AABIP JOURNAL CLUB

AMPLE(2) Activity:

Does drainage schedule impact activity in patients with indwelling pleural catheters for malignant pleural effusions?

THE CLINICAL QUESTION

Do indwelling pleural catheter (IPC) drainage regimens impact activity behaviors in patients with malignant pleural effusions (MPE) and is there an association between activity level and quality of life (QoL)?

TAKE HOME MESSAGE

Data suggest a modest difference in activity levels favoring daily drainage (DD) over symptom guided drainage regimen (SGD). Accelerometry measurements do correlate with patient QoL and are likely a useful tool for assessing subtle but potentially important differences between groups following different treatment regimens.

BACKGROUND

The goal of management for MPEs is to alleviate symptom burden and improve quality of life, with IPCs increasingly becoming first line management. IPCs have been shown to reduce hospital stays and repeat procedures for patients with MPE (AMPLE). Though there is still variability in drainage regimens, the

ASAP trial showed daily drainage led to increased rates of pleurodesis and decreased time to autopleurodesis when compared to every other day drainage. While the AMPLE-2 trial not only showed daily drainage, when compared to symptom guided drainage, led to increased rates of pleurodesis, but also better quality of life assessment, though no difference in breathlessness scores in the first 60 days. Though multiple breathlessness scores have been validated, there is concern that patients often adapt their lifestyle to avoid breathlessness, which may not be reflected in breathlessness scores currently used. Measurement of activity behaviors is an attractive outcome measurement when evaluating MPE management strategies, and may account for patient experiences not reflected in the current tools available.

STUDY DESIGN

Type of trial: A sub-study of those participants enrolled the lead site of a randomized multi-center, open label trial.

Study Groups:

N = 41, 20 daily drainage, 21 symptom guided drainage

Setting: Lead site of AMPLE-2 trial, Sir Charles Gairdner Hospital, Perth, WA, Australia

Enrollment: July 20, 2015 – Jan 26, 2017

Follow-up/Treatment period: Day of discharge until 5 months

Primary outcome: Activity behaviors as assessed by accelerometers, measurement of time spent sedentary, in light activity and moderate-to-vigorous physical activity, reported as % of daily wear time

Secondary outcome: Self-reported global quality of life (EQ-5D-5L), self-reported breathlessness (EQ-VAS) pre-insertion, at randomization and monthly up to 5-months.

Intervention(s):

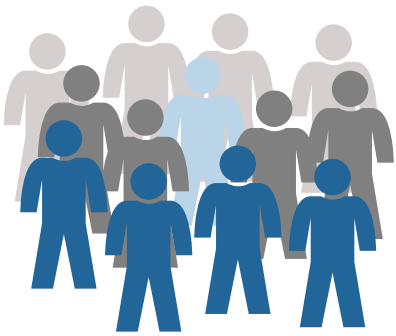
- Patients were randomly assigned within 72 hours of IPC insertion after maximum pleural fluid drainage to either daily drainage (DD) or symptom guided drainage (SGD)

- Daily drainage group: Drain IPC daily for at least 60 days, unless clinically contraindicated or spontaneous pleurodesis occurred.
- Symptom guided drainage group: Drain when effusion-related symptoms develop (breathlessness, cough or chest tightness). IPC assessed every 14 days for patency.
- Following randomization, the first accelerometry assessment was initiated on discharge from hospital. Participants were asked to wear the device for 7 continuous days and follow-up occurred every 30 days for 5 months. A valid day was ≥ 8 hours of wear

POPULATION

Inclusion criteria:

Adults requiring IPC placement for management of malignant pleural effusions.



Exclusion criteria:

Age <18, Expected survival <3 months, pleural infection, chylothorax, pregnancy, lactation, uncorrectable bleeding diathesis, previous ipsilateral lobectomy or pneumonectomy, significant loculations likely to preclude effective fluid drainage, significant visual impairment, inability to consent or comply with study protocol

Baseline Characteristics:

N = 41: Aggressive 20, Symptom guided 21

Both groups were well matched for age, sex, however the DD group had fewer participants with poor functional status (20% vs 38% in SGD), and participants in DD group were closer to their time of diagnosis (median 23 days compared to 44 days for SGD)

OUTCOMES

Primary outcome:
Activity behaviors assessed by accelerometer worn on the hip continuously: DD spent less time in sedentary behavior and more time in light activities in the 7 days following randomization and at 60-days.

