A COMPLEMENTARY BIAS RISK ASSESSMENT TOOL (BIRAT CHECKLIST) FOR OBSERVATIONAL HEALTH STUDIES: A METHODOLOGICAL STUDY*

Gözlemsel sağlık araştırmaları için tamamlayıcı bir yan tutma riski değerlendirme aracı (BiRDA kontrol listesi): Metodolojik bir çalışma*

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Abstract

Assessment of bias in health studies is important and not easy to measure objectively. The aim of this study was to develop an easy-to-use, comprehensive, cost-effective, and time-efficient bias control tool for observational studies. This was a methodological study conducted between June 2018 – June 2020. The main steps were the literature review to extract items, expert opinions, Delphi panels, construction of the framework and the tool's content, statistical analysis, and reporting of the study. The literature review was conducted with prespecified keywords by researchers. "Expert Assessment Form" was used to evaluate expert opinions. Although Content Validity Ratio (CVR) was used to check the content validity, it was mainly based on a consensus of experts. Three Delphi panels were carried out. The name of the developed tool was decided to be Bias Risk Assessment Tool (BiRAT). It was considered to use the abbreviations BiRAT-CS for cross-sectional studies, BiRAT-CC for case-control studies, and BiRAT-Co for cohort studies. Descriptive statistics A total of 71 expert assessment forms were sent to 67 experts, and 44 of them were received. As a result of the assessments made after the Delphi panels; 67-item BiRAT-CS, 69-item BiRAT-CC, and 70-item BiRAT-Co were developed. BiRAT tools may be used in training, preparing for a study, or publication process. However, bias assessment tools should be used with mobile/online applications or artificial intelligence technologies for easier use and further development since their use is generally impractical.

Keywords: Bias, health care research, scientific misconduct, bias risk assessment tool, BiRAT.

Özet

Sağlık araştırmalarında yan tutma önemli olup, bunu tarafsız bir şekilde ölçmek kolay değildir. Bu araştırmanın amacı; gözlemsel araştırmalar için kullanımı kolay olan, kapsamlı, maliyet ve zaman etkin bir yan tutma kontrol aracı geliştirmekti. Bu araştırma, Haziran 2018 – Haziran 2020 tarihleri arasında yürütülen metodolojik bir çalışmaydı. Araştırmanın ana basamakları; yan tutma sorgulanacak maddeler için literatür taramak, uzman görüşleri, Delphi panelleri, bias risk değerlendirme aracının ana hatlarının oluşturulmak ve içerik geliştirilmek, araştırmanın istatistiksel analizini yapmak ve sonucunu raporlamaktı. Literatür taraması, araştırmacılar tarafından önceden belirlenmiş anahtar kelimeler ile yapıldı. Uzman görüşlerini alabilmek için "Uzman Değerlendirme Formu" geliştirilip kullanıldı. Kapsam geçerliliğini değerlendirmek için Kapsam Geçerlilik Oranı (KGO) kullanılmış olsa da esas olarak uzman görüşüne dayalı olarak yapıldı. Üç Delphi paneli gerçekleştirildi. Geliştirilen aracın adının Bias Risk Değerlendirme Aracı (BiRDA) olmasına karar verildi. Kesitsel araştırmalar için BiRDA-Ke, vaka kontrol araştırmaları için BiRDA-VK, kohort araştırmaları için BiRDA-Ko olarak kullanılması kabul edildi. 67 uzmana toplam 71 adet uzman değerlendirme formu gönderildi ve bu formların 44'üne geri dönüş yapıldı. Delphi panellerinin sonucunda; 67 maddelik BiRDA-Ke, 69 maddelik BiRDA-VK ve 70 maddelik BiRDA-Ko araçları geliştirildi. BiRDA araçları, eğitimde, araştırmaya hazırlık aşamasında veya yayın süreçlerinde kullanılabilir. Fakat, bu tür araçların kullanımı genellikle pratik olmadığı için mobil/internet uygulaması olarak kullanımı veya ileri çalışmalarda yapay zekâ teknolojileri ile kullanımı kolaylaştıracaktır.

Anahtar kelimeler: Bias, sağlık hizmetleri araştırması, bilimsel suistimal, bias risk değerlendirme aracı, BiRDA.

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Introduction

Health studies consist of a variety of study designs and the number of these studies increases day by day. An observational study takes part among these studies and it is a kind of health studies commonly used study design in both in medical science and other sciences such as psychology (1, 2). The individuals are observed, or specific outcomes are measured and no intervention is made to influence the outcome in observational studies (3). A well-designed observational study has lots of advantages such as prevalence calculation and definition of diseases' risk factors, but when design, collecting data and reporting is not achieved correctly, it will mislead the scientists and so the population (4).

