Satisfaction with smoking, and smoking reduction, during pre-quit treatment with nicotine patch or varenicline

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Declarations

- SGF:
  - Has worked as a consultant for GSK & Chrono Therapeutic
  - Served on an advisory board for Johnson & Johnson
  - Has received travel funding from Pfizer
  - Study funding from Rusan Pharma
- Chappell has nothing to declare.
Funding

- This work was supported by researcher-initiated project grant funding from Pfizer (through the GRAND initiative; awarded to Ferguson)
- Additional funding was provided the Royal Hobart Hospital Research Foundation (awarded to Ferguson)
Improving the odds of success

- Outcomes of existing mono-therapies is disappointing
  - >60% of supported quit attempts fail
- Advances can come from improving current methods
- Understanding how methods works may suggest improvements to use
Rational for patch preloading

- Dissociate nicotine levels from smoking
  - Reduce reinforcement
  - Satisfaction ➔ Reduced Smoking ➔ Cessation
Rational for patch preloading

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Satisfaction with a lapse predicts relapse
Satisfaction with smoking predicts daily smoking rate: Single-group pilot study

Schüz & Ferguson 2014
Satisfaction with smoking predicts daily smoking rate: Single-group pilot study

- During pre-quit patch treatment, satisfaction with smoking predicts daily smoking rate
- Due to treatment?

Schüz & Ferguson 2014
Rational for patch preloading

- Dissociate nicotine levels from smoking
  - Reduce reinforcement
  - Satisfaction ➔ Reduced Smoking ➔ Cessation
Reduction promotes abstinence

28 day abstinence; Shiffman, Ferguson & Strahs (2009)
Rational for patch preloading

- Dissociate nicotine levels from smoking
  - Reduce reinforcement
  - Satisfaction ➔ Reduced Smoking ➔ Cessation

- Similar mechanism proposed for varenicline
- Potentially explains lack of effect for gum preloading
- Opportunity of tailoring?
- Target of new treatments?
Current study

- Test effect of pre-quit treatment on satisfaction with smoking and daily smoking
  - Larger sample
  - Control condition (no pre-quit treatment)
  - Varenicline

- H: Effect of pre-quit treatment on reduction will be mediated via satisfaction with smoking
  - Opportunity for tailoring treatment
PQT Study

- Three group, open-label RTC
  - Pre-quit Patch (PQP; n=72)
  - Varenicline (VAR; n=72)
  - Standard Patch (SP; n=69)
- Intensive, real-time monitoring (EMA)
  - 2wks before & 2wks after TQD
  - CPD, satisfaction, withdrawal & craving
EMA Monitoring Protocol

Protocol continues at all hours, adapts to subjects’ day

**LEGEND**
- **R** Randomly scheduled assessment
- **C** Cigarette with assessment
- **c** Cigarette with no assessment
- **w** Wake-up assessment
- **e** Evening assessment

Intervals free from random 'beeps'
- Suspended prompting
- Nap
- Sleep
EMA Monitoring Protocol

- Symptom severity & satisfaction w smoking

- Daily cigarette counts (w TLFB)
PQT Study

- 5 lab visits: TLFB, NNAL, CO, COT
- Focus: Pre-quit treatment period
- Full Protocol:
  - ACTRN12614000329662
PQT Study: Sample

- **N = 213**
- Predominately Caucasian (92%) males (58%)
- ~42 years old
- Moderately heavy smokers
  - ~19 CPD
  - 74% TTFC ≤ 30mins
  - Baseline CO = 21ppm
Pre-quit treatment promoted smoking reduction

- During the pre-quit period
  - PQP & VAR groups reduced their smoking
  - SP did not
Pre-quit treatment promoted smoking reduction

- PQP group reduced by ~6 CPD on average
- VAR group by ~7 CPD
- SP: no change
Biochemical markers confirmed self-reported smoking reduction

- Decline in NNAL levels steeper in VAR group (compared to SP)
See similar self-administration patterns in animal studies

Unpublished data
Change in satisfaction with smoking during pre-quit period, by group

- During the pre-quit period satisfaction with smoking
  - Fell in PQP & VAR groups
  - Stable in SP group
Satisfaction with smoking does mediate the effect of treatment on CPD ... but it’s weak

PQP: ~3%
VAR: ~6%
Summary

- VAR & PQP pre-quit treatment does result in
  - Reduced satisfaction with smoking
  - Reduced CPD
- Effect of pre-quit treatment on reduction is only partially mediated via satisfaction with smoking
  - Other drivers of reduction
  - Changes in stimulus control?
- Understand of mechanism of action may improve outcomes with pre-quit medication use
Acknowledgements

- Collaborators
  - Monica Lu, Katherine Chappell, Natalie Schüz, Gudrun Wells
  - Dr Kelly Clemens (animal studies)
  - Georgie Gallagher
  - BSRG staff & students

- Funding bodies
  - Pfizer (GRAND)
  - RHHRF