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Copas' method is sensitive to different mechanisms of publication bias

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ABSTRACT

Copas' method corrects a pooled estimate from an aggregated data meta-analysis for publication bias. Its performance has been studied for one particular mechanism of publication bias. We show through simulations that Copas' method is not robust against other realistic mechanisms. This questions the usefulness of Copas' method, since publication bias mechanisms are typically unknown in practice.

1. Introduction

In an aggregated data (AD) meta-analysis, published effect sizes from similar research studies are collected to determine a precise pooled effect size. When not all executed research studies are published, an AD meta-analysis may lead to a biased estimate. To correct the pooled estimate for this publication bias, various methods have been proposed (Jin et al., 2015; Mueller et al., 2016; Rücker et al., 2011). Selection model approaches implement a conditional or weighted likelihood function for estimation, where the weights are based on the selection mechanism (Hedges and Vevea, 2005). Copas' selection method (Copas and Shi, 2000, 2001) uses the standard errors of the study effect sizes to create these weights. The method gives a higher weight to studies with a lower probability of being published.

Copas' method has been compared to the Trim and Fill method (Duval and Tweedie, 2000b,a) using 157 meta-analyses. Even though both methods produced similar point estimates, Copas' method was preferred since it produced larger standard errors, making Copas' method somewhat more conservative (Schwarzer et al., 2010). Since direct likelihood-based methods may sometimes suffer from convergence issues, an expectation–maximization (EM) algorithm was developed for Copas' method (Ning et al., 2017). Furthermore, a Bayesian extension of Copas' method was developed for network meta-analysis (Mavridis et al., 2013). This all shows the importance of Copas' method in meta-analysis.

The performance of Copas' method has been investigated for one particular mechanism of publication bias using simulation studies, even though other (possibly realistic) mechanisms for publication bias have been mentioned in literature (Stanley and Doucouliagos, 2014; van Aert and van Assen, 2018; Hedges, 1984; McShane et al., 2016). We will demonstrate that Copas' method is sensitive to these selection bias mechanisms when mean differences (continuous outcomes) and log odds ratios (binary outcomes) are being pooled, indicating that Copas' estimation method should be used in practice with the utmost care. To demonstrate our findings, we will resort to simulation studies, since mathematical derivations of Copas' estimation method under any type of selection bias mechanism is complicated. In a simulation study we can control the true selection bias mechanism of an AD meta-analysis study and compare Copas' estimation with the known true effect size. In practical settings both the selection bias mechanism and the true effect size would be unknown making it impossible to know how good Copas' estimate truly is.

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2. Statistical methods

The information in an AD meta-analysis consists of the pair (D_i, S_i) for study $i = 1, 2, \ldots, m$, where D_i is the observed or collected effect size and S_i is the accompanied standard error. In some applications there may also exist a degrees of freedom for the standard error (Cochran, 1954), but this is ignored here.

2.1. The Copas method

Copas and Shi (2000, 2001) considered a population of study effect sizes that follow the random effects meta-analysis model

$$D_i = \theta + U_i + \varepsilon_i, \tag{1}$$

with θ the unknown mean effect size of interest, $U_i \sim N(0, \tau^2)$ the heterogeneity in study effect sizes, and $\varepsilon_i \sim N(0, \sigma_i^2)$ the residual independent of U_i with an unknown variance σ_i^2 that may vary with study. They assumed that only a selective subset of all studies has been published and introduced a selection model $Z_i = \alpha + \beta S_i^{-1} + \delta_i$, with α and β fixed parameters, $\delta_i \sim N(0, 1)$ being correlated with ε_i, $\rho = \mathrm{CORR}(\varepsilon_i, \delta_i)$, and D_i only being published when $Z_i > 0$. Note that studies with smaller standard errors have a higher probability of being published and when $\beta = 0$ and α is large, there is no publication bias present.