According to a dictionary of epidemiology, biases are defined as the "systematic deviation of results from truth". These deviations may occur in the collection, analysis, interpretation, reporting, publication or review of data in a study (5). A list of important biases was described to explain their negative effects on the studies (6). Therefore, the awareness of these biases is important for researchers about what they should do or not.

A wide variety of research methods have been developed to provide the most reliable evidence (7). Numerous guidelines have been created for reasons such as ethical concerns, writing rules, and thoughts about the high-level evidence. Criteria of International Committee of Medical Journal Editors (ICMJE), research checklists [such as Strengthening The Reporting of Observational Studies in Epidemiology (STROBE), Consolidated Standards of Reporting Trials (CONSORT)], bias risk assessment tools are the examples of these guidelines (8). There are also many other tools available to assess the risk of bias in health studies such as Risk of Bias (RoB), GRACE Good Research for Comparative Effectiveness (GRACE), Effective Public Healthcare Panacea Project (EPHPP) (9–11). However, the use of these tools in health studies is usually limited because of their insufficient content or difficulty of use. The aim of this study was to develop an easy-to-use, comprehensive, cost effective and time efficient bias control tool for observational studies.

Material and Method

This was a methodological study conducted between June 2018 – June 2020. Main steps of this study included literature review to extract items, expert opinions, Delphi panel, construction of the framework and the content of the tool. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

The study protocol was approved by Aydin Adnan Menderes University, Faculty of Medicine, Non-Interventional Clinical Research Ethics Committee (Date: 13.06.2019, Protocol Number: 2019/93). Verbal consent was obtained from each expert in the study.

Preparing for Study and Literature Search

Literature review to extract items was conducted between June 2018 – August 2019 by the author of this study when he was a research assistant. Both Turkish and English online resources were searched by the university based library from the Google search engine, Pubmed, Cochrane, Embase (12–14). Turkish and English keywords used for the search and these keywords were "Health Studies", "Observational Health Studies", "Health Research", Observational Health Research", "Checklist", "Scale", "Domain-based", "Research Error", "Bias". Corresponding Turkish meaning of them were also used for the literature review.

Expert Assessment Forms

"Expert Assessment Form (EAF)" was used to evaluate expert opinions. Former, this form was formed after literature review.

Later, it was discussed with 12 research assistants and two academicians from the public health department in September 2019 (First Delphi Panel). Then, the final version of the form was generated. This questionnaire form included three parts. First part (explanatory part) was about the introduction of the study and included no question. Second part (expert information part) was composed of sociodemographics and quantitative summary of academic publication history of the experts (nine questions). Third part was composed of the items about the tool; 77 items for cross sectional studies, 80 items for case control studies, 82 items for cohort studies. We requested from experts to choose one of the three options for each item: "Essential", "Essential / Insufficient" and "Not Essential". If they had suggestion, they had option to write it to the blank near to the options. EAFs were prepared in Turkish and evaluated by Turkish experts. We chose the experts who had been actively working or retired in the specialty of public health, epidemiology, biostatistics, the other experts in public health (nursing, midwifery, health economics, health management etc.) and the editors of the public health journals or reviewers in Turkiye. Total 67 experts (71 forms) were invited to give feedback to EAFs. 36 EAFs (50.7%) were sent by e-mail and mail (post), 34 EAFs (47.9%) were sent by e-mail and given by the author (three cities; Aydin, Izmir, Manisa), one EAF (1.4%) was sent by just e-mail (Table 1).

Table 1: Feedback proportion of the expert assessment forms.

Delivery Method	Those Who Gave Feedback		Those Who Did Not Give Feedback / Not Accepted by The Author		Total	
	n	%	n	%	n	%*
E-Mail + Mail (Post)	19	52.8	17	47.2	36	50.7
E-Mail + Given by Author	24	70.6	10	29.4	34	47.9
Just E-mail	1	100.0	0	0.0	1	1.4
Total	**44**	**62.0**	**27**	**38.0**	**71**	**100.0**

**Column Percentage*

Statistical Analysis

Descriptive statistics were presented as median (minimum-maximum), frequency and percentage. Distribution of normality was evaluated with Shapiro-Wilk Test. Statistical analyses were done with SPSS 26.0 (for MacOS) package program.

