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ΔΙΠΛΩΜΑΤΙΚΗ ΕΡΓΑΣΙΑ

Assessment of the quality of reporting of observational studies in headache published from 2001 to 2020 using the STROBE statement.

Αξιολόγηση της ποιότητας καταγραφής των δημοσιευμένων από το 2001 έως το 2020 μελετών παρατήρησης που αφορούν στην κεφαλαλγία με βάση τη δήλωση STROBE

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Contents

Abstract

Introduction: Chronic headache (CH) is a major cause of pain and disability. Observational studies have identified several prognostic factors for patients with CH. Evaluation of the quality of reporting of prospective studies regarding predictors of prognosis in CH is limited.

Objectives: To assess the quality of reporting of observational studies for predictors of prognosis in chronic headache published from 2001 to 2020 using the STROBE statement.

Methods: A literature search was conducted in MEDLINE (PubMed) and Cochrane Library, as well as a manual search of cited references in any observational cohort studies that were retrieved; their compatibility rate to the STROBE statement was estimated. Additionally, possible associations with the compliance rate of the abstracts to the STROBE statement and the journal impact factor (IF) were assessed.

Results: Ten eligible studies were identified. Mean adherence was 65.43% (sd=14.65, median=66.34%). According to non-parametric analysis, correlation between the quality of reporting of abstracts and articles was significant (Spearman's rho=0.629, p-value=0.051, Pearson's r=0.714, p-value=0.02<0.05). Correlation between STROBE adherence and journal ranking was insignificant (rho=-0.359, p-value=0.3>0.05, r=-0.364, p-value=0.183>0.05). Introduction and Discussion items were more adequately reported compared to methodological features and outcomes.

Conclusions: Adherence rates to the STROBE statement are moderate. Reporting of methods and results is comparatively insufficient.

Keywords: headache, chronic headache, predictors, prognosis, STROBE statement, cohort studies.

Περίληψη

Εισαγωγή: Η χρόνια κεφαλαλγία (ΧΚ) αποτελεί κύρια αιτία πόνου και ανικανότητας. Μελέτες παρατήρησης έχουν εντοπίσει διάφορους προγνωστικούς παράγοντες για ασθενείς με ΧΚ. Η αξιολόγηση της ποιότητας καταγραφής των προοπτικών μελετών αναφορικά με τους προγνωστικούς παράγοντες της ΧΚ είναι περιορισμένη.

Σκοπός: Να αξιολογηθεί η ποιότητα καταγραφής των μελετών παρατήρησης για τους παράγοντες πρόγνωσης της χρόνιας κεφαλαλγίας που δημοσιεύτηκαν από το 2001 έως το 2020, με τη χρήση της δήλωσης STROBE.

Μέθοδοι: Πραγματοποιήθηκε αναζήτηση στις βάσεις δεδομένων MEDLINE (PubMed), και Cochrane Library, καθώς επίσης, χειροκίνητη αναζήτηση στη βιβλιογραφία κάθε μελέτης παρατήρησης σειράς που ανακτήθηκε. Υπολογίστηκε το ποσοστό εναρμόνισης κάθε μελέτης με τη δήλωση STROBE. Επιπλέον εκτιμήθηκαν πιθανές συσχετίσεις με το ποσοστό συμμόρφωσης των περιλήψεων στην επέκταση της δήλωσης STROBE για τις περιλήψεις και τον συντελεστή βαρύτητας περιοδικού.

Αποτελέσματα: Εντοπίστηκαν δέκα μελέτες που πληρούσαν τις προϋποθέσεις. Η μέση εναρμόνιση υπολογίστηκε 65.43% (τυπική απόκλιση=14.65,διάμεσος=66.34%). Ο μη παραμετρικός έλεγχος ανέδειξε σημαντική συσχέτιση μεταξύ της ποιότητας καταγραφής περιλήψεων και άρθρων (Spearman's rho=0.629, p-value=0.051, Pearson’s r=0.714, p-value=0.02<0.05).Δεν αναδείχθηκε σημαντική συσχέτιση με τον συντελεστή βαρύτητας των περιοδικών(rho=-0.359, p-value=0.3>0.05, r=-0.364, p-value=0.183>0.05). Τα τμήματα της εισαγωγής και συζήτησης ήταν πιο επαρκώς καταγραμμένα σε σύγκριση με τη μεθοδολογία και την παρουσίαση των αποτελεσμάτων.

