ORİJİNAL ARAŞTIRMA ORIGINAL RESEARCH

DOI: 10.5336/biostatic.2018-63697

A MEDLINE Survey Study on Reporting of Design Effect and Degree of Compliance with STROBE

STROBE Maddelerine Uyum ve Tasarım Etkisinin Raporlanmasına Yönelik Bir MEDLINE Taraması

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Received: 06.11.2018
Received in revised form: 16.02.2019
Accepted: 05.03.2019
Available Online: 19.04.2019

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This study was presented as a poster at The 8th Conference of Eastern Mediterranean Region International Biometric Society, 11-15 May 2015, Nevşehir, Turkey.

ABSTRACT Objective: The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement is a checklist and has been developed to improve the reporting of observational studies. The design effect for observational studies is an important factor in sample size determinations however is not considered under STROBE. In this study, it is aimed to evaluate compliance with STROBE in the articles reviewed in MEDLINE and highlight the necessity of thinking out design effect. **Material and Methods:** A database search has been performed on the observational studies n=342, that are free full text, written in English and published in MEDLINE. The frequency of compliance with STROBE was examined and an auxiliary review with respect to the design effect was done by one reviewer. **Results:** 342 articles evaluated, 224 (65.5%) were cross-sectional and 118 (34.5%) cohort studies. The best compliance (above 90%) was for items 1(b), 2 and 14(a) while the worst fit (under 20%) was for items 12(d), 13(c) and 16(c). In n=6 (1.8%) cross-sectional studies design effect was reported. **Conclusion:** In terms of the quality of the reporting of observational trials, current observational studies in MEDLINE could still benefit from increased reporting of methodologic details including the reporting design effect, sample size determinations, methods taking account of sampling strategy for cross-sectional studies, power analyses and consideration of potential bias. For items under methods section (items 4–12) compliance is lower than other items. Discarding design effect has a potential of source of bias. Authors should report the design effect and can also be consider within the items 4 or 9 or 10.

Keywords: Observational study; STROBE; sample size; design effect; MEDLINE

ÖZET Amaç: STROBE (STrengthening the Reporting of OBservational studies in Epidemiology), gözlemsel araştırma türündeki makalelerin hazırlanması sırasında yazılması gereken bölümlere ışık tutan kontrol listesi niteliğinde bir rehberdir. Gözlemsel çalışmalar için tasarım etkisi, örneklem büyüklüğünün belirlenmesinde önemli bir faktördür: Ancak STROBE kapsamında ele alınmamıştır. Bu çalışmada MEDLINE' veritabanında incelenen makalelerde STROBE maddelerine uyumu değerlendirmek, tasarım etkisinin değerlendirilmesine olan gereksinimi vurgulamak ve tasarım etkisinin kullanım sıklığını gözden geçirmek amaçlanmaktadır. **Gereç ve Yöntemler:** MEDLINE'nın web arayüzü olan PubMed üzerinden tam metine bağlantı verilmiş ve dili İngilizce olan kohort ve kesitsel araştırma türü niteliğindeki makalelerin tamamı çalışmanın evrenini oluşturmaktadır. STROBE ile uyum incelenmiş ve tasarım etkisinin raporlanması ile ilgili bir ek değerlendirme yapılmıştır. **Bulgular:** Değerlendirilen n=342 makalenin, n=224'ü (65.5%) kesitsel ve n=118'i (34.5%) kohort çalışmasıdır. Uyumun en yüksek olduğu (90%'ın üzerinde) maddeler 1 (b), 2 ve 14 (a), en düşük olduğu (20% 'nin altında) maddeler ise 12 (d), 13 (c) ve 16 (c) olduğu gözlenmiştir. Ayrıca kesitsel çalışmada tasarım etkisinin dikkate alındığı makale n=6 (1,8%) oldukça azdır. **Sonuç:** MEDLINE'da gözlemsel çalışmaların raporlanma kalitesi bakımından, tasarım etkisinin raporlanması, örneklem büyüklüğü belirlenmesi, kesitsel çalışmalar için örnekleme stratejisini hesaba katan yöntemler, güç analizleri ve potansiyel yanlılık gibi metodolojik detayların rapor edilmesinden faydalanmaya devam etmelidir. Tasarım etkisinin "Gereç ve yöntemler"bölümündeki madde 4, 9 veya 10 kapsamında göz önünde bulundurmalıdır.

