

Improvement of beta-blocker prescribing in heart failure: a cluster-randomized trial (RRP 09-136)

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Background

- Frequency of BB use in HF improved
- Guideline-concordance often not achieved in actual practice
- PBM's VAMedSAFE impacts prescribing through medication safety interventions
- VAMedSAFE has not attempted a therapeutic intervention

Design

- Cluster-randomized trial
- Intervention at pharmacy level
 - Level 1: general information
site performance
 - Level 2: same, plus lists of patients
 - 6 month intervention
- Follow-up through PBM database
 - 6 month follow-up after first Rx in intervention

IRB

- Stations = “subjects”/ target of randomization
- Station + patients = cluster
- Waiver of consents
- Since station = subject, no station IRB approval needed, per Hines IRB

Eligibility of Clusters

- Station pharmacies: agreement to participate
- Station patients:
 - Had a BB Rx that was discordant with guidelines
 - No attempt at adherence in prior 12 months
 - ≥ 1 CHF admission between 3 and 9 mo prior
 - Ineligible if codes for diastolic HF present

Data sources

- Administrative VA databases
- Primary data collection from pharmacists
 - Facility characteristics
 - Reasons target doses could not be achieved
 - Provider type for Rx
 - Local protocol information
 - Evaluation of intervention

Analysis of Rxs

- Patient analytic eligibility
 - BB Rx fill < end of intervention
 - survived for 6 months after the fill
- Analysis accounted for clusters
 - Proportional odds logistic regression
 - Concordant, With Progress, With Regression
 - Final dose relative to target: >50%, 50%, <50%

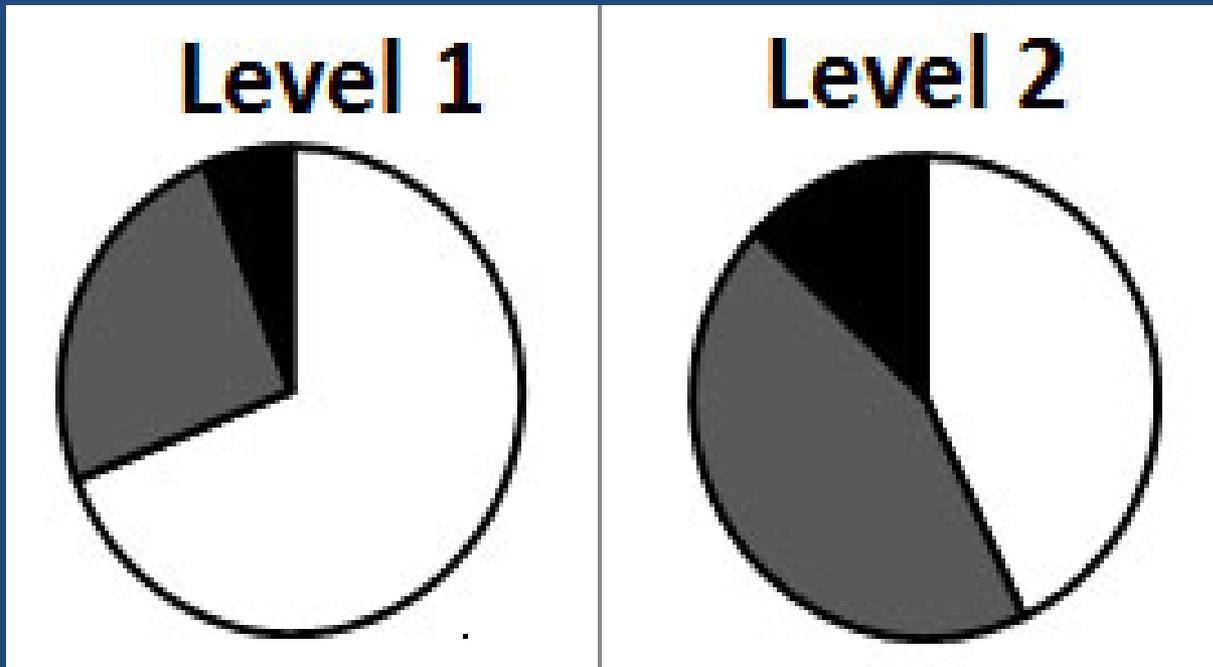
Results: Baseline

Characteristic	Level 1 (n=6)	Level 2 (n=6)
Patients at goal or prior attempt (mean)	38%	36%
Patients in intervention cohort (mean)	21	25
Patients in analytic cohort (mean)	16	20
Facilities with heart failure clinic	3	3

Rx changes after 6 months follow-up

Prescription status	Level 1 (n=98)	Level 2 (n=122)
Concordant with guideline goals, %	4	5
Not at goal but with progression, %	10	18
No change, %	76	72
Not at goal and with regression, %	10	5
Proportional OR (95% CI)	1.9 (1.1 – 3.3)	

