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Resilience Selection: A Grave Potential Bias in Clinical Trials

Milind Watve *, Shunyaka P. and Ashwini Keskar

Independent Researcher, Pune India; shunyaka.0.p@gmail.com (S.P.); ashwinikeskar22@gmail.com (A.K.)

* Correspondence: E-1-8, Girija Shankar Vihar, Karve nagar, Pune 411052, India; milind.watve@gmail.com

Abstract: Physiological and psychological resilience has important implications for health, disease and treatment. Resilience is shown to boost treatment compliance as well as response and thereby reduce mortality. We consider the possibility that individuals having lower resilience are more likely to discontinue treatment in response to side effects of a drug. In randomized control trials (RCT) if a greater proportion of individuals discontinue from the treatment group than the control group, the average resilience in the remaining treatment group would be greater. As a result, the frequency or severity of adverse outcomes in the treatment group will be smaller than the control even when the drug has no effect. This bias is more likely to be serious for drugs with more frequent and/or serious side effects such as the GLP 1RAs. We suggest testable predictions of the resilience selection bias hypothesis along with ways to quantify and correct for the bias in RCTs. Attempts to detect, measure and correct for the resilience selection bias should be considered necessary for realistic evaluation of drug action in a clinical trial.

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Clinical trials are designed with the intention of minimizing potential biases and confounding factors and reflect the effect of treatment in comparison with appropriate control group(s). Randomization, blinding and placebo control are the common practices used to minimize certain kinds of biases. Nevertheless, there are other possible biases that these practices are insufficient to arrest. It is necessary to identify them and design appropriate measures to minimize, if not eliminate, them. It is possible that with appropriate data the biases can be corrected. Further even when biases cannot be eliminated or corrected, knowing the possible biases, the contexts in which they arise and their possible misleading effects on the inference need to be taken in to account. We will describe one such bias that remains underappreciated so far and has the potential to mislead the inference significantly.

In a typical clinical trial, there is a randomized group under the drug being examined along with a placebo control group. For chronic diseases the treatment duration as well as follow up periods are typically long during which some attrition in the number in both the groups is inevitable. The attrition can be because of reasons unrelated to the treatment. Such drop outs are unlikely to introduce a systematic bias in the results. However the drug is also likely to have some side effects of varying severity and some individuals may quit because they cannot tolerate them. As a result, often attrition in the treatment group is greater than that in the control group. This attrition is non-random and thereby can partly negate the purpose and effect of randomization used in making the groups.

The Resilience Selection Bias Hypothesis:

Resilience is an identified factor in patient care and treatment. Although the definition of resilience varies in a context specific manner, a generalized definition is the capacity to achieve positive outcomes despite exposure to significant challenges. Resilience is a significant factor affecting coping with side effects and treatment adherence (Richardson 2002). Individuals with lower

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level of resilience are more likely to withdraw from the treatment wing of the clinical trial because of the side effects of the drug. If not complete withdrawal, they are less likely to be adherent to the treatment and thereby short of fulfilling the treatment target (Faria et al 2014, Meraz et al 2023, Saedi et al 2024). This is less likely to happen in the control group. This creates a potential bias. In life style interventions, coping with side effects may not be a concern, but the necessary self control and determination needs resilience. Furthermore it is also likely the ones who continue and comply with the intervention boost their resilience further. As a result although initially the groups might be randomized, after attrition, the treatment group has a greater probability of retaining more resilient individuals than the control group. This systematically creates a difference in the average resilience. Resilience is positively correlated with better treatment response and effectiveness for a number of disorders examined (Kim et al 2019, Kennedy et al 2017, Udumyan et al 2019, Blanc et al 2020, Babic et al 2020). Resilience helps in de-addiction (Alim et al 2012, Rogers and Leslie 2024). More resilient individuals also have a lower cause specific as well as all cause mortality (Nishimi et al 2023, Zhang et al 2024). Because of resilience selection, even when the treatment has no effect, the treatment group may report smaller frequency and/or severity of the symptoms/adverse outcomes. The inability to appreciate this bias may lead to a misleading belief in the efficacy of the drug (while there may not be any), or lead to overestimate the effect.