Anahtar Kelimeler: Gözlemsel çalışma; STROBE; örneklem büyüklüğü; tasarım etkisi; MEDLINE

Epidemiological studies concerning causal inference on diseases are mainly observational, namely either cohort, or case-control, or cross-sectional. Most journals endorse "Uniform Requirements of the International Committee of Medical Journal Editors (ICMJE)"for reporting of an observational study, which makes strengths and weaknesses of a study to be easily assessed.[1] ICMJE foster the checklist of items STROBE Statement to enhance reporting of observational studies.[2] The STROBE Statement includes 22 items which endorse reporting strategies for each part in a study such as article's title and abstract (item 1), introduction (items 2 and 3), methods (items 4–12), results (items 13–17), discussion (items 18–21) and funding (item 22) parts. 18 items are common for all study designs (case control, cohort and cross-sectional studies) while four items (6, 12, 14, and 15) have sub-items which are design specific.[3] The declaration of study design and calculation of sample size take part under the 'methods' section. This section in STROBE does not take design effect into consideration. However design effect is commonly used in survey sampling to plan sample design and to account for the effect of sample design on estimation and analysis.[4]

Kish (1965) defined design effect as ratio of the variance of an estimator under a sample design that the variance estimator under simple random sampling.[5]

$$D^2(\hat{\Theta}) = \frac{\mathrm{Var}(\hat{\Theta})_{\mathrm{complex}}}{\mathrm{Var}(\hat{\Theta})_{\mathrm{srs}}}$$

where,

$D^2(\hat{\Theta})$: design effect for the sample estimate, $\hat{\Theta}$;

$\mathrm{Var}(\hat{\Theta})$complex: variance of $\hat{\Theta}$ under complex sample design; and

$\mathrm{Var}(\hat{\Theta})$srs: variance of $\hat{\Theta}$ under simple random sample design.

As in the formula, the design effect determinants are complex sample design and simple random sampling (SRS). When these determinants are compared, it is revealed that the SRS method has a higher power under the same sample size assumption. The inclusion of the design effect in the studies increases the power of the studies using the complex sampling method. In other words, the inclusion of design effect in the study eliminates the disadvantage of the complex design.[6] When the design effect of complex data sources is not taken into account, variances are not estimated appropriately. Thereby standard errors are often too small, that increase type I errors and decrease post hoc power.[7] Compared to the SRS method, by multiplying the sample size in SRS by the design effect in the complex sampling method, it will be possible to eliminate disadvantage of decrease in post hoc power.[8]

Vandenbrouck et al. (2007) and White et al. (2015) stated that according to effect of the study design sample size and post hoc power should be evaluated.[3,9,10] The aim of the study is to examine the compliance of the cross sectional and cohort studies published in MEDLINE with the items in STROBE. With this purpose in mind, to review the reporting frequency of design effect in the articles is an auxiliary review done by author (BDH).

MATERIAL AND METHODS

A database search was performed on the survey studies that are free full text, written in English, including "cross sectional" and "cohort study" keywords in title or summary and published in the years 2013 and 2014 in the MEDLINE. n=3008 articles were identified. A systematic sampling was made and 342 (p=0.50, α=0.05 and margin of error=0.05) articles were identified for the purpose of examining the concordance with STROBE. The study does not require ethical approval.

The articles were checked out in terms of 22 items of STROBE Statement and data is collected by author BDH.

RESULTS

The total number of articles under cross-sectional and cohort study design was n=3008. When 'study type' was considered the number of the cross-sectional studies appeared to be n=1969 (65.5%), and there were n=1039 (34.5%) cohort studies. The counts and percentages of concordance to checklist are given under Table 1.

TABLE 1: The counts and percentages of concordance to checklist of 342 articles.

