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Investigation of the Factors Affecting the Consistency Assumption of Network Meta-Analysis: A Simulation Study

Ağ Meta Analizinde Tutarlılık Varsayımını Etkileyen Faktörlerin Araştırılması: Bir Benzetim Çalışması

Didem DERİCİ YILDIRIM[a], Sahure ÖZERTÜRK[a], Damla Hazal SUCU[a]

[a]Department of Biostatistics and Medical Informatics, Mersin University Faculty of Medicine, Mersin, Türkiye

ABSTRACT Objective: This study aimed to examine the factors affecting consistency assumption with simulated data for network meta-analyses. Network pattern, number of studies per comparison, individual study sample sizes, and probabilities of the event were investigated that may affect the consistency assumption. **Material and Methods:** Data were produced with R 4.1.0 for the combination of different sample sizes (N: 100, 150, 200), the different success probability of three treatments (p_1, p_2, p_3 changes in interval 0.01-0.90), and the number of study per comparison (M=5, M=10, M=20, M=30). Then the mean and standard error of ratios of odds ratios (ROR) were calculated and this process was repeated 1,000 times. **Results:** We found that the success probability of treatments and the number of studies in the network affected the inconsistency assumption more than the study sample size for N=100 and N=150. Also, the results indicated that in sample size 200, the study sample size affected the ROR values in addition to the other factors. **Conclusion:** Network meta-analysis is wide-spreading in recent years. Therefore, it is important to obtain reliable results with the providing assumptions. Especially, consistency assumption must be considered and the researchers may realize the affecting factors of the consistency assumption with this study.

Keywords: Network meta-analysis; consistency assumption; indirect comparison

ÖZET Amaç: Bu çalışma, ağ meta analizi için simüle edilmiş verilerle, tutarlılık varsayımını etkileyen faktörleri incelemeyi amaçlamıştır. Tutarlılık varsayımını etkileyebilecek; ağ modeli, karşılaştırma başına çalışma sayısı, bireysel çalışma örneklem büyüklükleri ve tedavilerin başarı olasılıkları dikkate alınmıştır. **Gereç ve Yöntemler:** Veriler farklı örneklem büyüklüklerinin kombinasyonu (N: 100, 150, 200), 3 tedavinin farklı başarı olasılığı (0,01-0,90 aralığında değişen p_1, p_2, p_3) ve karşılaştırma başına çalışma sayısı (M=5, M=10, M=20, M=30) için R 4.1.0 yazılımı ile üretilerek, sonuçlar elde edilmiştir. Daha sonra göreceli olasılıklar oranı [ratios of odds ratios (ROR)] değerleri için ortalama ve standart hata hesaplanmış ve bu işlem 1.000 kez tekrar edilmiştir. **Bulgular:** N=100 ve N=150 için tedavilerin başarı olasılığının ve ağdaki çalışma sayısının tutarsızlık varsayımını, çalışma örneklem büyüklüğünden daha fazla etkilediği tespit edilmiştir. Ayrıca sonuçlar, örneklem büyüklüğü 200 olduğunda, diğer faktörlere ek olarak, örneklem büyüklüğünün de ROR değerlerini etkilediğini göstermiştir. **Sonuç:** Ağ meta analizi son yıllarda gittikçe yaygınlaşmaktadır. Bu nedenle sağlanan varsayımlarla güvenilir sonuçlar elde etmek önemlidir. Özellikle tutarlılık varsayımının incelenmesi gerekir ve araştırmacılar bu çalışma ile tutarlılık varsayımını etkileyen faktörleri dikkate alabilirler.

Anahtar kelimeler: Ağ meta analizi; tutarlılık varsayımı; dolaylı karşılaştırma

In recent years, there has been an exponential growth in the application of systematic reviews and meta-analyses in medical science with the increase in the importance of evidence-based medicine.[1] Traditional meta-analysis is a statistical method combining the results from multiple studies which compare the same two interventions or treatments.[2,3] The results of the meta-analysis are strong evidence for health policies and guides. However, there are often more than two treatments for most diseases in practice. The comparison of the effectiveness of multiple treatments requires a new method called network meta-analysis (NMA).[4-8]

Correspondence: Didem DERİCİ YILDIRIM
Department of Biostatistics and Medical Informatics, Mersin University Faculty of Medicine, Mersin, Türkiye
E-mail: didemderici@hotmail.com