After the the feedback of expert opinions; the items' with values of the Content Validity Ratio (CVR) that were equal or below the zero and other suggestions of experts related to the items were assessed in Delphi panels (15–17).

CVR=(Ne-N/2)/(N/2)

Ne equals the number of EAFs rating an item as "Essential" and N equals the total number of EAFs providing ratings.

According to Ayre and Scally, minimum CVR values were 0.600 for cross sectional studies (15 experts), 0.444 for case control studies (18 experts) and 0.636 for cohort studies (16). Actually, we also planned to calculate Content Validity Index (CVI) but, most of the CVR values of the items were below the cutoff values for all three methods of study designs (15). Therefore, CVR values were just used to evaluate the items which had insufficient values and to discuss these items in second and third Delphi panels. If we had plan to do a scale, we would have used those CVR values of Ayre and Scally.

Delphi Panels

Total three Delphi panels were organized. First one was done with mainly research assistants to make up the EAF in Aydin Adnan Menderes University, Faculty of Medicine (Aydin, Province). Second Delphi was done to evaluate the results of EAFs of cross-sectional studies with nine experts in February 2020 in Aydin Adnan Menderes University, Faculty of Nursing (Aydin,

Province). Third Delphi was done to evaluate the results of EAFs of both case control and cohort studies with nine experts in March 2020 in Akdeniz University, Faculty of Medicine (Antalya, Province).

BiRAT Checklist

After the Delphi panels, construction of the framework was designed. According to reviews of experts in these panels, we built a scheme for these studies. At the beginning of this study, we could not decide the style of this tool. Therefore, we started to work general (scale, checklist, or rubric). We decided that checklist would be the better for this subject in the middle of the study. The name of the developed tool was decided to be Bias Risk Assessment Tool (BiRAT) (Bias Risk Değerlendirme Aracı, BiRDA in Turkish). It was considered to use the abbreviations BiRAT-CS for cross-sectional studies, BiRAT-CC for case-control studies and BiRAT-Co for cohort studies (Table 2). Research and bias control are management processes. Therefore, we divided these processes into three time-intervals: "Before the collection of study data", "During the collection of study data" and "After the collection of study data".

Table 2: Titles, subtitles, and number of items of BiRAT chectlist.

Title / Subtitle	Number of Items (n)		
	Cross Sectional Studies	Case Control Studies	Cohort Studies
Bias resources before the collection of study data			
Basic Items (BI)	5	5	5
Literature Reading / Screening (LRS)	3	3	3
Selection of Sample and Sampling (SSS)	15	14	15
Bias resources during the collection of study data			
Pollster / Supervisor Factors (PSF)	4	4	4
Survey / Data Collection Form (SDCF)	7	7	7
Recall Factors (RF)	3	3	3
Measurement Factors (MF)	3	5	4
Communication Factors (CF)	3	3	3
Data Source Factors (DSF)	4	4	5
Bias resources after the collection of study data			
Literature Reading / Screening / Using (LRSU)	2	2	2
Data Entrance / Analysis / Presentation (DEAP)	14	15	15
Interpretation / Publication of Results (IPR)	4	4	4
Total	**67**	**69**	**70**

Final versions of BiRAT tools were Turkish. It was planned to do a mobile / online application to use tools easily. Reliability study could not be done because of COVID-19 pandemic, but it was considered.

Results

A total of 71 EAFs were sent to 67 experts and 44 of them were received. The numbers of the experts giving feedback for BiRAT-CS, BiRAT-CC and BiRAT-Co were 15, 18 and 11, respectively.

The numbers of experts had an academic degree of associated professor or professor that gave feedback for EAFs for BiRAT-CS, BiRAT-CC and BiRAT-Co were 12 (80.0%), 16 (88.9%) and 9 (81.8%),

respectively. The numbers of public health experts in this step for BiRAT-CS, BiRAT-CC and BiRAT-Co were 14 (93.3%), 15 (83.3%) and 10 (90.9%), respectively.

Proportion of women experts were 46.7%, 61.1%, and 63.6% in BiRAT-CS, BiRAT-CC, and BiRAT-Co, respectively. The median value of the total working time in the field of their expertise were 232.0 (111.0 – 255.9), 236.0 (137.0 – 354.0), and 232.0 (132.0 – 360.0) months in BiRAT-CS, BiRAT-CC, and BiRAT-Co, respectively.

