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SHORT COMMUNICATION

Assessing intervention effects in a community-based trial to reduce self-harm: A methodological case study

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Summary This paper considers the assessment of the impact of a community-based randomized controlled trial to reduce repeat deliberate self-harm. It considers the drawbacks in simplistic applications of conventional significance testing procedures, as well as possible failures regarding the statistical assumptions underlying such tests. Instead, the paper considers how relevant prior information might be incorporated within a fully Bayesian-model-based assessment procedure. The model includes a latent trait approach to patient morbidity; controlling for morbidity and other patient characteristics enhances the impact of the intervention (measured by a hazard rate ratio). If allowance is made for external information (e.g. ethical approval of the treatment), the weight of evidence shifts towards a positive intervention effect.

Introduction

The prevalence of self-harm (SH) is a serious public health problem and a common reason for emergency hospital admission, with potential for health gain from intervention.[1] We designed a randomized controlled trial ($n=467$) in which all patients had access to routine care while patients in the intervention group were offered an additional treatment package comprising a psychosocial assessment, a negotiated care plan and direct access to a case manager. The full design and methodology are reported elsewhere.[2]

The main outcome measure was binary, re-attendance or not at an accident and emergency (A&E) department within 12 months of the index event. Nineteen (19/220) patients in the intervention group re-attended A&E with a SH event within 12 months compared with 24/247 patients in the comparison group; these rates are lower than have been observed in other studies.[3] A simple significance test shows no treatment effect. However, classical tests of significance of the treatment effect in this situation may be misleading for

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several reasons. They are based on asymptotic normality, and may be misleading when the density of the effect measure (e.g. simple relapse or re-attendance rate, or hazard ratio in a survival analysis) is asymmetric or otherwise non-normal. Such non-normality is especially likely for small samples and for certain types of response, such as binary data, as in this study.[4] A simple significance test also does not account for differences in patient risk (e.g. psychiatric history) or duration of time exposed to risk of repeat SH. Thus patients accepting the intervention in this study were more likely to have a psychiatric history [25/107 (23%) vs 12/113 (11%), $\chi^2=5.5$, $P=0.02$], alcohol problems [21/107 (20%) vs 5/113 (4%), $\chi^2=10.8$, $P=0.001$], and to have previously self-harmed [44/107 (41%) vs 18/113 (16%), $\chi^2=16.0$, $P<0.001$].

Given the lower than expected incidence of the index event, differences in patient profiles, and the relatively small treatment group, some form of sensitivity analysis to standard tests seems advisable. Various non-parametric tests are available but we have proceeded with a Bayesian analysis as this allows (with modern sampling methods) for assessing significance when effect measures are non-normal; for example, one can obtain probabilities that the treatment effect lies below or above a critical threshold. A Bayes approach also allows for the inclusion of prior knowledge (e.g. on treatment effects and risk factors for deliberate SH) so that the analysis is not in isolation of the existing evidence base; this is sometimes known as a 'subjective' Bayes approach, especially when 'informative' priors are used explicitly.

Risk estimate models

An important feature of the data, substantively and statistically, is the interval between the initial event and any repeat event, and a survival analysis is indicated to make full use of the available information. A Weibull hazard rate model is used involving a power form of time dependence: the exponent of time t is $\alpha-1$, with α between 0 and 1 if the chance of a repeat SH falls with time, and above 1 if the chance of a repeat event increases with time.[5] The chance (hazard rate) of repeat SH is then

$$h(t,x) = \rho(x)\alpha t^{\alpha-1}$$

where $\rho(x)=\exp(\beta x)$ includes the effect of patient risk factors x. In contrast to the Weibull model, the exponential model assumes $h(t,x)=\rho(x)$, namely that the chance of a repeat SH is invariant with regard to time since the previous SH.

We consider Models A–E that progressively investigate aspects of patient risk and also consider an informative prior on the treatment effect. A baseline model (Model A) relates the outcome to treatment in a hazard rate model where the independent variable x is simply a three-category intervention variable. The categories are control and treatment groups, while a third category relates to subjects offered extended treatment but refusing it. The estimated regression effects are log hazard ratios comparing against a reference category. This model is then extended to allow for variations in susceptibility: initially (in Model B), an indicator of history of contact with psychiatric services represents these. In Model C, we also include age group and sex. While SH is known to occur at higher levels among younger adults, especially women, this may not apply to repeated SH events.

As a final elaboration regarding the modelling of patient risk, we regard five binary indicators (short-term psychiatric history, serious mental illness, longer-term psychiatric history, chronic physical problem and chronic alcohol problem) as imperfect measures of an underlying morbidity construct or 'trait' in Model D. A structural equations model provides weights linking the observed indicators to the latent construct[6] (see Appendix). The construct score is then used together with age, sex and treatment to predict time to repeat SH.

Model E combines Model D with an informative prior on the treatment effect. Specifically, we reason a priori that the intervention combined with routine care is unlikely to raise the risk of repeat deliberate SH by more than 25% compared with routine care. Adverse effects (e.g. potential 50% excess risk on the new treatment) are unlikely to be entertained by medical ethics committees, and a rationale for such an excess is hard to devise.

Results

Table 1 contains details of independent variables and shows the parameter estimates (hazard ratios) under the Bayesian modelling approach, using the package WINBUGS.[7] Results are based on running three parallel chains from dispersed starting values with convergence assessed using Gelman–Rubin criteria.[8] First, consider the estimates of the hazard ratios of the treatment effects obtained from Model A.

The 'offer effect' compares the repeat SH risk for those offered treatment but who refused it with the risk for those not offered treatment. The