Testable Predictions of the Resilience Selection (RS) Bias Hypothesis:

Having identified a potential source of bias, it is important to consider ways to detect the presence of such bias. How can we examine whether such a bias is present in a given clinical trial and whether it is serious enough to mislead the inference?

(i) A provision for detection and correction of RS bias needs to be there in the design of the clinical trial itself. Indices to quantify resilience have been used in specific contexts (Galvin et al 2021, Sehgal et al 2021, Nova 2023). If an appropriate context specific index is available, resilience should be estimated for every individual in the treatment as well control groups. After attrition, it is possible to see whether there is systematic difference in the distribution of resilience scores. It is also possible to see whether resilience is significantly related to the incidence or severity of adverse events in both the groups. If it is seen to be significant, an attempt to correct the bias can be made. The limitation of this approach is that currently there is heterogeneity in resilience measurements (Ghulam et al 2022) and more research is needed to standardize and choose the right index in the right context.

(ii) If follow up data are collected on the group that discontinued the treatment then qualitatively the presence of RS bias can be detected as well as quantitatively a crude estimate of the possible impact of RS bias on the results can be obtained by the following model.

Table 1. Variables used in the model.

	Placebo control arm		Treatment arm	
Numbers recruited	*Np*		*Nt*	
	Number of individuals	Event Rate	Number of individuals	Event Rate
Continued	*Npc*	*Rpc*	*Ntc*	*Rtc*
Discontinued	*Npd*	*Rpd*	*Ntd*	*Rtd*

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We assume that in both the arms some individuals continue with the treatment (denoted by the suffix *c*) and some discontinue (*d*) in the placebo (*p*) and treatment (*t*) arms. If some proportion of individuals discontinue because of the treatment side effects, we expect $Npd/Np < Ntd/Nt$.

Assuming that discontinuation from the placebo group is for reasons independent of the treatment, we expect the rate of the adverse event in both to be similar, i.e. $Rpc = Rpd$. If resilience bias exists then it is expected that $Rtd > Rpc$. This inequality can be used as a testable prediction of resilience bias as this difference will be independent of the treatment effect. If *Rtd* is not significantly different from *Rpc*, the absolute risk reduction (ARR) will be given by $Rpc - Rtc$. But if significant bias is detected, a corrected ARR can be calculated as

Rpc – (Rtc.Ntc + Rtd.Ntd)/Nt.

(iii) Alternatively all results can be expressed on the intension to treat (ITT) basis, i.e. ignoring whether the treatment was continued or discontinued, compliance or non-compliance, treatment target achieved or unachieved, the group intended to be treated should be considered as treated and compared with the intended control group. Unless attrition is not too large, the difference will remain significant if the treatment is really effective.

(iv) Even when resilience scores are not maintained and follow up on the drop outs is not available, some attempt to suspect RS bias is possible. Since resilience is a more generalized phenomenon (Babic et al 2020), related to a wide diversity of conditions and treatment effects, one should find lower frequencies in the treatment group for a multiple, even unrelated outcomes. It should be easy to monitor this in the groups even at a later stage for trials in which a provision for resilience data is not made from the beginning. Finding favourable effects of the treatment on multiple (but not necessarily all) unintended outcomes is a strong indicator, though not a proof, of RS bias.

(v) If the absolute risk reduction is greater than the absolute attrition difference i.e. $Rpc - Rtc > (Ntd/Nt - Npd/Np)$, the treatment can be safely concluded to be effective. For example, if ARR is 10 % but the attrition difference is only 5%, resilience selection cannot account for this difference and the treatment must be effective. The reverse is not necessarily true, if the attrition difference is greater than ARR, it is not sufficient to conclude that ARR is only a result of resilience selection.

(vi) The RS bias hypothesis expects that in the long run, meta-analysis of several drug trials will show a positive correlation between severity of side effects or proportion of treatment drop outs and absolute risk reduction.

Using one or more of the testable predictions it should be possible to estimate how common and how serious the RS bias is across different clinical trials. Also in future clinical trials it should be possible to maintain the data necessary to detect and even correct RS bias, if any.