Based on the population and selection model for effect sizes, a weighted or conditional log likelihood function is constructed $\ell\left(\theta, \tau^2, \rho\right) = \sum_{i=1}^{m} \left[\log p\left(D_i | Z_i > 0, S_i\right)\right]$, with $p\left(D_i | Z_i > 0, S_i\right)$ the conditional probability density of an effect size given that the study is selected. Using a joint normality assumption on $(\varepsilon_i, \delta_i)$ and assuming that $(\varepsilon_i, \delta_i)$ is independent of U_i, the conditional log likelihood function can be written in the following explicit expression (Copas and Shi, 2000, 2001)

$$\sum_{i=1}^{m} \left[-\tfrac{1}{2} \log\left(\tau^2 + \sigma_i^2\right) - \frac{(D_i - \theta)^2}{2(\tau^2 + \sigma_i^2)} - \log \Phi(\alpha + \beta S_i^{-1}) + \log \Phi(V_i) \right], \tag{2}$$

with Φ the standard normal cumulative distribution function, $V_i = [\alpha + \beta S_i^{-1} + \tilde{\rho}_i (D_i - \theta)/(\tau^2 + \sigma_i^2)^{1/2}]/[1 - \tilde{\rho}_i^2]^{1/2}$, and $\tilde{\rho}_i = \sigma_i \rho / [\tau^2 + \sigma_i^2]^{1/2}$. The unknown variance σ_i^2 in (2) is replaced by $S_i^2/[1 - c_i^2 \rho^2]$, with $c_i = \lambda(\alpha + \beta S_i^{-1})[\alpha + \beta S_i^{-1} + \lambda(\alpha + \beta S_i^{-1})]$, $\lambda(z) = \phi(z)/\Phi(z)$, and ϕ the standard normal density function.

For fixed values of α and β, the log likelihood function in (2) is maximized over θ, τ^2, and ρ and their confidence intervals are based on asymptotic theory. By studying a grid of different values for α and $\beta > 0$, such that $0.01 \leq P(Z_i > 0 | S_i) \leq 0.99$ for the smallest and largest value of S_i, the sensitivity of the pooled estimator $\hat{\theta}$ on α and β can be investigated (Copas and Shi, 2000, 2001). Settings for α and β for which selection bias is not rejected would fit best with the data. This selection bias is tested with a form of Egger's test (Egger et al., 1997). The random effects model is extended to $D_i = \theta + \gamma S_i^{-1} + U_i + \varepsilon_i$ and $H_0 : \gamma = 0$ is tested with a likelihood ratio test (Copas and Shi, 2000, 2001; Carpenter et al., 2009). We used the R-package "copas" to carry out the Copas method (Carpenter et al., 2009).

2.2. Selection models

The selection model of Copas is based on the positiveness of the latent variable $Z_i = \alpha + \beta S_i^{-1} + \delta_i$, with δ_i correlated with the residual in the random effect model in (1). However, there may be alternative approaches that would be based on the standardized effect sizes D_i/S_i. Indeed, standardized effect sizes closer to zero would be less likely to be published and large effect sizes (at one side or in one direction) would be more likely to be published (Hedges, 1984).

Selection models based on the p-value of the study effect have been proposed in literature (Stanley and Doucouliagos, 2014; van Aert and van Assen, 2018; Hedges, 1984; McShane et al., 2016). When the effect size is significant (assuming more positive effect sizes), i.e., $D_i/S_i > z_{1-\alpha}$, with α the significance level and z_q the q^{th} quantile of a standard normal distribution, the study is included. To add randomness to the non-significant studies, a uniform distributed random variable $U(0, 1)$ and a parameter π_{pub} can be used. If the uniform random variable is smaller than or equal to $1 - \pi_{\text{pub}}$, the non-significant study is included too, and otherwise it is excluded.

An alternative approach, is to use D_i/S_i in a selection model similar to Copas' selection model. Study i is published when the latent variable $Z_i = a + bD_i/S_i + \delta_i$ is positive, with a and b fixed parameters, and with $\delta_i \sim N(0, 1)$, now being independent of the residual in model (1). We do not need a non-zero correlation between δ_i and ε_i, since the correlation with the population effect size or the selection of studies is now directly induced by the standardized effect size. The probability that study i is selected is $P(Z_i > 0 | D_i = d, S_i = s) = \Phi(a + bd/s)$.

2.3. Simulation model

We will first draw a population of effect sizes and standard errors, i.e., draw pair (D_i, S_i), that is calculated from individual participant data (IPD) for two groups in each study. Then we will use the different selection models to eliminate studies from the population.