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NMA, is an extended method of the traditional meta-analysis, that enables the simultaneous analysis of both direct comparison and indirect comparison (not compared in a head-to-head-evidence) among the network of treatments.[5,6,9,10] Indirect comparisons may combine that each of the treatments of interest has been directly compared with other treatments.[11] NMA has provided stronger evidence by combining the direct and indirect comparisons contrary to only direct evidence. NMA has a more complex structure and more assumptions than traditional meta-analysis because of indirect comparison.[12]

There are three main assumptions for NMA. Similarity and consistency assumptions are different from the traditional meta-analysis. But the homogeneity assumption is the same as the traditional one. Similarity assumption is subjective and so there are no methods of evaluating objectively. The assumption of consistency is the main object of this study and means that there is no difference between the results of direct and indirect comparisons. It differs from the heterogeneity and random error of the studies. This assumption is related to indirect comparison especially, some simulation studies are conducted to evaluate the method performance under inconsistency but no study investigates the affecting factors of consistency assumption.[5,10,12]

In the light of this information, this study aims to investigate the affecting factors such as the network pattern, number of studies per comparison, individual study sample sizes, and probabilities of the event on the consistency assumption.

MATERIAL AND METHODS

LOOP INCONSISTENCY

Consistency assumption means that direct and indirect estimates are assumed to be the same. In Figure 1, the straight lines indicate the direct estimation, the dashed line shows indirect estimation. There are 3 treatments (A, B, and C), and in-network patterns there are pairwise and direct comparisons for A-B and A-C but all studies in the network do not compare B and C treatments. Therefore, there is an indirect estimation for B and C comparison.[13-23]

$$(d^{dir}_{BC}=di^{ndir}_{BC}d^{indir}_{BC}=d^{dir}_{AC}-d^{dir}_{AB})$$

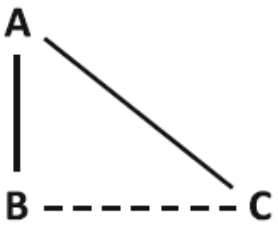

FIGURE 1: Graphic for loop inconsistency in two-arm trials.

Consistency is more about a loop, a closed network, rather than individual pairwise comparisons. The logit model, originally proposed by Lu and Ades, is a contrast-based model that uses the log odds ratio to estimate the relative effects of the two treatments. To detect loop inconsistency, Lu and Ades suggested using a parameter they call the inconsistency factor (w).[11,16,17]

$$d_{BC}=d_{AB}+d_{AC}+W_{ABC} \quad (1)$$

The posterior distribution of W reflects the degree of inconsistency in a given evidence cycle. The number of inconsistency degrees of freedom is m-(n-1). The posterior distribution of the W_{ABC} parameter added above measures the effect of the inconsistency in the relevant loop. The issue of how large the inconsistency factor must be for the network to be considered inconsistent is not explained.[16] Therefore, a measurement of the ratio of odds ratios (ROR) was proposed to evaluate the consistency assumption.[3]

The ROR

We defined inconsistency with a ROR in this study.

$$ROR_{BC} = \frac{OR_{BC}^{indirect}}{OR_{BC}^{direct}} \quad (2)$$

If ROR=1, there is no inconsistency;

If ROR<1, there is inconsistency and the difference from 1 shows the severity of inconsistency. For example, 0.80 shows moderate inconsistency and 0.60 shows severe inconsistency for ROR. The ROR<1 indicates that the effect of newer treatments is greater in direct comparison than in indirect comparison.[18]

SIMULATION PLAN

We simulated data for 4 different indirect comparison patterns as Figure 2. Such data structures are unbalanced incomplete block designs. We plan networks with 3 treatments because indirect comparisons can be conducted more truly and easily. But networks for more than 3 treatments, it is too hard to calculate indirect comparisons. Therefore, we created three equally effective treatments (Treatment A, Treatment B) relative to one less effective reference treatment (Treatment C). In this study, closed loops with two-arm trials are created, all pairwise comparisons are made and then indirect comparisons are obtained for comparison of Treatment B and Treatment C.

The parameters of interest in this study

1. The study sample size of each study (N) was 100, 150, and 200.

2. The number of studies (M) was 5, 10, 20, and 30 respectively.

3. The number of events for binary outcome were randomly generated assuming a binomial distribution $R_{ki} \sim Binomial(N_{ki}; P_{ki})$, R_{ki}: the number of event of i^{th} treatment for k^{th} study; P_{ki}: the probability of success of i^{th} treatment for k^{th} study. The probabilities were generated as intervals as 0.01-0.10; 0.11-0.20; 0.21-0.30; 0.31-0.40; 0.41-0.50; 0.51-0.60; 0.61-0.70; 0.71-0.80; 0.81-0.90.