Συμπεράσματα: Το ποσοστό συμμόρφωσης στη δήλωση STROBE είναι μέτριο.Η καταγραφή των μεθόδων και των αποτελεσμάτων είναι συγκριτικά μη επαρκής.

Λέξεις κλειδιά: κεφαλαλγία, χρόνια κεφαλαλγία, προγνωστικοί παράγοντες, πρόγνωση, δήλωση STROBE, μελέτες σειράς.

Introduction

Observational studies, when appropriately designed, conducted, and reported provide valuable clinical and public health knowledge [1]. The majority of research papers published in clinical speciality journals present observational research [2,3]. The three main types of observational studies are cohort, case-control, and cross-sectional studies. In cohort studies, investigators follow people over time. They collect data about people and their baseline exposure, let time pass, and then assess the occurrence of outcomes [4].

The reporting of observational studies is often of insufficient quality. Poor reporting hampers the assessment of the strengths and weaknesses of a study and the generalizability of its results. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement was developed to improve the quality of reporting of observational studies [4,5].

The STROBE Statement consists of a checklist of 22 items, which relate to the title, abstract, introduction, methods, results and discussion sections of articles. Eighteen items are common to cohort studies, case-control studies, and cross-sectional studies and four are specific to each of the three study designs [4,5]. The STROBE Statement is being endorsed by a growing number of biomedical journals. Nevertheless, quality of reporting does not always align with methodological quality [4,5].

Chronic headache (CH)—headache occurring on 15 or more days per month for at least 3 months [6] - is a common medical complaint and cause of pain and disability in children and adults [7,8]. Chronic migraine has a population prevalence of around 1% - 4% [9, 10] and chronic tension-type headache of about 2, 2% [11]. Medication overuse headache affects about 1% of the population [12].

Several demographic, clinical, psychological, and social factors influence prognosis for patients with CH [13]. Predictors of prognosis are factors, measured at baseline, that affect outcome [14]. Identifying factors that predict poor prognosis would be beneficial for clinical providers and researchers alike, as it may contribute to the development of more efficient care models. A number of studies have been conducted on this topic. However, assessment of the reporting quality of those studies is insufficient.

The objective of this study was to evaluate the quality of reporting of observational studies for predictors of prognosis in chronic headache published from 2001 to 2020 using the STROBE statement.

Methods

A retrospective assessment of observational cohort studies on the subject of the predictors of prognosis in chronic headache published between January 1, 2001, and August 2020 was conducted.

Search Method

We searched for English-language publications reporting observational cohort studies that reported on predictors of prognosis in CH from peer-reviewed journals in Cochrane, MEDLINE/PubMed, supplemented by backward citation tracking, from January 1, 2001, to August, 2020.

The search strategy used the MeSH terms 'chronic headache' and 'prognosis' plus the terms 'headache', 'migraine', and 'predictors of prognosis' as title or abstract words combined with the Boolean Operators 'OR' and 'AND'. The references quoted by observational cohort studies as well as reviews were manually searched.

Eligibility Criteria

Observational cohort studies that measured factors at baseline and used a timeline to outcomes at follow-up to explore the associations between factors were included. Study participants were adults (18 years and over), children and adolescents, who suffered from chronic headache as defined by the International Classification of Headache Disorders1 with at least 15 headache days/ month for at least 3 months. We included chronic headache, chronic migraine, and chronic tension-type headache, with or without medication overuse headache. In studies that included episodic headache patients, prognostic factors had to be analyzed and reported separately for chronic headache.