Re-Examining Some of the Recent Clinical Trials for the Possibility of RS Bias:

In one recently published clinical trial the data are indicative of RS bias. This trial is not of a drug but of a diet regime that led to significant weight loss as compared to the control group (Lean et al 2024). The trial has certain parallels but also certain differences with the context that we described above. Not involving any drug, there is no question of side effects. However, the diet regime was very strict and we expect only individuals with high resilience to comply with it and reach the weight loss and other targets. The paper gives data on the mortality and diabetic complications among the target achieved and unachieved groups. If inability to achieve the target is at least partly because of low resilience we can use some of the testable predictions above. The main success claimed by Lean et al (2024) was that the group that achieved the weight loss target at one year by the treatment had an incidence of major adverse diabetic events (MADE) of 12.8 % and the group not achieving the target had 23 % (see table S9 in supplementary appendix of Lean et al 2024). This difference was significant and the authors take it as evidence for the success of the treatment. But if we look at the corresponding control group the incidences were 15.9 % for target achieved (presumably

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spontaneously) and 16.1 for non-achieved group and the difference was non-significant. Here we see that the condition *Rtd* > *Rpc* is satisfied. This inequality was significant by chi square test (chi sq = 8.35, $p < 0.05$), but *Rtc* was not significantly different than the control group (chi sq = 1.35, NS). We tested that going by ITT, no difference is seen between the control and intervention. The same pattern was seen for other targets such as *HbA1c* or remission at 1 year. Wherever Lean et al (2024) claim that the target achieved intervention group had significantly reduced incidence, it is seen to be accompanied by increased incidence in the target unachieved group. This is very likely to be resilience selection bias.

Further the RS bias is also likely to be potentially relevant to the GLP-1 RA drugs that have made a sensational entry as promising anti-obesity drugs. Interestingly apart from weight loss, glucose normalization and diabetic complications, GLP 1RAs are also being claimed to be effective in preventing a wide variety of conditions (O'keefe et al 2024, Rivera et al 2024) including 10 different types of cancers (Wang et al 2024), chronic kidney disease (Perkovic et al 2024) alcohol and other drug abuse disorders (Wang et al 2024, Lähteenvuo et al 2025), Alzheimer's disease (Wang et al 2024), cardiovascular outcomes (Lincoff et al 2023), fertility (Pavli et al 2024), seizure and epilepsi (Sindhu et al), sleep apnea (Malhotra et al 2024), Steatohepatitis (Loomba et al 2023), inflammatory bowel disease (Gorelik 2024), Type 1 diabetes (Guyton et al 2019, Pasqua et al 2025) and all cause mortality (Rivera et al 2024). The apparent effectiveness of the drugs against widely different end points is the first suggestion (but not a proof) that RS bias may be at work.

In many of the GLP1 RA trials over 2 to 5 fold greater proportion of participants discontinued in the treatment group as compared to the control (Qin et al 2024, Packer et al 2024, Ryan 2024). Outside RCTs treatment adherence is reported to be less than 50% (Lassen et al 2024). The resilience bias is therefore expected to be very strong for GLP 1RA drugs. Unfortunately there is no data on resilience score, also no follow up on the dropouts seems to be available in these trials. Potentially it should be still possible to collect follow up data on the drop outs. In the absence of such efforts the results of GLP 1RA clinical trials should be considered inconclusive. The RS bias principle needs to be applied to many other clinical trials for long term treatment aimed at preventing complications in chronic conditions.

Limitations of the Concept:

As of today, the definition of resilience, the possible psychological and physiological components, mechanisms and pathways are not clearly known (Lima et al 2023). But so is the case of placebo. The mechanisms of placebo effect are also not clearly known, but still the effects are demonstrable and accepted in designing the trial protocols as a routine. Resilience Selection bias needs to be incorporated as another necessary routine in clinical trials to make the inferences more robust.

The second limitation is that the indices for resilience measurement also need to be refined and validated for context of the underlying types of disorders, treatment effect and side effects. Some refinement of statistical methods is also needed on application of the RS bias correction. All this needs research inputs but such developments are certainly possible in near future and crucial for increasing the reliability of clinical trials.

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