4. If the simulated number of events was 0 for the 2x2 contingency table, 0.5 was added to the cells.

5. We also evaluated the heterogeneity between studies with consistency. ($0.50<I^2<0.70$). The random-effects model was used to combine direct and indirect estimates because of the heterogeneity.

6. The mean and standard error of ROR values were obtained for all scenarios. R 4.1.0 (R Foundation for Statistical Computing, Vienna, Austria) was used for simulation and each scenario was replicated 1,000 times.

m=5

Value	Value	NA
Value	Value	NA
Value	Value	NA
Value	NA	Value
NA	Value	Value

m=10

Value	Value	NA
Value	Value	NA
Value	Value	NA
Value	Value	NA
Value	Value	NA
Value	Value	NA
Value	NA	Value
Value	NA	Value
NA	Value	Value
NA	Value	Value

m=20

Value	Value	NA
Value	Value	NA
Value	Value	NA
Value	Value	NA
Value	Value	NA
Value	Value	NA
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Value	Value	NA
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m=30

Value	Value	NA
Value	Value	NA
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NA	Value	Value
NA	Value	Value

FIGURE 2: Unbalanced incomplete data structures of different networks.

NA is a missing value indicator, different missing structures for the number of studies are 5, 10, 20, 30, respectively.

In the simulation study, we aimed to investigate the effect of study sample sizes, the number of studies in the network, and the probability of success for treatments on assuming consistency assumption.

RESULTS

According to the results obtained from the simulation study, there was a stronger discrepancy in the results from the simulation study, especially for the high probability of success. The results were summarized for sample size 100 in Table 1. ROR values decreased with the increase in the number of studies for all the probabilities.

TABLE 1: The mean and standard errors of ROR values according to the number of studies and probabilities of success for 3 treatments for the sample size is 100.

	M=5	M=10	M=20	M=30
p1=(0.81-0.90) p2=(0.71-0.80) p3=(0.51-0.60)	0.280±0.003	0.265±0.002	0.257±0.002	0.257±0.001
p1=(0.71-0.80) p2=(0.61-0.70) p3=(0.41-0.50)	0.390±0.004	0.377±0.002	0.372±0.002	0.373±0.001
p1=(0.61-0.70) p2=(0.51-0.60) p3=(0.31-0.40)	0.444±0.004	0.432±0.003	0.427±0.002	0.428±0.001
p1=(0.51-0.60) p2=(0.41-0.50) p3=(0.21-0.30)	0.464±0.004	0.451±0.003	0.445±0.002	0.446±0.002
p1=(0.41-0.50) p2=(0.31-0.40) p3=(0.11-0.20)	0.462±0.006	0.443±0.004	0.434±0.003	0.435±0.002
p1=(0.31-0.40) p2=(0.21-0.30) p3=(0.01-0.10)	0.655±0.027	0.550±0.017	0.465±0.010	0.446±0.008

M is the number of studies; p_1 is the success probability of Treatment A; p_2 is the success probability of Treatment B; p_3 is the success probability of Treatment C; ROR values were summarized as mean±standard error; ROR: Ratio of odds ratios.

Table 2 showed that the results were so similar with N=100 for N=150. The smaller ROR value showed more severe inconsistency. Therefore, inconsistency was higher for the high probability combination of treatments. The strongest consistency was obtained for the interval of p (0.01-0.40) and M=5 (ROR=0.624±0.023).

TABLE 2: The mean and standard errors of ROR values according to the number of studies and probabilities of success for 3 treatments for the sample size is 150.

	M=5	M=10	M=20	M=30
p1=(0.81-0.90) p2=(0.71-0.80) p3=(0.51-0.60)	0.280±0.003	0.271±0.002	0.259±0.001	0.259±0.001
p1=(0.71-0.80) p2=(0.61-0.70) p3=(0.41-0.50)	0.389±0.003	0.382±0.002	0.372±0.002	0.373±0.001
p1=(0.61-0.70) p2=(0.51-0.60) p3=(0.31-0.40)	0.443±0.004	0.436±0.002	0.425±0.002	0.427±0.001
p1=(0.51-0.60) p2=(0.41-0.50) p3=(0.21-0.30)	0.463±0.004	0.454±0.003	0.443±0.002	0.445±0.002
p1=(0.41-0.50) p2=(0.31-0.40) p3=(0.11-0.20)	0.461±0.005	0.446±0.004	0.431±0.002	0.433±0.002
p1=(0.31-0.40) p2=(0.21-0.30) p3=(0.01-0.10)	0.624±0.023	0.528±0.015	0.441±0.009	0.436±0.007

M is the number of studies; p_1 is the success probability of Treatment A; p_2 is the success probability of Treatment B; p_3 is the success probability of Treatment C; ROR values were summarized as mean±standard error; ROR: Ratio of odds ratios.

