患肢有發紅、發熱、或異常腫脹時，應儘速求醫。

二、術後運動：

表一手臂復健項目

運動項目	說明	時機	基本原理
1.手掌運動	手指屈曲及伸展動作（手掌握拳狀，一收一放）	手術後第1～5天	※藉由骨骼機收縮，促進末稍血循及刺激淋巴液流動 ※預防及減輕患臂暫時性手臂腫脹
2.手腕運動	腕部屈曲及伸展、過度伸展動作：將手心朝內屈曲90度，再往外伸直、伸展	手術後第1～5天	※藉由骨骼機收縮，促進末稍血循及刺激淋巴液流動 ※預防及減輕患臂暫時性手臂腫脹
3.手肘運動	肘關節屈曲及伸展動作	手術後第1～5天	※等長收縮以維持肌肉強度 ※藉由骨骼機收縮，促進末稍血循及刺激淋巴液流動 ※預防及減輕患臂暫時性手臂腫脹
4.搖擺運動	彎腰，兩手臂自然下垂，如鐘擺式左右平行來回運動	術後傷口引流管拔除後（約術後第7天）	※等長收縮以維持肌肉強度 ※維持肌肉強度及肩關節外展運動範圍 ※降低肩部僵硬，預防冰凍肩
5.爬牆運動	距30cm面牆站立，雙手掌貼牆，同時沿牆向上爬行，高度至以不拉扯傷口引起疼痛爲原則	術後傷口引流管拔除後（約術後第7天）	※維持肌肉強度及肩關節屈曲運動範圍
6.梳頭運動	患側手臂外展至水平，再向內彎曲至頭頸後作梳頭動作，同時將兩臂向外伸直後，再向內彎至頸後兩手互相拉做挺胸動作	術後傷口引流管拔除後（約術後第7天）	※降低肩部僵硬，預防冰凍肩 ※維持肌肉強度及肩關節外轉運動範圍 ※降低肩部僵硬，預防冰凍肩
7.拉繩運動	將一長繩繞於一穩固的掛衣鉤上（替代滑輪），由健側手握住繩子一端帶動患側手臂抬高（外展）及內收的動作	術後傷口引流管拔除後（約術後第7天）	※維持肌肉強度及肩關節外展運動範圍 ※降低肩部僵硬，預防冰凍肩
8.轉圈運動	患臂向前伸直（肩關節前屈），以順時鐘及逆時鐘方向交替作肩部畫大圓圈動作	術後傷口引流管拔除後（約術後第7天）	※維持肌肉強度及肩關節旋轉運動範圍 ※降低肩部僵硬，預防冰凍肩
9.推牆運動	距一臂長距離面牆站立，雙手平舉向前貼於牆上，身體往前壓手肘慢慢彎曲，類似伏地挺身動作，直到額頭碰到牆壁，再慢慢將手肘伸直直到身體直立爲止	當肩關節前屈運動範圍達90度時，可開始此運動	※增強肌肉強度及肩關節水平外展運動範圍 ※降低肩部僵硬，預防冰凍肩

※1～3項爲基礎運動；4～9項爲進階運動

資料來源：丁肇鳳、史麗珠（2006）．乳房切除後的手臂復健運動方案．腫瘤護理雜誌，6（1），19－27。

本篇文獻提到的運動方式 ：

Table 1| **Overview of different treatment modalities applied during individual sessions of exercise therapy, with duration of 30 minutes a session, and their purpose and description of method in patients after unilateral axillary lymph node dissection for breast cancer**

Modality	Purpose	Method
Mobilisation of shoulder	To improve passive and active shoulder mobility	Average 10 minutes per session. Angular passive mobilisation of shoulder (especially anteflexion and abduction) combined with traction/translation to prevent articular problems and impingement
Stretching breast muscles	To improve muscle flexibility and passive and active shoulder mobility	Average 10 minutes per session (together with scar tissue massage). Passive and active stretching and transverse strain of major and minor pectoral muscle
Scar tissue massage	To improve flexibility of scar tissue	Mobilisation of scar tissue, by gripping scar tissue between thumbs and index fingers and moving hands in opposite direction
Exercise schemes	To improve muscle flexibility, endurance, and strength and active shoulder mobility and to stimulate lymphatic transport	Average 10 minutes per session. 10 exercise schemes built steadily and incrementally in difficulty. Each exercise scheme consisted of exercise with proprioceptive neuromuscular facilitation (3×); active stretching of breast muscles (3×15 s); four different exercises—for example, scheme 1: 1) lying supine and both hands on shoulder, perform anteflexion of both shoulders; 2) same, but abduction; 3) same, but circumduction; 4) lying supine, hands crossed, elbows straight and 90° anteflexion of shoulder, perform protraction of both shoulders. Scheme 5: 1) standing, holding stick in both hands on buttock with straight elbows, perform retroflexion of both shoulders; 2) same, but on thighs, perform anteflexion of shoulders; 3) same and 90° anteflexion of shoulder, perform horizontal abduction of affected shoulder; 4) standing, holding stick in both hands at shoulder height, straighten elbows above head. At start of each exercise scheme, exercises were performed 7×, then 10×, then 10× slow and 5× fast, and finally 10× slow and 10× fast. Patients were asked to perform exercises from scheme twice/day at home, as taught during treatment sessions

討論結果：

同意23人　　懷疑2人　　不同意0人