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

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Abstract

Objective To determine the preventive effect of manual lymph drainage on the development of lymphoedema related to breast cancer.

Design Randomised single blind controlled trial

Setting University Hospitals Leuven, Leuven, Belgium

Participants 160 consecutive patients with breast cancer and unilateral axillary lymph node dissection. The randomisation was stratified for body mass index (BMI) and axillary irradiation and treatment allocation was concealed. Randomisation was done independently from recruitment and treatment. Baseline characteristics were comparable between the groups.

Intervention For six months the intervention group (n=79) performed a treatment programme consisting of guidelines about the prevention of lymphoedema, exercise therapy, and manual lymph drainage. The control group (n=81) performed the same programme without manual lymph drainage.

Main Outcome Measures Cumulative incidence of arm lymphoedema and time to develop arm lymphoedema, defined as an increase in arm volume of 200 mL or more in the value before surgery.

Results Four patients in the intervention group and two in the control group were lost to follow-up. At 12 months after surgery, the cumulative incidence rate for arm lymphoedema was comparable between the intervention group (24%) and control group (19%) (odds ratio 1.3, 95% confidence interval 0.6 to 2.9; P=0.45). The time to develop arm lymphoedema was comparable between the two group during the first year after surgery (hazard ration 1.3, 0.6 to 2.5; P=0.49). The sample size calculation was based on a presumed odds ratio of 0.3, which is not included in the 95% confidence interval. This odds ratio was calculated as (presumed cumulative incidence of lymphoedema in intervention group/presumed cumulative incidence of no lymphoedema in intervention group) x (presumed cumulative incidence of no lymphoedema in control group/presumed cumulative incidence of lymphoedema in control group) or (10/90) x (70/30).

Conclusion Manual lymph drainage in addition to guidelines and exercise therapy after axillary lymph node dissection for breast cancer is unlikely to have a medium to large effect in reducing the incidence of arm lymphoedema in the short term.