Five experts in BiRAT-CS, eight experts in BiRAT-CC, one expert in BiRAT-Co had role as editor and reviewer, in at least one scientific journal (national or international). One expert in BiRAT-CC and BiRAT-Co had no role as editor or reviewer, all others had role at least as reviewer in at least one scientific journal (national or international). 66.7% of the experts in BiRAT-CS, 44.4% of the experts in BiRAT-CC, 54.5% of the experts in BiRAT-Co had been in an ethical council formerly or at the time of this study.

In Table 3, total number of items assessed by experts for each study design and the number (percentage) of insufficient items with low CVRs were demonstrated. Delphi panels were composed of two phases and conducted after this analysis step. In first phase, reviews of experts in EAFs were evaluated, quantitatively. The items with CVR values equal or below zero were identified. In second phase, reviews of all items in EAFs (coded anonymous such as CS1, CC10, Co8) were evaluated, qualitatively and a digital / printed document prepared to use for second and third Delphi panels. A digital / printed presentation including the items that had insufficient CVR values and experts' suggestions about these items were prepared. After the quantitative and qualitative evaluations, all items were assessed by experts using these documents and presentations in second and third Delphi panels.

At the end of the Delphi panels, it was decided that BiRAT tool was a checklist. Then, a user guide for each BiRAT tool was prepared and final version of the BiRAT tools were completed in May 2020. As a result of the assessments made after the Delphi panels; 67-item BiRAT-CS, 69-item BiRAT-CC and 70-item BiRAT-Co were developed. After the Delphi panel final accepted number for each study type was presented in Table 2.

Table 3: Total number of items in expert assessment forms and insufficient items.

Study Design	Total Number of Items in EAFs	Number and Percentage of Insufficient CVRs	Subtitle and Number of Insufficient Items
Cross Sectional	77 Items	7 Items (9.1%)	• Selection of Sample and Sampling: *Four Items* • Survey / Data Collection Form: *Two Items* • Communication Factors: *One Item*
Case Control	80 Items	14 Items (17.5%)	• Selection of Sample and Sampling: *Three Items* • Pollster / Supervisor Factors: *One Item* • Survey / Data Collection Form: *One Item* • Recall Factors: *Three Items* • Measurement Factors: *One Item* • Communication Factors: *One Item* • Data Entrance / Analysis / Presentation: *One Item* • Interpretation / Publication of Results: *Three Items*
Cohort	82 Items	12 Items (14.5%)	• Literature Reading / Screening: *One Item* • Selection of Sample and Sampling: *Three Items* • Survey / Data Collection Form: *One Item* • Recall Factors: *Three Items* • Measurement Factors: *One Item* • Interpretation / Publication of Results: *Three Items*

EAFs; *Expert Assessment Forms,* ***CVR;*** *Content Validity Ratio*

Discussion

The strength of the BiRAT is that bias assessment starts from the planning of the study and finish at the publishing (timeline). Thus, it could provide researchers more systematic bias assessment (10, 18, 19). Theoretically, this systematic approach enables more fluent assessment of the article, less time consuming, and easier assessment when compared with the other tools.

BiRAT-CS, BiRAT-CC, BiRAT-Co includes 67, 69 and 70 items, respectively. The numbers of items may be accepted as comprehensive, when compared with some other tools (10,20,21). Prominent bias resources before, during and after the collection of study data were included in this study. The items that were not assessed or understood easily, and including extreme information were excluded from BiRAT or included in the checklist by altering.

BiRAT might be the first methodological study about bias evaluation in Turkiye. The strength of this study was that BiRAT was conducted mainly with the field experts in health. The numbers of the experts giving feedback for BiRAT-CS, BiRAT-CC and BiRAT-Co were 15, 18 and 11, respectively. BiRAT like tools had been mainly developed by special working groups such as Cochrane and CASP, therefore sociodemographic data could not be compared with other studies (18, 19).

Reliability of BiRAT could not be evaluated, but the reliability of the other bias assessment tools unfortunately is also too low (19, 21). Thus, the reliability of BiRAT tool might be lower as expected. The difference between experts' knowledge and interpretation about research methods could be the reason to explain the low reliability. Asking questions (items) more detailed and continuously upgrading the tool may solve this reliability problem. Yet, it is not easy to provide such implementations because of rapid changes in medicine.

Unresponsiveness of experts for EAFs was present, especially high in cohort studies. Feedback proportion of manually given forms by the author (plus e-mail) and posts (plus e-mail) was 70.6% and 52.8%, respectively. Face-to-face communication with experts might increase the proportion of the experts' feedback.