ROR values were systematically decreased dependent on the increase in the probability of success of treatments for sample size 200 and the results were given in Table 3. For sample size 200, ROR values were lower than the sample sizes 100 and 150.

TABLE 3: The mean and standard errors of ROR values according to the number of studies and probabilities of success for 3 treatments for the sample size is 200.

	M=5	M=10	M=20	M=30
p1=(0.81-0.90) p2=(0.71-0.80) p3=(0.51-0.60)	0.276±0.003	0.267±0.002	0.259±0.001	0.255±0.001
p1=(0.71-0.80) p2=(0.61-0.70) p3=(0.41-0.50)	0.386±0.003	0.379±0.002	0.374±0.002	0.370±0.001
p1=(0.61-0.70) p2=(0.51-0.60) p3=(0.31-0.40)	0.440±0.003	0.433±0.002	0.428±0.002	0.424±0.001
p1=(0.51-0.60) p2=(0.41-0.50) p3=(0.21-0.30)	0.460±0.004	0.452±0.003	0.447±0.002	0.442±0.002
p1=(0.41-0.50) p2=(0.31-0.40) p3=(0.11-0.20)	0.458±0.005	0.443±0.004	0.436±0.002	0.430±0.002
p1=(0.31-0.40) p2=(0.21-0.30) p3=(0.01-0.10)	0.401±0.004	0.389±0.003	0.385±0.002	0.381±0.002

M is the number of studies; p_1 is the success probability of Treatment A; p_2 is the success probability of Treatment B; p_3 is the success probability of Treatment C; ROR values were summarized as mean±standard error; ROR: Ratio of odds ratios.

The changes in ROR values were summarized in Figure 3. For sample sizes 100 and 150, ROR values had a similar distribution for each combination. But, for sample size 200, ROR values were obtained lower for each combination.

DISCUSSION

Active treatment was compared versus placebo in most randomized controlled trials. In the traditional meta-analysis, two treatments were compared only. For comparison of more than two active treatments, NMA was proposed by researchers. NMA had become popular for clinicians for decision-making in recent years. The most important assumption of NMA was the consistency assumption. This assumption must be provided to combine direct and indirect estimations. Therefore, we investigated the influencing factors like the number of studies, network pattern, study sample sizes, and probability of an event on consistency assumption for NMA in our study. Moreover, heterogeneity had count for disagreement between indirect and direct comparisons.[1,19,20]

The simulation was done in a situation of high heterogeneity. According to these results, as p ratios decreased, an increase was observed in ROR. Contrary to p ratios, ROR values decreased with the increase in the number of studies in the network. The ROR values were similar for M=20 and M=30. In addition, when the sample size was 200, ROR values had a normal distribution according to p ratios. ROR values for each number of the study were tested with Shapiro-Wilk when the sample size was 200. According to the test results, it was determined that the ROR values of all study numbers provided the assumption of normality (m=5, p=0.124; m=10, p=0.125; m=20, p=0.114; m=30, p=0.106). In this normal curve, the peak for ROR was calculated as a result of the data set produced with p_1=(0.51-0.60); p_2=(0.41-0.50); p_3=(0.21-0.30) ratios (Figure 3).

