

## CARDIAC RESYNCHRONISATION THERAPY LEADS TO REVERSAL OF HEART FAILURE INDUCED SARCOPENIA

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Background Sarcopenia, a reduction in skeletal muscle performance, is common in heart failure (HF) and grip strength (GS) is a measure of such. No trial has investigated the role of cardiac resynchronisation therapy (CRT) in reversing sarcopenia.

Methods GS was measured at baseline and 12 months following CRT. The patient group were 94% male, mean age  $69 \pm 8$  years, New York Heart Association (NYHA) functional class II-IV, QRSd 173  $\pm$  21 ms and had a left ventricular ejection fraction (LVEF)  $26 \pm 8\%$ .

Results 70% of patients were found to have responded at 12 months. Responders had significant improvements in VO<sub>2</sub> (12.6  $\pm$  1.7 to 14.7  $\pm$  1.5 ml/kg/min, p < 0.05), quality of life score (43  $\pm$  23 to 24  $\pm$  22, p < 0.01), left ventricular end diastolic volume (210  $\pm$  125 ml to 173  $\pm$  125 ml, p < 0.01), 6 min walk distance (379  $\pm$  117 m at baseline to 418  $\pm$  105 m (p < 0.05) and N-terminal pro-B-type natriuretic peptide (2422  $\pm$  829 to 1732  $\pm$  976 pg/ml, p < 0.01). GS significantly increased, by over 18% in responders during follow-up. Conclusion This study demonstrates responders demonstrate a significant improvement in GS following CRT. This demonstrates that CRT improves not only cardiac performance but also secondary gains in skeletal muscle function.

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# REPORTING QUALITY OF RANDOMISED CONTROLLED TRIALS INVESTIGATING EFFICACY OF PHARMACOLOGICAL THERAPIES FOR HEART FAILURE WITH PRESERVED EJECTION FRACTION

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Introduction Randomised controlled trials (RCT) provide the highest level of evidence on healthcare interventions. Accurate interpretation of results and meta-analysis requires adequate reporting. The CONSORT statement, first published in 1996 and later revised in 2001 and 2010, aims to improve reporting quality of RCTs. Heart failure with preserved ejection fraction (HFPEF) is a major cause of morbidity and mortality, comparable to HF with reduced ejection fraction. While many studies have investigated the efficacy of various pharmacological agents, scarcity of consensus guidelines reflects the conflicting results generated from such RCTs.

The aims of this study are to: 1) systematically identify RCTs investigating the efficacy of pharmacological therapies in HFPEF, 2) assess reporting quality with CONSORT 2010 statement and 3) identify trends in reporting quality.

Methods Medline, EMBASE and CENTRAL were systematically searched from 1 January 1996 to 1 September 2015 using pre-specified inclusion-exclusion criteria (Table 1). Titles and abstracts were assessed for relevance. Full texts were independently assessed by three authors for inclusion. Reporting quality was independently assessed by two authors using the CONSORT 2010 score, with each item scored and weighted

Abstract 3 Table 1 Example search strategy and inclusion/ exclusion criteria

#### HFPEF search strategy for Ovid MEDLINE(R)

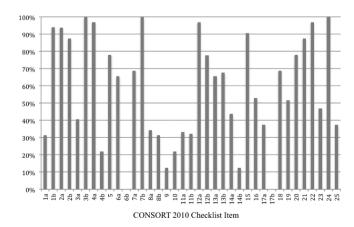
- 1. Heart failure
- 2. Normal ejection fraction
- 3. Preserved cardiac function
- 4. Preserved ejection fraction
- 5. 1 and 2
- 6. 1 and 3
- 7. 1 and 4
- 8. Diastolic heart failure
- 9. Diastolic dysfunction
- 10. HFPEF
- 11. HFNEF
- 12. or/5-11

Inclusion criteria

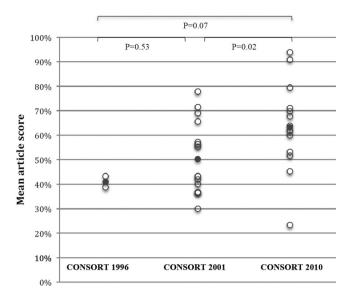
- 1. Randomised controlled trial
- Trial inclusion criteria specifying heart failure signs and symptoms, left ventricular ejection fraction >40%
- 3. Pharmacological intervention with placebo or other pharmacological comparison
- Outcomes including all-cause and cardiovascular mortality, hospitalisation, changes in NYHA class, exercise capacity (6-min walking distance, VO<sub>2Max</sub>) or quality of life Exclusion criteria
- 1. Non-English language
- 2. Abstracts or conference publication
- 3. Unpublished studies
- 4. Healthy controls

equally. An overall reporting quality score was calculated for each study. Statistical analysis was performed with SPSS.