2.3.1. Population of aggregated data

We consider a meta-analysis with m studies, having sample sizes n_i, $i = 1, \ldots, m$. The number of participants n_i for study i is drawn using an overdispersed Poisson distribution with parameter λ. The value $\gamma_i \sim \Gamma(a_0, b_0)$, with $\Gamma(a_0, b_0)$ a gamma distribution with parameters a_0 and b_0, is drawn to make a study specific parameter $\lambda_i = \lambda \exp(0.5\gamma_i)$. Then n_i is drawn from a Poisson distribution with parameter λ_i, i.e., $n_i \sim \text{Pois}(\lambda_i)$. This sample size is then split in two sample sizes using a Binomial distribution with parameter p, i.e., $n_{i0} \sim \text{Bin}(n_i, p)$ and $n_{i1} = n_i - n_{i0}$.

Then a continuous response Y_{ijk} for individual $k(= 1, \ldots, n_{ij})$, in group $j(= 0, 1)$, for study $i(= 1, 2, \ldots, m)$ is simulated according to a linear mixed model:

$$Y_{ijk} = \mu + \beta_j + U_{ij} + \epsilon_{ijk}, \tag{3}$$

with μ a general mean, β_j an effect of group j ($\beta_0 = 0$ and $\beta_1 = \theta$), U_{ij} a study-specific random effect for group j, and residual $\epsilon_{ijk} \sim N(0, \zeta^2)$. We assume that $(U_{i0}, U_{i1})^T$ is bivariate normally distributed with zero means and variance–covariance matrix Σ given by

$$\Sigma = \begin{bmatrix} \sigma_0^2 & \rho_{01}\sigma_0\sigma_1 \\ \rho_{01}\sigma_0\sigma_1 & \sigma_1^2 \end{bmatrix}.$$

Furthermore, the continuous outcome is also used to simulate a binary response $E_{ijk} \in \{0, 1\}$, with $E_{ijk} = I_{[\mu,\infty)}(Y_{ijk})$, where $I_A(x)$ is an indicator function that takes value 1 when $x \in A$ and 0 otherwise. Here we choose to use μ as cutoff such that the odds of an event in the control group is equal to 1. This binary response has a natural interpretation: diseases (E_{ijk}) such as hypertension are often defined in terms of some physiological measurements (Y_{ijk}) being larger than a certain threshold (μ).

After simulating the individual responses, the study effect size for the continuous outcome is calculated by the mean difference $D_i = \bar{Y}_{i0.} - \bar{Y}_{i1.}$, with $\bar{Y}_{ij.} = \sum_{i=1}^{n_{ij}} Y_{ijk}/n_{ij}$ the average of group j in study i. It is straightforward to see that D_i satisfies model (1) with $U_i = U_{i0} - U_{i1} \sim N(0, \sigma_0^2 - 2\rho_{01}\sigma_0\sigma_1 + \sigma_1^2)$ and $\varepsilon_i \sim N(0, \zeta^2[n_{i0}^{-1} + n_{i1}^{-1}])$. The standard error S_i was estimated using the formula $S_i = \sqrt{S_{i0}^2/n_{i0} + S_{i1}^2/n_{i1}}$, with $S_{ij}^2 = \sum_{k=1}^{n_{ij}}(Y_{ijk} - \bar{Y}_{ij.})^2/(n_{ij} - 1)$ the sample variance of group j in study i, not assuming that the residual variance in model (3) is homogeneous. For the binary outcome, the study effect size is calculated by the log odds ratio $D_i = \log(K_{i11}K_{i00}/K_{i01}K_{i10})$ where $K_{ijl} = \sum_{k=1}^{n_{ij}} I_{\{l\}}(E_{ijk})$ is the total number patients with event $l \in \{0, 1\}$ in study i of group j. The estimated standard error S_i is then given by $S_i = [K_{i11}^{-1} + K_{i00}^{-1} + K_{i01}^{-1} + K_{i10}^{-1}]^{1/2}$. The way we simulate the binary outcome also implies that the true value of the overall log odds ratio is equal to $\Phi(\theta/\sqrt{\zeta^2 + \sigma_1^2})/(1 - \Phi(\theta/\sqrt{\zeta^2 + \sigma_1^2}))$. Note that we have chosen parameter values such that it is unlikely to have zero counts for K_{ijl} in an AD meta-analysis. Our simulation studies did not encounter any zero cells for each simulated study.