STROBE Statement—checklist of items that should be included in reports of observational studies (Cross-Sectional and Cohort Studies)					
	Item No	**Recommendation**	**Cross-Sectional n (%)**	**Cohort n (%)**	**Total n (%)**
Title and abstract	1	*(a)* Indicate the study's design with a commonly used term in the title or the abstract	74 (33.0)	55 (46.6)	129 (37.7)
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	217 (96.9)	116 (98.3)	333 (97.4)
Introduction					
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	219 (97.8)	117 (99.2)	336 (98.2)
Objectives	3	State specific objectives, including any prespecified hypotheses	196 (87.5)	92 (78.0)	288 (84.2)
Methods					
Study design	4	Present key elements of study design early in the paper	181 (80.8)	116 (98.3)	297 (86.8)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	154 (68.8)	101 (85.6)	255 (75.6)
Participants	6	*(a) Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up			65 (55.1)
		Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	104 (46.4)	65 (55.1)	104 (46.4)
		(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed		32 (27.1)	32 (27.1)
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	183 (81.7)	104 (88.1)	287 (83.9)
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	195 (87.1)	91 (77.1)	286 (83.6)
Bias	9	Describe any efforts to address potential sources of bias	23 (10.3)	40 (33.9)	63 (18.4)
Study size	10	Explain how the study size was arrived at	69 (30.8)	8 (6.8)	77 (22.5)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	158 (70.5)	75 (63.6)	233 (68.1)
Statistical methods	12	*(a)* Describe all statistical methods, including those used to control for confounding	176 (78.6)	104 (88.1)	280 (81.9)
		(b) Describe any methods used to examine subgroups and interactions	124 (55.4)	69 (58.5)	193 (56.4)
		(c) Explain how missing data were addressed	33 (14.7)	53 (44.9)	86 (25.1)
		(d) Cohort study—If applicable, explain how loss to follow-up was addressed			48 (40.7)
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	31 (13.8)	48 (40.7)	31 (13.8)
		(e) Describe any sensitivity analyses	33 (14.7)	51 (43.2)	84 (24.6)
Results					
Participants	13*	*(a)* Report numbers of individuals at each stage of study—e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	182 (81.3)	105 (89.0)	287 (83.9)
		(b) Give reasons for non-participation at each stage	60 (26.8)	36 (30.5)	96 (28.1)
		(c) Consider use of a flow diagram	33 (14.7)	20 (16.9)	53 (15.5)
Descriptive data	14*	*(a)* Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders	214 (95.5)	103 (87.3)	317 (92.7)
		(b) Indicate number of participants with missing data for each variable of interest	60 (26.8)	49 (41.5)	109 (31.9)
		(c) Cohort study—Summarise follow-up time (e.g., average and total amount)		39 (33.1)	39 (33.1)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time		84 (71.2)	84 (71.2)
		Cross-sectional study—Report numbers of outcome events or summary measures	116 (51.8)		116 (51.8)
Main results	16	*(a)* Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included	84 (37.5)	41 (34.7)	125 (36.5)
		(b) Report category boundaries when continuous variables were categorized	126 (56.3)	51 (43.2)	177 (51.8)
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	11 (4.9)	3 (2.5)	14 (4.1)
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	119 (53.1)	46 (39.0)	165 (48.2)
Discussion					
Key results	18	Summarise key results with reference to study objectives	206 (92.0)	88 (74.6)	294 (86.0)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	175 (78.1)	89 (75.4)	264 (77.2)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	135 (60.3)	61 (51.7)	196 (57.3)
Generalisability	21	Discuss the generalisability (external validity) of the study results	118 (52.7)	68 (57.6)	186 (54.4)
Other information					
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	101 (45.1)	53 (44.9)	154 (45.0)

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

TABLE 2: Article names, journal names, study designs and design effect coefficients of articles which comment on design effect.

Article Name	Published Journal	Study Design	The size of design effect
Factors associated with dental fluorosis in school children in southern Brazil: a cross-sectional study	Brazilian oral research	Cross-sectional	2
Recreational screen-time among Chinese adolescents: a cross-sectional study	Journal of Epidemiology	Cross-sectional	3
Malnutrition, overweight, and obesity among urban and rural children in north of west Azerbaijan, Iran.	Journal of Obesity	Cross-sectional	1.5
Television time among Brazilian adolescents: correlated factors are different between boys and girls	*The Scientific World Journal*	Cross-sectional	2
Social capital and chronic post-traumatic stress disorder among survivors of the 2007 earthquake in Pisco, Peru	*Social science & medicine*	Cross-sectional	1.25
HIV screening among TB patients and co-trimoxazole preventive therapy for TB/HIV patients in Addis Ababa: facility based descriptive study	PloS one	Cross-sectional	Calculated using sample size (2*n+(10.0%)*n)