Exclusion criteria included: (1) reports not published in English (2) unavailable full articles (3) cross-sectional, prevalence studies and case-control studies (4) pilot studies (5) conference abstracts (6) studies that included any other chronic pain conditions.

All titles and abstracts retrieved were systematically reviewed. Articles for possible inclusion were fully assessed.

Data Extraction

The 2007 revised STROBE statement for cohort studies comprises of 22 items, 2 of which are divided into 2 parts. Each of the 24 items was assessed equally by 1 point when adequately reported, 0 when either inadequately reported or absent and as not applicable according to certain features of the studies. Items reported more than once were assessed by 0 in case of inconsistency. Items comprising of 3 or more sections were subdivided and valued equally (1/ number of sections) so as to assess the study more accurately. Based on STROBE 2007 explanation and elaboration document we decided to subdivide item 13a into 5 sections. Items 6b (matching criteria), 7 (diagnostic criteria), 8 (comparability of assessment methods), 11 (description of the chosen grouping), 12d (how loss to follow-up was addressed), 12e (sensitivity analysis), 16a (confounder-adjusted estimates and their precision), 16b (category boundaries), 16c (translation of estimates of relative risk into absolute risk) were not assessed in case of non-applicability. The proportion of compatibility to the STROBE statement was determined without taking not applicable items into consideration. Consequently, each study was rated against a different number of items.

Table 1 | STROBE Statement—Checklist of items that should be included in reports of *cohort studies* (adaptation after the addition of subdivisions)

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***		
	Item No	**Recommendation**
Title and abstract	1a	Indicate the study's design with a commonly used term in the title or the abstract
	1b	Provide an informative and balanced summary of what was done and what was found in the abstract
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6a	Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up
	6b	For matched studies, give matching criteria and number of exposed and unexposed
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
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
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, explain how loss to follow-up was addressed
		(*e*) Describe any sensitivity analyses
Results		

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) Summarise follow-up time (e.g. average and total amount)
Outcome data	15*	Report numbers of outcome events or summary measures over time
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
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—e.g. analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
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
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
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
*Give information separately for exposed and unexposed groups.		

Item 1b (Structured summary) was assessed separately based on the STROBE for Abstracts extension, which comprises of 11 items. A 10-item version was deployed after the removal

of the contact details item (specific to conference abstracts). Reported items inconsistent with the full text were assessed by 0. Item 1b was assessed by 1 when ≥5 of the 10 items were satisfied.

Table 2 | —Items to be included when reporting observational studies in a conference abstract

	STROBE Statement—Items to be included when reporting observational studies in a conference abstract	
	Item	**Recommendation**
1	Title	Indicate the study's design with a commonly used term in the title (e.g. cohort, case control, cross sectional)
2	Authors*	Contact details for the corresponding author
3	Study design	Description of the study design (e.g. cohort, case-control, cross sectional)
4	Objective	Specific objectives or hypothesis
	Methods	
5	Setting	Description of setting, follow-up dates or dates at which the outcome events occurred or at which the outcomes were present, as well as any points or ranges on other time scales for the outcomes (e.g., prevalence at age 18, 1998-2007).
6	Participants	Cohort study—Give the most important eligibility criteria, and the most important sources and methods of selection of participants. Describe briefly the methods of follow-up
		Cohort study—For matched studies, give matching and number of exposed and unexposed
7	Variables	Clearly define primary outcome for this report.
8	Statistical methods	Describe statistical methods, including those used to control for confounding
	Results	
9	Participants	Report Number of participants at the beginning and end of the study
10	Main results	Report estimates of associations. If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period Report appropriate measures of variability and uncertainty (e.g., odds ratios with confidence intervals
11	Conclusions	General interpretation of study results

**this item is specific to conference abstracts*

Some additional information was researched and applied to our analysis. Specifically the following elements were collected: journal ranking for the publication year (according to the Journal IF published each summer by Clarivate Analytics (Thomson Reuters) via Journal Citation Reports), date of publication, STROBE endorsement by the corresponding journal, country of origin, sample size.