In a study of Deeks et al. in 2003, 194 bias assessment tools evaluating non-randomized studies (22), and 14 of them were accepted as qualified (18, 20, 21, 23–30). Most of these qualified tools were designed for experimental studies. Recently, it has become a significant research topic for researchers due to a great number of such tools. The reason for this number of tools could be the absence of "ideal" tool.

Frequently used observational study methods should be known in health area, especially in public health. ICMJE criteria (8) and STROBE checklist indicates the minimum level of essential assessment criteria. These tools are not mainly focused on whether the desired information is present in manuscript. Especially, STROBE suggested to researchers that the tool was a guide about how to write a manuscript and it should not be used just before sending a manuscript to the journal. Our tool differs from STROBE when we considered from this aspect. We aim that BiRAT may be used before, during and after a manuscript is completed. Therefore, we defined BiRAT as a "complementary tool". Researchers should not depend on these tools since; these might not demonstrate the actual bias resources. Therefore, bias assessment tools should be considered to define possible bias resources.

Some of the bias assessment tools are patient and disease oriented, but BiRAT principles focus on other non-patient-oriented situations, too (eg; studies that data is collected from health records). A checklist had been designed according to patient statements (31). Therefore, BiRAT have been considered more inclusive than these tools, although it had been designed for specific studies.

Basic items include primary worklist before a study begin. Eg; ethical council, consent form, conflict of interest were assessed here. Checking the items in this subtitle will contribute to lower the bias preparing the researchers for a study. In addition, some tools may accept these items as a bias. For example, "conflict of interest" was accepted as bias in a study of systematic review and metanalysis (32).

In BiRAT, subtitles of “selection of sample and sampling” and “data entrance / analysis / presentation” were the most discussed items. Each of the subtitles had more than 10 items. We had to give more details on these topics. This might show us that important or common errors may be about them.

Assessing the reporting and publication bias was very controversial in this study. There are some tools that assess the reporting bias (20, 33). In our study, we could not make an item in BiRAT. This may be due to insufficient knowledge about reporting bias, or a need to assess the reporting and publication bias in other methods. But we think that these assessments are not sufficient, they should be improved.

Some tools had common items that were not applicable to three study types (11, 21). In this study, most of the items are similar but, some key items were added for each study type. Some tools are similar to BiRAT on the aspect of specialized tools for study designs (10, 18). Most of the bias assessment tools were derived for the clinical treatment and prognosis studies (10, 18–20, 34). Therefore, they have limited roles in public health studies. BiRAT could be used for both clinical and public health studies, although most of the experts were from public health professionals.

Applying the statistical analysis to develop such bias assessment tools would be a problem for content validity. According to our experience in collecting data and analysis, developing expert opinion-based algorithms instead of quantitative analysis-based algorithms (CVR, CVI, kappa value etc.) would be better.

BiRAT may have a role in reducing bias in observational studies in the field of health (especially public health), to produce accurate and high-quality scientific data, to ensure the preparation of higher quality and scientific guidelines. This tool may also be used for training in epidemiology, especially learning study methods. Journals, editors, and reviewers might also benefit from this checklist.

BiRAT tools, could be used free with citation. This study was a medical specialty thesis and published in Turkish (35). Therefore, it is a cost-effective tool. Time efficiency could not be assessed; therefore, it could be given after the field experience. Fortunately, it was used in two systematic reviews (BiRAT-CS) with permission (36, 37). We had requested to authors for advantages and disadvantages of the tool, yet we could not get a return to our e-mail.

Conclusions

It was observed that evaluating bias concept with short and comprehensive questions was difficult when BiRAT and other bias assessment tools were considered. Short tools could not assess the bias efficiently, long, and detailed tools need additional guides / manuals to be comprehended. BiRAT seems to be between these two tips, it does not assess bias concept neither superficially nor deeply. Therefore, it is a good tool to be used. In this study, items include all the important areas of the bias resources except reporting and publication bias. Thus, new bias tools assessing the reporting and publication are needed.

Face-to-face communication is very important to get back expert assessment forms from experts to increase feedback proportion. Therefore, it would be better to distribute forms to the experts from hand-to-hand and collect back.

Intra-rater and inter-rater reliability problems might occur for bias assessment tool studies. Therefore, it is not recommended to analyse reliability according to this research. Instead, it is better to build working groups to continue expert opinion-based algorithms will be b etter for future studies.

BiRAT could be used to assess bias in observational studies (cross-sectional, case-control, and cohort). This tool may be used in training, preparing for a study, or publication process. Bias assessment tools should be used with mobile / online applications or artificial intelligence technologies for easier use and further development since their use is generally impractical.

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