

Pill Management Strategies and Pill Count Estimated Adherence in A Pragmatic Clinical Trial

Matthew Genelin¹, Laura Helmkamp², John Steiner^{1,3}, Julie A. Maertens², Rebecca Hanratty^{1,4}, Suma Vupputuri⁵, Edward P. Havranek^{1,4,7,8}, L. Miriam Dickinson^{1,2}, Irene V. Blair⁶, Stacie L. Daugherty^{1,2,7,8}

¹ University of Colorado School of Medicine, Aurora, CO. ² Adult and Child Consortium for Outcomes Research and Delivery Sciences (ACCORDS), University of Colorado, Aurora, CO. ³ Kaiser Permanente Colorado, Institute for Health Research, Denver, CO. ⁴ Denver Health and Hospital Authority, Department of Medicine, Denver, CO. ⁵ Kaiser Permanente Mid-Atlantic States, Mid-Atlantic Permanente Research Institute, Rockville, MD. ⁶ University of Colorado Boulder, Department of Psychology and Neuroscience, Boulder, CO. ⁷ Colorado Cardiovascular Outcomes Research Group, Denver, CO. ⁸ University of Colorado School of Medicine, Department of Medicine, Division of Cardiology, Aurora, CO.

Background

- In controlled clinical trials, medications are dispensed at regular intervals with pill amounts set by the study team, often in prepared packaging (i.e., blister packs), strengthening the accuracy of pill count measured adherence.
- In pragmatic clinical trials, medication refill intervals and pill amounts vary by patient and pill count measured adherence may be affected by patient medication management strategies (e.g., use of pill boxes)
- In a pragmatic clinical trial, we evaluated the association between patients' medication management strategies and adherence measured using pill counts.

Methods

Study Population (N= 595):

- Hypertensive on treatment
- Self-identified Non-Hispanic African American/ Black patients or White patients
- >55% Women, >50% African-American
- Patients recruited from 11 primary care clinics in Colorado and Maryland
- At enrollment, all asked if they use the following strategies:

- Combine like pills
- Finish previous refills first
- Combine different pills
- Missed doses
- Doctor told to take PRN
- Wants medication change
- Pill dispenser
- Shares pills
- Takes different dose, doctor order
- Takes different dose, self-choice
- Other

Analysis:

- Pill Count Adherence calculation:

$$\frac{(\# \text{ pills dispensed}) - (\# \text{ pills remaining})}{\# \text{ of pills expected since refill}}$$

For each strategy, we compared

- Median adherence
- Frequency of apparent outliers
 - >1.0, apparent over-adherence
 - <0.0, apparent under-adherence

To those who did not use strategy

Results

Figure 1: Proportion Using Each Strategy Overall (White boxes) and Comparison of Mean Pill Count Adherence between Different Strategies (Bars)