Broadly speaking, cross-sectional and cohort studies demonstrate similar behavior with respect to the compliance percentages to STROBE. The largest difference is in terms of indicating sample size calculation. That is, n=69 (30.8%) of cross-sectional studies indicate sample size calculation in contrast to n=8 (6.8%) of cohort studies. The best compliance above 90% is performed for items 1(b) ("*Provide in the abstract an informative and balanced summary of what was done and what was found*"), item 2 (*"Explain the scientific background and rationale for the investigation being reported"*) and item 14(a) (*"Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders"*). The worst fit (below 20%) is performed for items 12(d) (*"Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy"*), item 13(c) (*"Consider use of a flow diagram"*) and 16(c) (*"If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period"*).

The cross-sectional studies that reported design effect is n=6 (1.8%). Information pertaining to these n=6 articles are given in Table 2.

DISCUSSION

The underlying assumption of statistical approaches, observations being independent and identically distributed, are not appropriate for most sample surveys. When this is the case the calculated variances needs to be adjusted due to the effects of design (e.g. inflation due to clustering).[11] Therefore the drawn sample due to the variance-covariance structure is characterized by significant sampling bias.[12] In terms of the quality of the reporting of observational trials, current observational studies in MEDLINE could still benefit from increased reporting of methodologic details including the reporting design effect, sample size determinations, methods taking account of sampling strategy for cross-sectional studies, power analyses, consideration of potential bias and sensitivity analyses.

There are studies which reported design effect in the literature. Typical values of the design effect for a complex survey are from 1.5 to 3.5. Survey sampling practically results in an increase of design effect while stratification, if used intelligently, may decrease design effect.[8] In the simulation study of Salganik (2006), the estimation of the design effect requires comparing variance estimates of prevalence under different sampling methods. The design effect from the complex survey sampling can range from as high as 10 to less than 1. Generally, but not always, it is greater than 1, which point out estimates were less precise than estimates from simple random sampling.[13] To solve this problem, Rowe et al. advice that the calculated sample size must be multiplied by the size of the design effect.[14] In addition, Janjua (2006) stated that

there is a relationship between design effect and intraclass correlation coefficient (ICC). With the study of Janjua, it is possible to estimate design effect depending on ICC value. For ICC values less than 0.04, design effect is less than 2 and for values greater than 0.1, design effect is greater than 4; the greater the ICC the larger sample size. The smaller cluster size the smaller design effect and the smaller sample size.[15]

CONCLUSION

A database research performed on the survey studies that are free full text, written in English, including "cross sectional" and "cohort study" keywords in title or summary, published in MEDLINE shows that:

1. the compliance to ICMJE criteria is relatively low for methods section (items 4–12)

2. the reporting of design effect in observational studies is almost nil.

Although several journals encourages to follow STROBE, we have seen that the quality of the reporting of observational trials' guideline are not fully followed for observational studies. Whereas for some of them there seems to be a perception that asking supplementary information and thus can be discarded. For items under methods section (items 4–12) compliance is lower than other items.

According to the literature, in the observational studies which has complex sampling design, the power of the study and the sample size theoretically depends on the design effect.[3,9] Discarding design effect may cause less precise estimates and should also be seen as a source of bias. Therefore authors should declare the design effect and consider under items 4 or 9 or 10.

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: *Zeliha Nazan Alparslan;* ***Design:*** *Betül Dağoğlu Hark, Duygu Sıddıkoğlu, Zeliha Nazan Alparslan;* ***Control/Supervision:*** *Zeliha Nazan Alparslan;* ***Data Collection and/or Processing:*** *Betül Dağoğlu Hark, Duygu Sıddıkoğlu;* ***Analysis and/or Interpretation:*** *Betül Dağoğlu Hark, Duygu Sıddıkoğlu, Zeliha Nazan Alparslan;* ***Literature Review:*** *Betül Dağoğlu Hark;* ***Writing The Article:*** *Betül Dağoğlu Hark, Duygu Sıddıkoğlu, Zeliha Nazan Alparslan;* ***Critical Review:*** *Betül Dağoğlu Hark, Duygu Sıddıkoğlu, Zeliha Nazan Alparslan.*

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