Results Initial search identified 3426 studies; 32 were included in the final analysis. There was inter-observer agreement for 1078 out of 1184 values (91.1%); Cohen's kappa score for inter-observer variability was 0.85. The mean score was 55.3% (range 23.3–93.8%, SD 17.3%). Under half of published studies (41%, 13/32) did not adequately report more than half of all relevant sections. The best reported criteria, where applicable, were protocol referencing (*criterion 24*) (100%, 12/12), interim analysis (7b) (100%, 6/6), changes to methods (3b) (100%, 6/6), statistical methods (12a) (96.9%,



**Abstract 3 Figure 1** Percentage of studies adequately reporting each CONSORT 2010 checklist item where applicable



**Abstract 3 Figure 2** Individual study CONSORT 2010 score (open) grouped by available CONSORT statement (1996, 2001 or 2010) at time of study publication. Mean score (filled) shows increasing mean scores with revisions to CONSORT statement. Increase after introduction of CONSORT 2010 was significant (difference +13.1%, P = 0.02)

31/32) and result interpretation (22) (96.9%, 31/32). The worst reported were reporting of binary outcomes (17b) (0%, 0/7), abstract (1b) (9.4%, 3/32), allocation concealment mechanism (9) (12.5%, 4/32) and trial ending (14b) (12.5%, 4/32) (Figure 1). The reporting scores showed highly significant correlation with journal impact factor ( $\mathbf{r}=0.54$ ,  $\mathbf{P}<0.01$ ), 5-year impact factor ( $\mathbf{r}=0.49$ ,  $\mathbf{P}<0.01$ ) and publication year ( $\mathbf{r}=0.49$ ,  $\mathbf{P}<0.01$ ). Mean scores increased after publication of each updated CONSORT statement: from 41.0% (range 38.7–43.3%, SD 3.3) to 48.6% (30.0–77.8%, SD 14.5) after CONSORT 2001 (p=0.53), and from 48.6% to 63.3% (23.3–93.8% SD 17.6) after CONSORT 2010 ( $\mathbf{P}=0.02$ ) (Figure 2).

Conclusion This study identified all RCTs involving pharmacological interventions in HFPEF, and demonstrated that while reporting standards have improved with time, at present the majority of studies do not meet the CONSORT standards for reporting of RCTs. Better compliance is needed.

## 4 MORTALITY IS HIGHER IN HEART FAILURE PATIENTS DISCHARGED FROM HOSPITAL ON WEEKENDS

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Introduction Heart failure is common and one of the top contributors to mortality in the United Kingdom. There is some highly controversial evidence to support a "weekend-effect" with mortality rates elevated for patients admitted or discharged from hospital on the weekend. The impact of weekend discharge on mortality rates of heart failure patients in the United Kingdom has not been previously studied though, and was the focus of this study. We did this using a large database of patients discharged with heart failure to hospitals in the North of England, UK between 2000–2013.

Methods Anonymous information on patients with heart failure was obtained from hospitals in North England, UK between 1st January 2000 and 31st March 2013. This data was analysed according to the ACALM (Algorithm for Comorbidities, Associations, Length of stay and Mortality) study protocol. ICD-10 and OPCS-4 codes were used to trace patients coded for heart failure, day of discharge, patient demographics, prevalence of comorbidites and mortality data. The impact of day of discharge on mortality in heart failure patients was analysed by Kaplan-meier survival analysis and cox regression analysis adjusted for age, gender, ethnicity and the 9 top contributors to mortality (Ischaemic Heart Disease, colon cancer, breast cancer, lung cancer, pneumonia, cerebrovascular disease, Chonic Obstructive Pulmonary Disease and dementia). P values of <0.05 were taken as statistically significant.

Results Of 929552 patients admitted during the study period there were 31760 patients with heart failure. 27944 (88.8%) of patients were discharged on weekdays and 3816 (11.2%) were discharged on weekends. Demographics for patients discharged on weekdays (mean age  $74 \pm 14$  and 50.3% male) was similar to those discharged on weekends ( $74 \pm 14$  and 50.1% male). Similarly, prevalence of the 9 top contributing conditions to mortality in the UK were similar in both groups (see Table 1). Crude all-cause mortality for heart failure patients discharged on weekends (69.2%) was higher than those discharged on weekdays (66.0%). Mortality was

Abstract 4 Table 1 Demographics of heart failure patients discharged on weekdays and weekends

77 PM	Discharged on Weekday	Discharged on Weekend
N	27 944	3 816
Mean age±sd (years)	74 ± 14	74 ± 14
Male, n %	14054 (50.3%)	1911 (50.1%)
% dead, n %	18450/27944 (66.0%)	2640/3816 (69.2%)
Mean Length of Hospital stay ±sd (days)	11.8±21.2	10.1±17.2