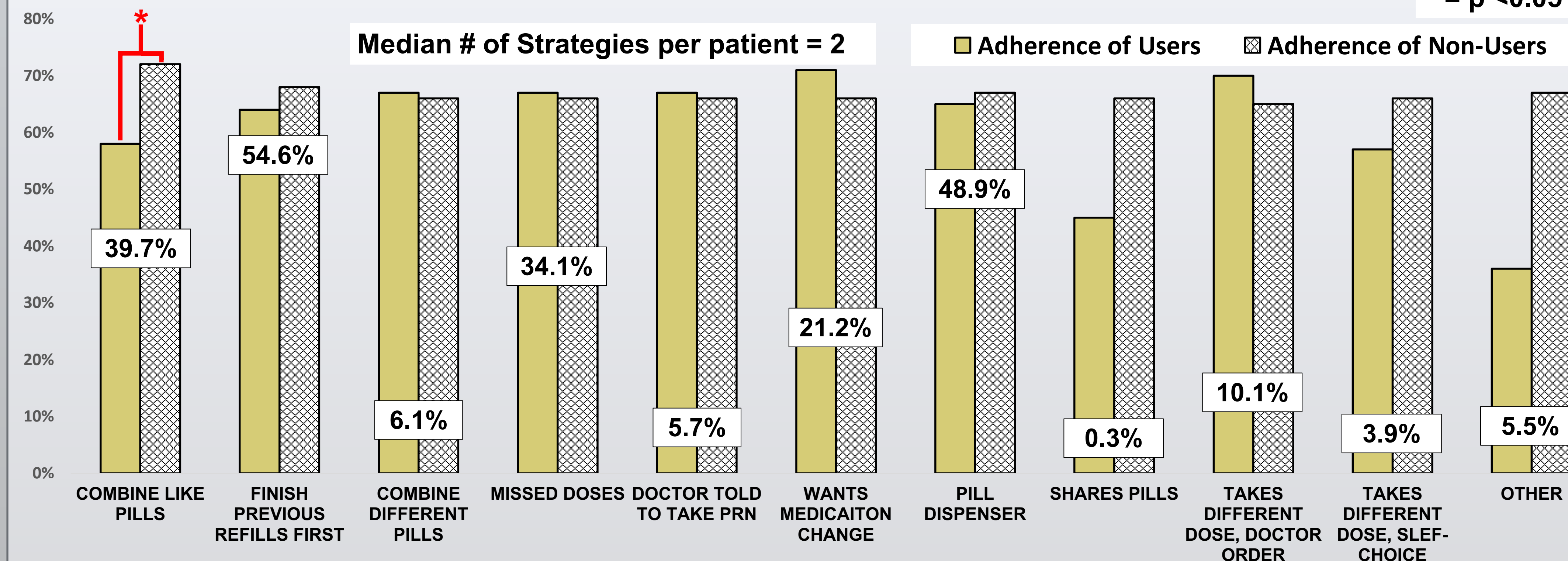


Figure 2: Strategies Associated with Apparent Under-adherence (<0.0)