Objectives

The primary objective was to assess the proportion of adherence to the STROBE statement for each observational study. The mean and median adherence, the standard deviation (SD), the minimum and maximum adherence are calculated.

The secondary objectives of the study were to investigate the correlations between adherence to the STROBE statement and adherence to the STROBE extension for abstracts as well as Journal IF for the respective publication year. The proportion of observational studies reporting each STROBE-item was estimated.

Statistical Analysis

Statistical analyses were performed with Excel 2010 Software Version 14.0. The statistic measures of central tendency and dispersion were primarily calculated. The identification of correlations through calculation of the Spearman's rank correlation coefficient (Spearman's rho, non parametric) and graphical presentation on scatter plots supplemented the analysis. In case of normally distributed data (according to the Shapiro-Wilk test) the Pearson Correlation Coefficient (Pearson's r) was additionally determined.

Results

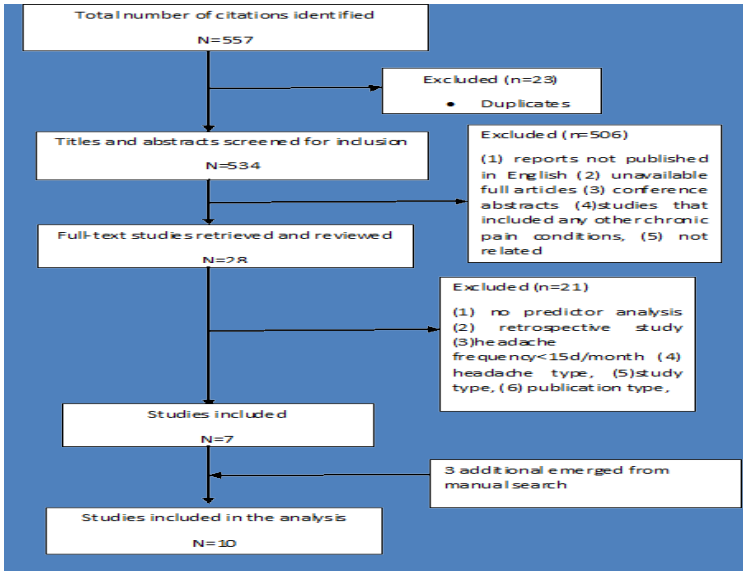
The literature research for the terms “chronic headache”, “migraine”, “prognosis”, using the filters for article type:” observational study” and “review”, and for publication date: “from 2001/1/1 to 2020/8/30” identified 557 studies. The manual search provided us with 3 additional studies. The eligible studies to be included in our analysis were 10 [15-24] (Fig. 1). The basic characteristics of those studies are presented in table 3.

Table 3 I Study characteristics

study	Publication year/journal	Journals IF*	STROBE endorsement**	country	Sample size	Predictors of prognosis	population
Lu	2001 Cephalalgia	3,502	yes	Taiwan	108	Age, onset, duration, medication overuse, “daily headache”	adults and adolescents
Zwart	2003 Neurology	5,678	yes	Norway	32.067	Overuse of analgesics	adults
Bigal	2006 Cephalalgia	6,046	yes	USA	176	BMI	adults
Boardman	2006 Cephalalgia	6,046	yes	UK	2.141	Sleep problems, caffeine consumption, anxiety, other pain	adults
Wang	2007 Neurology	6,014	yes	Taiwan	122	Gender, chronic migraine, medication overuse, major depression, anxiety disorders	adolescents
Buse	2012 Headache	3,042	yes	USA	7.169	sociodemographics; headache days per month; a composite migraine symptom severity score (MSS); an average pain severity rating during the most recent long-duration headache; depression; and anxiety	adults
Houle	2012 Pain	6,51	no	USA	55	Stress and sleep duration	adults
Lundqvist	2012 Pain	6,51	no	Norway	195	Severity of Dependence Scale (SDS) score used as predictor	adults
Louter	2013 Brain	9,915	yes	Netherlands	2.331	Cutaneous allodynia	adults
Orr	2019 Headache	3,749	yes	USA	13.160	age, sex, chronic migraine, status migrainosus, depressive symptoms, PedMIDAS scores, use of nutraceuticals, caffeine drinkers, headache frequencies, use of pharmaceuticals	children

