Abstract: **P254**

# Assessment of patient selection bias in prospective studies for heart failure

**Authors:**
JJG De Vries[1], I Sokoreli[1], G Geleijnse[1], SC Pauws[1], JM Riistama[1], A Tesanovic[1], A Crundall-Goode[2], KM Goode[2], JG Cleland[3], AL Clark[2], [1]Philips Research, Healthcare - Eindhoven - Netherlands, [2]University of Hull - Hull - United Kingdom, [3]Imperial College London, National Heart & Lung Institute - London - United Kingdom,

**Topic(s):**
Chronic heart failure ( other )

**Citation:**
European Journal of Heart Failure Abstracts Supplement ( 2016 ) 18 ( Supplement 1 ), 55

**Purpose:** Various types of recruitment bias can occur in clinical studies. These may occur deliberately through the use of pre-specified trial inclusion/exclusion criteria, or indirectly as a consequence of the place and method of enrolment; due to a patient's perception of the value, risk and inconvenience of being involved; or pre-selection bias by the clinicians approaching the patient. We set out to explore these biases. **Methods:** OPERA-HF is a prospective, observational study enrolling patients hospitalized for or with heart failure. Other inclusion criteria are: age >18 years, treatment with loop diuretics and at least one of the following: left ventricular ejection fraction ≤40%, left atrial dimension >4.0 cm or NT-ProBNP >400 pg/mL (if sinus rhythm) or >1200 pg/mL (if atrial fibrillation). Three different study participation levels were possible: full, partial and routine care (via audit). All patients were eligible for the study, but might not be approached if the clinician thought it inappropriate; patients could choose which group to join if they declined to take part in the full study. Relative risk, for binary variables, and Wilcoxon rank-sum tests, for continuous variables, were estimated to compare data at different study participation levels. **Conclusion:** Patients recruited into the full study had fewer comorbidities and used less medication than those recruited into the partial and routine care arms. They also had a lower risk of readmission and mortality. Trials should be interpreted in the light of possible selection bias for less ill patients. Whether the selection bias was due to clinicians/nurses or patient choice needs further study.

| | Full Participation (n = 428) | Partial Participation (n = 110) | Routine Care (n = 243) |
|---|---|---|---|
| Age | 74 [66 - 81] | 77 [68 - 84]* | 77 [69 - 83]* |
| NT-proBNP | 4924 [2010 - 10085] | 3942 [1962 - 9803] | 5288 [2476 - 10912] |
| Myocardial infarction | 45 (10.6%) | 21 (19.6%)* | 43 (18.4%)* |
| Cerebrovascular accident | 33 (9.1%) | 11 (11.0%) | 28 (20.9%)* |
| Ace inhibitor | 217 (50.6%) | 53 (48.2%) | 170 (70.0%)* |
| Beta blocker | 259 (60.4%) | 75 (68.2%) | 192 (79.0%)* |
| 30 day readmission | 8 (3.0%) | 3 (2.9%) | 15 (7.8%) |
| 1 year death | 41 (20.4%) | 22 (23.4%) | 65 (33.3%)* |

Results of key characteristics by study participation level, represented as median [IQR] or # (%). Missing data were excluded. * Indicates significant ($p < 0.05$) difference compared with Full Participation.