- At day seven post randomization DD had a more favorable sedentary-to-light activity ratio (2.4 in DD vs 3.2 p = 0.047).
- At day 60 DD spent more time per day in light activity (33% vs 24% p = 0.04), resulting in lower sedentary-to-light ratio (2.0 for DD compared to 2.9 p = 0.016) and reported better QoL (p = 0.014)
- At all other time points there was increased light activity in the DD group when compared to the SGD group, but it was not statistically significant.

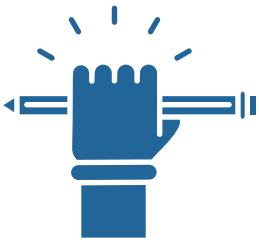
Secondary outcomes:
Self-reported global quality of life (EQ-5D-5L), self-reported breathlessness (EQ-VAS) pre-insertion, at randomization and monthly up to 5-months.

- At day seven post randomization the DD group had and less breathlessness (p = 0.007).
- There was a statistically significant correlation between activity behaviors and QoL and breathlessness at multiple timepoints, with mobility and EQ-5D-5L index scores being frequently related.

Adverse events:
None reported in this subpopulation study

COMMENTARY

Strengths:
There was good participation with 41 of 45 participants enrolled provided at least one valid accelerometry assessment.



Limitations:

- This was a small sub-study conducted at a single site of a RCT, therefore limited by potential for bias.

- No adjustment for confounders (e.g. active chemotherapy)
- Daily drainage group was closer to their time of diagnosis (23 days vs 44 days for SGD group)
- Daily drainage group had fewer participants with poor baseline performance status (20% vs 38% of SGD group)
- Accelerometer data does not distinguish between sitting and standing

FUNDING

FUNDING

Cancer Council Western Australia; Sir Charles Gairdner Research Advisory Group

SUGGESTED READING

1. 1.Muruganandan S, Azzopardi M, Fitzgerald DB, Shrestha R, Kwan BC, Lam DC, et al. Aggressive versus symptom-guided drainage of malignant pleural effusion via indwelling pleural catheters (AMPLE-2): An open-label Randomised Trial. The Lancet Respiratory Medicine. 2018;6(9):671–80.

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3. Wahidi MM, Reddy C, Yarmus L, Feller-Kopman D, Musani A, Shepherd RW, et al. Randomized trial of pleural fluid drainage frequency in patients with malignant pleural effusions: the ASAP trial. American Journal of Respiratory and Critical Care Medicine. 2017;195(8):1050–7.

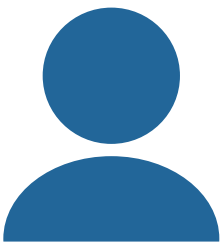
4. Jeffery E, Lee YCG, McVeigh J, Straker L, Wooding T, Newton RU, et al. Feasibility of objectively measured physical activity and sedentary behavior in patients with malignant pleural effusion. Supportive Care in Cancer. 2017;25(10):3133–41.

5. Mishra EK, Corcoran JP, Hallifax RJ, Stradling J, Maskell NA, Rahman NM. Defining the minimal important difference for the visual analogue scale assessing dyspnea in patients with malignant pleural effusions. PLOS ONE. 2015;10(4).

ARTICLE CITATION

Peddle-McIntyre CJ, Muruganandan S, McVeigh J, Fitzgerald DB, Straker L, Newton RU, et al. Device assessed activity behaviours in patients with indwelling pleural catheter: A sub-study of the Australasian Malignant PLeural Effusion (AMPLE)-2 randomized trial. Respirology [Internet]. 2023; Available from: http://dx.doi.org/10.1111/resp.14451

CONTRIBUTORS



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