*according to Journal IF published each summer by Clarivate Analytics (formerly Thomson Reuters) via Journal Citation Reports for the publication year
**according to the presently provided instructions to authors by each journal

Figure 1 | Flow chart of the literature search



STROBE Compliance

The main objective was to estimate the proportion of STROBE adherence for each study. The following results were obtained:

Zwart et al. (10.8/23, 47.17%), Wang et al (15.1/24, 62.9%), Orr et al (17.3/23, 75.2%), Houle et al (10.8/24,45%), Boardman et al (18.1/24, 75.4%), Lu et al (16.4/24, 68.3%), Bigal et al (12.5/24, 52.1%), Buse et al (21.4/23, 93%), Lundqvist et al (14.8/23, 64.3%), Louter et al (17/24, 70.8%).

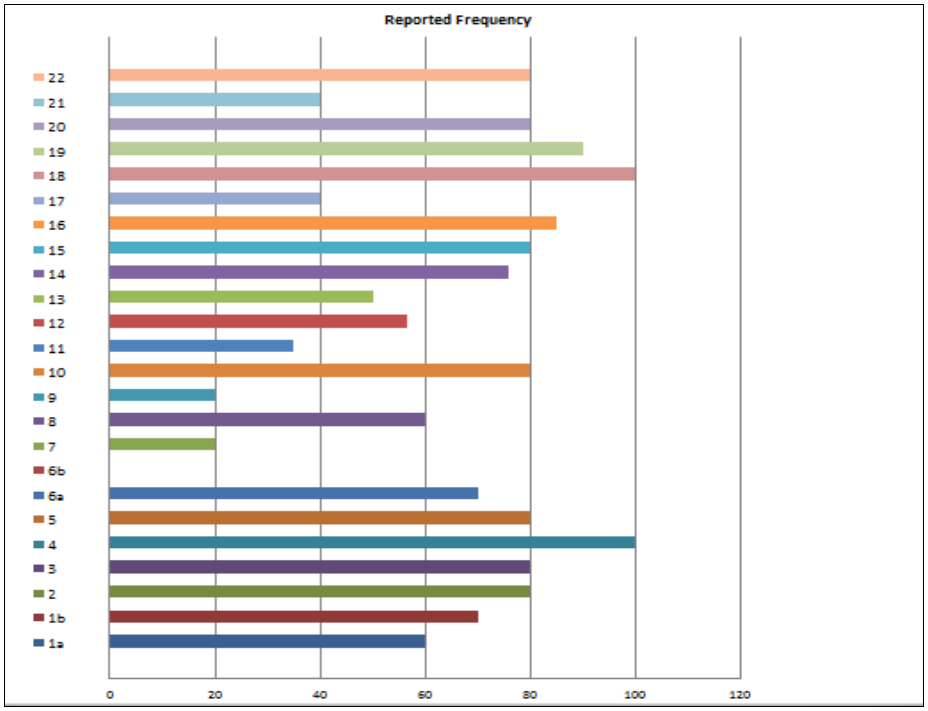
The mean STROBE adherence was calculated at 65.43% with sd=14.65. The median was 66.34% and the minimum and maximum adherence 45% and 93% respectively.

Adherence per STROBE item was evaluated (table 4). Item 6b was assessed as not applicable in 4 studies. Items 7 (variables), 9 (bias), 11 quantitative variables),17 (analyses of subgroups, interactions, sensitivity analyses) and 21 (generalizability) were underreported. Regarding items 12 (statistical methods),13 (participants),14 (descriptive data) and 16 (main results) proportions were estimated by excluding from the denominator the not applicable sub-items. The best compliance (100%) was noticed in items 4 (study design) and 18 (key results).

