scPharmaceuticals

Poster # LBCT-004
Control # 2602

Significantly Reduced Healthcare Costs With Home Furoscix Versus In-Hospital IV Diuresis: Results From The FREEDOM-HF Study

Daniel Bensimhon[1], William S. Weintraub[2], W. Frank Peacock[3], Tamas Alexy[4], Dalton McLean[1], Donald Haas[5], Kathleen L. Deering[6], Matthew M. Goodwin[7], John F. Mohr[7]

[1]Cone Health, Greensboro, NC; [2]MedStar Health Research Institute, Hyattsville, MD; [3]Ben Taub Hospital, Houston, TX; [4]University of Minnesota, Minneapolis, MN; [5]Abington Hospital, Abington, PA; [6]EPI-Q, Inc., Oak Brook, IL; [7]scPharmaceuticals, Burlington, MA

Background

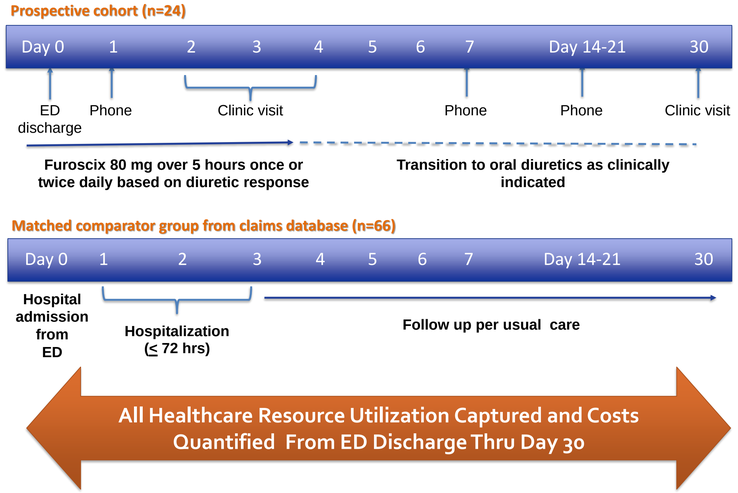
- Up to 90 % of pts presenting to the ED with worsening heart failure (HF) are admitted
- 50% of these hospitalizations may be avoidable
- Furoscix is a pH neutral formulation of furosemide in development for subcutaneous (SC) administration via an on-body drug delivery system (*Figure 1*)
- **80 mg** of furosemide is administered SC over 5-hours (30 mg over the 1st hour; 12.5 mg/hour over the subsequent 4 hours)
- It has demonstrated **99.6% bioavailability** relative to the same dose of IV furosemide with comparable diuresis and natriuresis

Figure 1. Furoscix On-body infusor

Study Objectives and Design

- **Compare healthcare resource utilization and direct medical costs** between patients treated with Furoscix at home vs. a matched cohort admitted for IV diuresis
- Evaluate the safety of Furoscix administration outside of the hospital setting
- **Multicenter, open label, comparative study** with an adaptive sample size of chronic HF pts presenting to the ED with worsening congestion despite oral diuretic therapy. Outcomes were compared to a matched cohort from IBM® MarketScan® Commercial Claims and Medicare Supplemental Database (*Figure 2*)

Figure 2. FREEDOM-HF study schematic



Methods

Key enrollment criteria

Furoscix group

- NYHA Class II-III HF pts aged 18-80 years presenting to the ED with worsening HF and evidence of volume overload
- On background oral diuretic therapy (40-160 mg furosemide equivalent daily)
- Deemed to be a candidate for SC diuresis after initial treatment, by meeting **all** of the following:
  - O_2 sat ≥ 90% on exertion; RR < 24 breaths per minute; resting HR < 100BPM; SBP > 100 mmHg
- Creatinine clearance > 30 mL/min and no evidence of acute renal failure as determined by investigator
- Absence of other conditions that require immediate hospitalization or anticipated admission within 30 days

Comparator group

- Pts with worsening HF (DRG 291, 292, 293) admitted to the hospital ≤ 72 hrs from IBM® MarketScan® Commercial Claims and Medicare Supplemental Database (2018-2019)
- Patients were matched to the prospective group applying the same inclusion and exclusion criteria

Matching and cost analysis

- Pts were matched up to **4:1** (4 comparators to 1 Furoscix patient) based on 7 key variables (*Table 1*)
- Cost benchmarks (actual reimbursements paid by health plans plus any patient cost sharing) were used to estimate overall and HF-related healthcare costs (including HF hospitalizations, HF-related ED and clinic visits) from the comparator population and applied to both groups through the 30-day follow-up

Primary endpoint

- The difference in 30-day overall and HF-related healthcare costs between the two groups

Secondary endpoints

- Number and duration of all-cause and HF hospitalizations

Table 1. Baseline patient characteristics (key matching variables)[a]