The settings of the parameters are chosen such that the simulation corresponds approximately with a meta-analysis of clinical trials on hypertension treatment. Parameter settings used to generate the aggregated data are $m \in \{30, 50, 100\}$, $\lambda = 100$, $a_0 = b_0 = 1$, $p = 0.5$, $\mu = 160$, $\theta = -0.5$, $\zeta^2 = 100$, $\sigma_0^2 \in \{0, 2\}$, $\sigma_1^2 \in \{0, 3\}$, and $\rho_{01} \in \{0, 0.7\}$. We will run all combinations of parameter choices and simulate 1000 meta-analysis studies. Note that this implies that we study five levels of heterogeneity, i.e., $\tau^2 = \sigma_0^2 - 2\rho_{01}\sigma_0\sigma_1 + \sigma_1^2 \in \{0, 2, 5 - 1.4\sqrt{6}, 3, 5\}$, but we will only report three levels $\{0, 5-1.4\sqrt{6}, 5\}$. These settings correspond to an intraclass correlation coefficient (ICC) of approximately 0%, 40%, and 68%, respectively, since we expect an average sample size per treatment group to be equal to 85 individuals. All simulations were conducted with SAS version 9.4. The analysis was conducted in SAS as well, by reading in the [R] package "copas". Programming codes can be requested from the last author.

2.3.2. Selection of studies

Copas' selection model requires simulation of $Z_i = \alpha + \beta S_i^{-1} + \delta_i$, with δ_i being correlated to ε_i in (1). The residual ε_i can be calculated from the simulation of the individual data for the continuous outcome, since $\varepsilon_i = \bar{\epsilon}_{i0.} - \bar{\epsilon}_{i1.}$, with $\bar{\epsilon}_{ij} = \sum_{k=1}^{n_{ij}} \epsilon_{ijk}/n_{ij}$. Then δ_i can be drawn from a normal distribution

$$\delta_i | \bar{\epsilon}_{i0.} - \bar{\epsilon}_{i1.} \sim N\left(\rho[\bar{\epsilon}_{i0.} - \bar{\epsilon}_{i1.}]/\sqrt{\zeta^2[n_{i0}^{-1} + n_{i1}^{-1}]}, 1 - \rho^2\right),$$

where $\rho = \text{CORR}(\delta_i, \varepsilon_i)$ is the correlation parameter taken equal to $\rho \in \{0, 0.9\}$. The parameters α and β will depend on the simulated population data and vary with each simulation run. For the binary outcome, only the setting with $\rho = 0$ will be considered since the data generating mechanism of the log odds ratio does not directly correspond to the random effect meta-analysis model (1).

We used the 5% and 95% quantiles of the set of precision estimates S_1^{-1}, S_2^{-1}, …, S_m^{-1} for one meta-analysis, say q_5 and q_{95}, respectively. The values α and β are chosen such that $P(Z_i > 0 | S_i^{-1} = q_{95}) = 0.99$ and $P(Z_i > 0 | S_i^{-1} = q_5) = p_0$, with $p_0 \leq 0.50$. A study with a small standard error is almost always selected, while studies with larger standard errors are more likely eliminated from the meta-analysis. Solving the two equations results in parameters $\alpha \approx (z_{p_0} q_{95} - 2.33 q_5)/(q_{95} - q_5)$ and $\beta \approx (z_{p_0} - \alpha)/q_5$, when the random term δ_i is independent of all other terms. A study i was selected if $Z_i > 0$, and it was eliminated when $Z_i \leq 0$. We tuned the parameter p_0 such that we select approximately 70% of all simulated studies under the same settings.