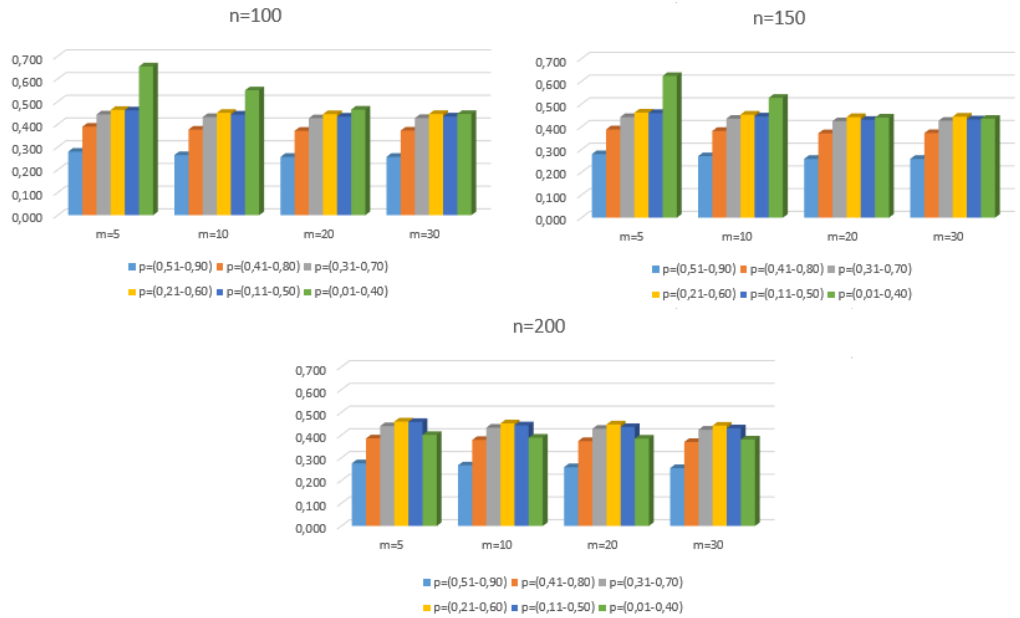

FIGURE 3: The ratio of odds ratios values of all combinations of simulation for each sample sizes.

There were studies about consistency assumptions in NMA. Veroniki et al. investigated the prevalence of inconsistency from data from 40 studies. Inconsistency was detected in 2 (%) to 9 (%) of the studies.[21] Song et al. declared that 16 cases of 112 (14%) included trial networks, and the inconsistency between the direct and indirect comparison was not provided. At the same time, it was stated by Song et al. that as the loop becomes more complex in-network, the probability of not providing the consistency assumption will increase.[18] Generally, the effects of homogeneity and consistency assumptions on average effect sizes are mixed. Because the reasons that lead to heterogeneity also lead to inconsistency. It is very unlikely that these two hypotheses can be completely separated from each other. A very high heterogeneity increases the probability of inconsistency. We simulated the data by considering the variance between studies in the simulation phase of our study. The random-effects model was identified as Equation 3.

$$\theta_i = \theta + \delta_i \qquad (3)$$

θ_i is the true effect size in the study and θ is the average effect across all studies. δ_i is the between-study heterogeneity. Meta-analysis methods typically assume that and $\delta_i \sim N(0, \tau^2)$. The heterogeneity variance parameter is a measure of the variance of θ_i around θ and is denoted by τ^2. The inverse-variance method is used to estimate θ in the model. We also evaluated the heterogeneity between studies with consistency with I^2 values. These values were calculated using τ^2 parameter estimates.[20-25]

The strength aspect of our study is the first article that evaluated the affecting factors on consistency assumption. Because there was a little sufficient simulation study about consistency assumptions in NMA. However, simulation studies are important in terms of methodological evaluation.[1,2]

CONCLUSION

NMA has become popular in recent years. Especially for the comparison of two or more treatments, NMA has been preferred more than traditional meta-analysis. The assumptions of the method are too important to obtain reliable results. Consistency assumption is the most important one for NMA. Inconsistency between the direct and indirect comparisons is more prevalent than has been predicted. Therefore, inconsistency must be considered in NMA by researchers. This assumption is especially true for indirect comparisons. For this reason,

statistical methods continue to evolve. They may realize the affecting factors of the consistency assumption with this study. According to our study, the success probability of treatments and the number of studies in the network affected the consistency assumption more than the study sample size for N=100 and N=150.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and/or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: *Didem Derici Yıldırım, Sahure Özertürk;* ***Design:*** *Didem Derici Yıldırım, Sahure Özertürk;* ***Control/Supervision:*** *Didem Derici Yıldırım, Sahure Özertürk, Damla Hazal Sucu;* ***Analysis and/or Interpretation:*** *Didem Derici Yıldırım, Sahure Özertürk, Damla Hazal Sucu;* ***Literature Review:*** *Didem Derici Yıldırım, Sahure Özertürk;* ***Writing the Article:*** *Didem Derici Yıldırım, Sahure Özertürk, Damla Hazal Sucu;* ***Critical Review:*** *Didem Derici Yıldırım, Sahure Özertürk, Damla Hazal Sucu.*

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