Variable	Overall (n=90)	Furoscix (n=24)	Comparator (n=66)	p-value[b]
Age, median (Q1-Q3) [a]	56 (48-66)	56 (48-67)	58 (51-67)	0.49
Males, n (%) [a]	62 (69)	16 (67)	46 (70)	>0.99
Heart failure[a]				>0.99
Systolic HF	39 (43)	11 (46)	28 (42)	
Diastolic HF	39 (43)	10 (42)	29 (42)	
Combined	12 (13)	3 (13)	9 (13)	
History of chronic kidney disease (CKD) [a]				>0.99
No history of CKD, n (%)	62 (69)	17 (71)	45 (68)	
CKD Stage 2	5 (6)	1 (4)	4 (6)	
CKD Stage 3	23 (26)	6 (25)	17 (26)	
≥ 1 HFH within 6 months[a]	43 (48)	15 (63)	28 (42)	0.43
COPD, n (%) [a]	33 (37)	6 (25)	27 (41)	0.26
Diabetes, n (%) [a]	62 (69)	12 (50)	50 (76)	0.12

HFH: Heart Failure Hospitalization
[a] Key matching variable; [b] P-values were weighted based on count of control patients within each Furoscix match set, and were obtained from the t-test statistic.

Table 2. Baseline patient co-morbidities and HF medications

Variable	Overall (n=90)	Furoscix (n=24)	Comparator (n=66)
Prior MI, n (%)	16 (18)	2 (8)	14 (21)
Hypertension, n (%)	86 (96)	22 (92)	64 (97)
Hyperlipidemia, n (%)	71 (79)	15 (63)	56 (85)
Arrythmia, n (%)	49 (54)	12 (50)	37 (56)
Valvular disease, n (%)	27 (30)	7 (29)	20 (30)
Unstable angina, n (%)	25 (28)	6 (25)	19 (29)
Daily furosemide equivalents (mg), mean (SD) (n=23)*	NA	139 (98)	NA
Furosemide, n (%)	71 (79)	12 (50)	59 (89)
Bumetanide, n (%)	12 (13)	4 (17)	8 (12)
Torsemide, n (%)	8 (9)	7 (29)	1 (2)
None, n (%) [a]	1 (1)	1 (4)	0
Metolazone, n (%)	11 (12)	5 (21)	6 (9)
Beta blockers, n (%)	48 (53)	15 (63)	33 (50)
ARNI/ACEi/ARB, n (%)	63 (70)	11 (46)	52 (79)
Nitrate, n (%)	16 (18)	4 (17)	12 (18)
Aldosterone antagonist, n (%)	24 (27)	10 (42)	14 (21)
Hydralazine, n (%)	11 (12)	6 (25)	5 (8)

[a] 1 patient received metolazone 2.5mg daily and no loop diuretics

Results

- **90 subjects** were enrolled in the study, 24 in the Furoscix group and 66 in the comparator group
- Baseline patient characteristics (key matching variables) were similar between the study groups (*Table 1*)
- The incidence of co-morbidities and HF medication use were also similar between the cohorts (*Table 2*)

- **Furoscix utilization led to a significant reduction in HF-related and overall healthcare costs (Primary endpoint, *Table 3*)**

Table 3. HF-related and overall healthcare costs (Primary endpoint)

Outcome	Furoscix (n=24)	Comparator (n=66)	Difference (95% CI)	P-value
HF-related healthcare costs[a]				
Mean (SD)	$2,920 (7,073)	$20,673 (12,727)	- $17,753 (-23,660, -11,846)	<0.0001
Median (Q1, Q3)	$1,375 (1,375, 1,555)	$15,182 (12,658, 17,692)	- $13,807 (-17,083, -13,476)	<0.0001
Overall healthcare costs[a]				
Mean (SD)	$7,090 (11,872)	$37,658 (32,276)	- $30,568 (- 44,539, -16,598)	<0.0001
Median (Q1, Q3)	$1,735 (1,555, 3,020)	$19,246 (16,854, 22,626)	- $17,511 (-17,992, -14,817)	<0.0001

[a] The cost include the index visit costs for both groups. Furoscix – HF-related emergency department; Control – HF-related emergency department visit and hospitalization ≤3 days; Cost of Furoscix not included in the analysis

Secondary endpoints

- **All** 24 patients in the Furoscix group avoided the initial HF hospitalization
- Only 1 patient from the Furoscix group had a HF admission during the 30-day follow-up (4%) vs. 7 (11%) from the comparator group
- Non-HF hospitalizations occurred in 4 (17%) of the Furoscix patients vs. 6 (9%) in the comparator group

Safety

- Injection site bruising (29%), discomfort (29%), and dizziness (13%) were the most common side effects of Furoscix; all were mild in severity
- There were 9 SAEs (hospitalization) in 6 Furoscix subjects, all unrelated to study drug
- There were no deaths and no subjects withdrew from the study due to an AE

Conclusions

- HF pts with mild to moderate volume overload (despite oral diuretic use) can be **safely discharged** from the ED with SQ Furoscix, enabling outpatient decongestion
- Furoscix use was associated with **significantly reduced overall and HF-related healthcare costs** through the reduction of HF hospitalizations

Disclosures

D. Bensimhon: scPharmaceuticals. **W.S. Weintraub:** scPharmaceuticals. **W.F. Peacock:** ScPharmaceuticals. **T. Alexy:** None. **D. McLean:** None. **D. Haas:** None. **K.L. Deering:** scPharma, EPI-Q, Inc. **M.M. Goodwin:** scPharmaceuticals. **J.F. Mohr:** scPharmaceuticals.