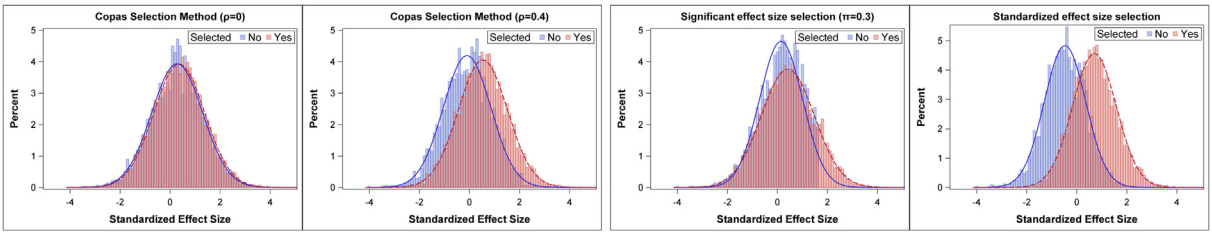

Fig. 1. Visualization of the selection of studies for the mean difference for various selection models.

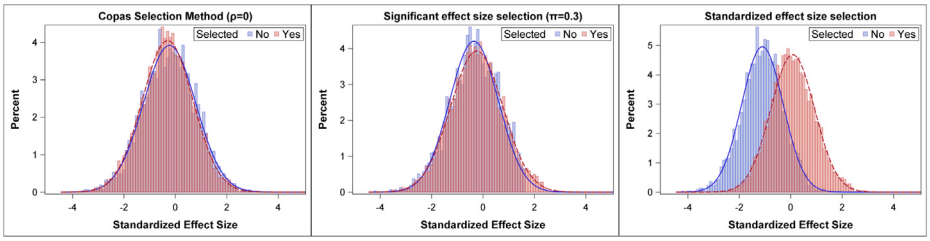

Fig. 2. Visualization of the selection of studies for the log odds ratio for various selection models.

Simulation of the selection models based on standardized effect sizes D_i/S_i are more straightforward. For latent variable $Z_i = a + bD_i/S_i + \delta_i$, we draw δ_i from a standard normal distribution, independent of anything else. Here we use a and b in the same way as α and β, but the quantiles q_5 and q_{95} are now calculated from the set of standardized effect sizes D_1/S_1, D_2/S_2, …, D_m/S_m (assuming D_i' s are mostly positive, otherwise we could use $-D_i/S_i$). For the p-value based selection of studies, we searched for values of π_{pub} such that approximately 70% of the studies are included.

The average effective number of studies $\bar{m}$ included in the simulations for the three selection models will be reported.

3. Results

Fig. 1 shows the distributions of the standardized effect sizes of the mean differences for the selected (red) and non-selected (blue) studies for the selections mechanisms: (from left to right) Copas selection model without ($\rho = 0$) and with ($\rho = 0.4$) correlation to the random effects model, the significant effect size selection method, and the standardized effect size selection method, respectively ($\sigma_0^2 = 2$; $\sigma_1^2 = 3$; $\rho_{01} = 0.7$). Fig. 2 shows the same figures for the log odds ratios (but without the correlated Copas selection mechanism, i.e., only $\rho = 0$).

The mechanisms based on the standardized effect sizes have a stronger effect on selection of studies than Copas' selection model. The selection model based on D_i/S_i also show a different mechanism. The p-value based selection model shows the truncation of being significant, $Z_i = a + bD_i/S_i + \delta_i$ shifts the distribution, while Copas' selection models essentially eliminate higher standardized effects sizes with lower probabilities.

The performance of Copas' method on estimation of the pooled effect size (θ) for the different selection methods is evaluated with the Mean Squared Error (MSE), the bias, and the coverage probability (CP). The results of the simulations are presented in Table 1 for $m = 30$. The results for other numbers of study sizes are very similar to the results of $m = 30$.

Introducing publication bias according to Copas' selection model results in the lowest MSE and bias (as expected). However, it is affected by the correlation (ρ) between the random effects model and the selection mechanism. A correlation of $\rho = 0.4$ induces a bias and increases the MSE compared to an uncorrelated selection mechanism. Thus the coverage probability of the overall effect size is only close to nominal when the correlation coefficient ρ is neglectable. The coverage probability for the overall effect size with Copas' estimation method under mis-specified selection models is in general liberal. The selection mechanism based on the significant effect seems to have a stronger influence on the mean difference than on the log odds ratio. For a mean difference, Copas' estimation method introduces a bias, but this is less pronounced for log odds. When the selection mechanism is based directly on the standardized effect sizes, Copas' model seem to fail completely for both types of effect sizes (mean differences and log odds). Copas' method does not correct the estimate enough for the continuous outcome while over-corrects in the binary case, leading to very high biases and low coverage probabilities. It should be noted that the results seem unaffected by the simulation settings, making Copas' method robust against different forms of heterogeneous effect sizes.