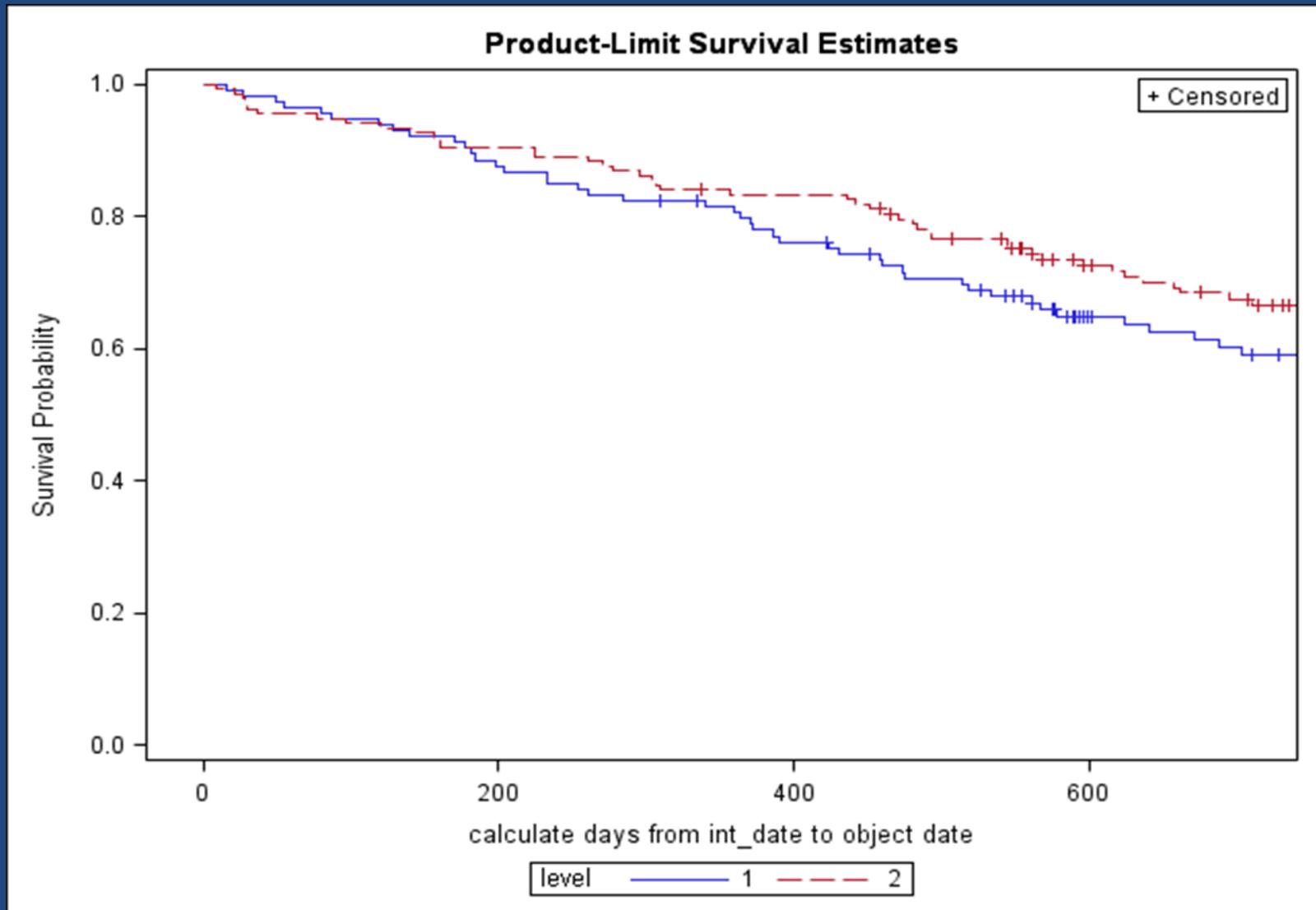
Dose distribution of guideline drug at end of follow-up



Main reason goal not achieved (Level 2)

Reason	%
adverse events (bradycardia, hypotension, etc.)	34
non-systolic/preserved ejection fraction HF	32
pharmacist's inability to engage the provider	17
patient logistics	5
insufficient facility resources	5
non-guideline beta-blocker for co-morbidity	4

All-cause mortality



Pharmacist Survey

- Study resources helpful
- Facilitators
 - Staff support
 - titration clinics
 - staff engagement
 - clinical pharmacist's role
- Barriers
 - Provider issues
 - Inadequate staffing
 - Protocol (short duration, patient identification)

Discussion

- Meeting guideline goals not common
 - Whellan et al 2001
 - Intensive medication management
 - Patients at target dose: from 6% to 13%
 - Jain et al 2005
 - HF clinic instituted
 - Patients on “medium” or “high” dose: from 18% to 57%

Discussion

- Implications of sub-target dosing
 - Bristow et al 1996
 - Randomized to range of carvedilol doses
 - Suggestive of benefit when 25-50% of target
 - Metra et al 2005
 - Carvedilol superior to metoprolol tartrate @ low doses
 - Wikstrand et al 2002
 -  mortality with metoprolol succinate @ 38% target
 - Heart rate reduction hypothesis

Limitations

- Incomplete identification of non-systolic HF
 - Distracted site resources
 - Use medical records to reduce these in future
- Lack of study-directed local protocol
 - We can not provide details of local protocol
 - Also a strength, as more generalizable

Conclusions

- Target doses unlikely in actual practice
 - Tolerability limits dose
 - PCPs and cardiologists similar
 - Intervention can promote progress
- Need research: Is “progress” beneficial?