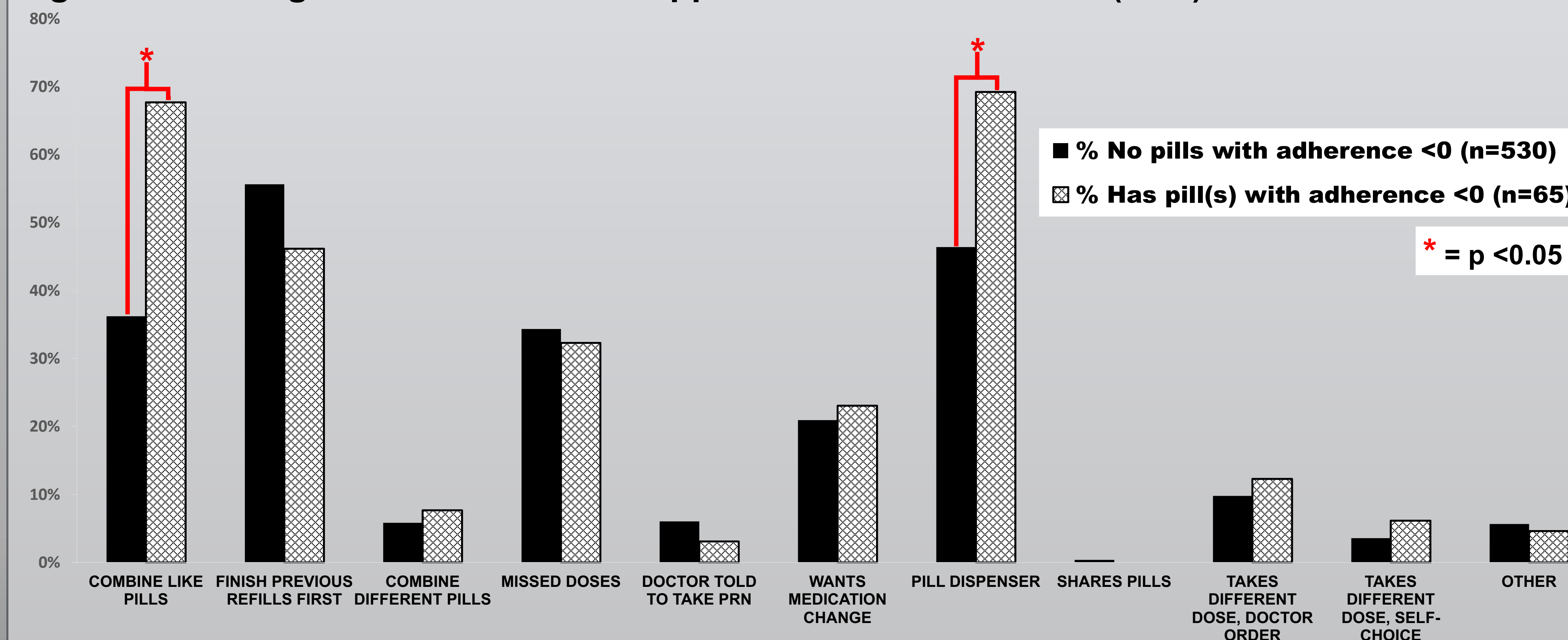
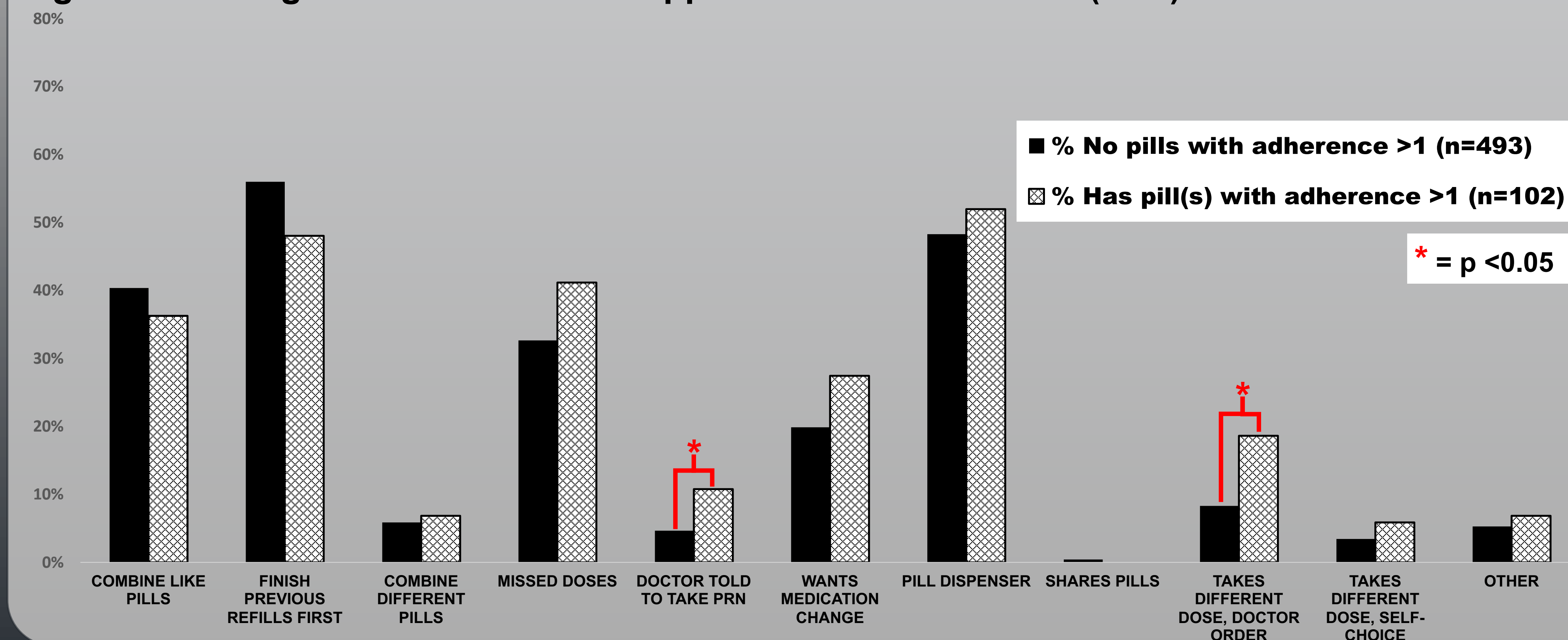


Figure 3: Strategies Associated with Apparent Over-Adherence (>1.0)



Summary of Results

- Patients used a median of 2 strategies
- Finishing prior prescriptions first and using pill boxes/sorters were the most common pill management strategies
- Combining like medicines was associated with lower measured pill count adherence (p<0.01)
- Apparent under-adherence was associated with combining like medicines (p<0.01) and use of a pill box (p<0.01)
- Apparent over-adherence was associated with taking pills differently than bottle directed (p<0.01) or as needed (p=0.02)

Limitations

- Up to 19% of patients did not bring pill bottles to their enrollment visit
- Pills removed from bottles do not guarantee pills were consumed
- The association between strategies and other measures of adherence (e.g., pharmacy fill, self-report) or clinical outcomes (e.g., blood pressure) was not measured

Conclusions and Implications

- Some pill management strategies (e.g., combining pills into a single bottle) may result in imprecise adherence estimates using pill counts, particularly in a pragmatic clinical trial.
- Pill count adherence requires that bottles be brought to appointments and may be subject to missingness.
- Clinicians and researchers should discuss pill management strategies with patients to understand how these strategies may unduly influence what is presumed to be objective measures of patient adherence.



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