4. Discussion

The purpose of this paper was to investigate the performance of Copas' method for adjusting the pooled estimate from an aggregated data meta-analysis in the presence of different types of publication bias. We focused on effect sizes in the

Table 1
Performance of Copas' method (MSE, bias and CP(%)) for estimation of the pooled estimate ($\theta = -0.5$; publication rate $\approx 70\%$; $m = 30$) for the mean differences and log odds ratio.

σ_0^2	σ_1^2	ρ_{01}	Selection method		Mean differences				Log odds ratio			
					MSE	Bias	CP(%)	$\bar{m}$	MSE	Bias	CP(%)	$\bar{m}$
0	0	0	Copas	$\rho = 0$	0.108	0.012	94.6	21.7	0.004	0.001	95.7	21.2
0	0	0		$\rho = 0.4$	0.145	−0.134	90.4	20.9	NA	NA	NA	NA
0	0	0	Significant effect		0.158	−0.091	91.5	21.8	0.006	0.007	94.5	21.2
0	0	0	Standardized effect		0.334	−0.454	69.9	20.7	0.015	0.101	67.0	20.7
2	3	0.7	Copas	$\rho = 0$	0.120	−0.082	94.3	21.7	0.004	−0.001	93.8	21.2
2	3	0.7		$\rho = 0.4$	0.146	−0.137	90.9	20.9	NA	NA	NA	NA
2	3	0.7	Significant effect		0.151	−0.097	92.5	21.9	0.005	0.006	94.0	21.3
2	3	0.7	Standardized effect		0.342	−0.457	69.4	20.7	0.015	0.099	68.5	20.8
2	3	0	Copas	$\rho = 0$	0.111	0.007	94.1	21.7	0.004	−0.001	94.4	21.2
2	3	0		$\rho = 0.4$	0.140	−0.139	90.8	20.9	NA	NA	NA	NA
2	3	0	Significant effect		0.158	−0.094	93.4	21.9	0.005	0.005	93.6	21.2
2	3	0	Standardized effect		0.340	−0.459	70.0	20.7	0.015	0.100	67.9	20.7

form of mean differences and log odds ratios, and studied three different selection models for publication bias. These selection models were all (indirectly or directly) related to the effect size of a study (Hedges, 1984; McShane et al., 2016). We conducted only simulation studies, since the mathematics for the bias and mean squared error of the Copas correction method under a mis-specified selection model is highly complex.

The Copas method performs best and corrects adequately when publication bias follows Copas' selection model and without a strong association with the residuals of the effect size. Our results are comparable to results on bias and coverage in literature (Ning et al., 2017). However, when the mechanism behind publication bias is different from that used in the Copas' selection model, Copas' estimation method performs rather poorly. This happens in particular when the standardized effect size (mean difference or log odds ratio) is the statistic that would drive publication bias. Thus Copas' estimation method is sensitive to the selection bias mechanism, making its use in practice less suitable.

Other reasons for publication bias, which we did not study, have been mentioned in literature as well (Sterne et al., 2011), e.g., language bias, availability bias, and cost bias. It is unknown how Copas' method deals with these forms of biases, but we feel that it is unlikely that Copas' method corrects appropriately, since these biases are probably not described well by Copas' selection model either. We recommend to improve Copas' method to make it more robust against different forms of publication bias.

CRediT authorship contribution statement

Osama Almalik: Methodology, Software, Formal analysis, Investigation, Writing – original draft, Funding acquisition. **Zhuozhao Zhan:** Validation, Conceptualization, Supervision, Writing – review & editing, Visualization. **Edwin R. van den Heuvel:** Conceptualization, Methodology, Validation, Formal analysis, Investigation, Writing – review & editing, Supervision, Project administration, Funding acquisition.

Data availability

No data was used for the research described in the article.

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