Table 4 I Adherence per STROBE item

item	Reported % frequency	Not applicable	item	Reported % frequency	Not applicable	item	Reported % frequency	Not applicable
1a	60	0	7	20	0	15	80	0
1b	70	0	8	60	0	16	85	0
2	80	0	9	20	0	17	40	0
3	80	0	10	80	0	18	100	0
4	100	0	11	35	0	19	90	0
5	80	0	12	56.5	0	20	80	0
6a	70	0	13	50	0	21	40	0
6b	0	4	14	76	0	22	80	0

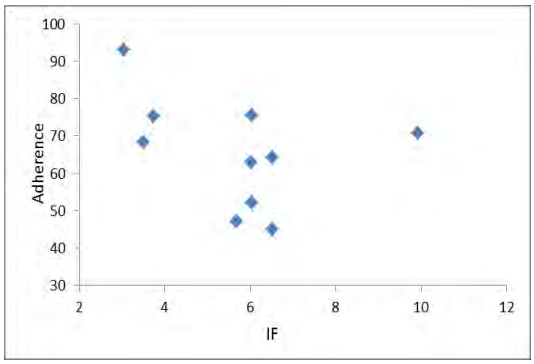
Figure 2 | Compliance per STROBE item



Journal Ranking

The Spearman's rho between STROBE and journals' IF was (-0.359, p-value=0.3>0.05), which is suggestive of a weak negative correlation, but is not statistically significant. We determined the Pearson's and the result was not statistically significant either (-0.364, p-value=0.183).

Figure 3 I Trends between STROBE adherence and journal ranking (IF)



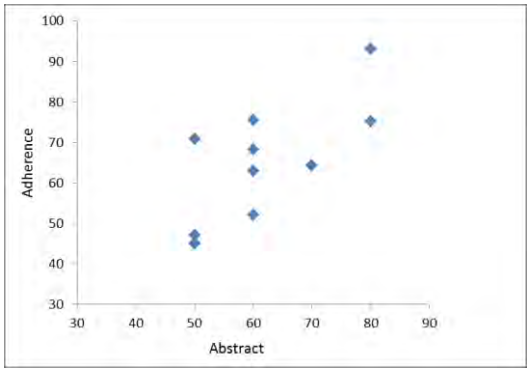
Reporting Quality of Abstracts

We evaluated the reporting quality of each abstract based on the STROBE for Abstracts extension. The following results were obtained: mean=60%, sd=11,35, median=60% min=50% and max=80%.

Zwart et al. (5/10, 50%), Wang et al (6/10, 60%), Orr et al (8/10, 80%), Houle et al (5/10, 50%), Boardman et al (6/10, 60%), Lu et al (6/10, 60%), Bigal et al (6/10, 60%), Buse et al (8/10, 80%), Lundqvist et al (7/10, 70%), Louter et al (5/10, 50%).

The Spearman's rho between STROBE adherence and adherence to the STROBE extension for abstracts was calculated (0.629, p-value=0.051). The result was indicative of a moderate positive correlation between abstract and article reporting quality and was marginally statistically significant. Pearson's r was also determined (0.714, p-value=0.02<0.05), a stronger positive correlation was identified, and the result was statistically significant.

Figure 4 I Trends between Article and Abstract STROBE adherence



Conclusions

The reporting quality of observational cohort studies on the predictors of prognosis in chronic headache according the STROBE statement was evaluated. All observational cohort studies published between 2001 and 2010 were included in our literature research. We identified 10 eligible studies, which were assessed for compliance to the 2007 STROBE statement. We estimated an overall reporting quality of 65.43%, which was classified as moderate. Only 3 studies had a proportion of adherence to the STROBE items above 70%. The STROBE items relating to methodology and its results were inadequately reported, whereas items concerning background and discussion were sufficiently presented.

Our secondary objectives included the investigation of the correlation between the adherence to the STROBE statement and adherence to STROBE extension for abstracts as well as journal ranking. An abstract should concisely report the aims and outcomes of a research so that readers know exactly what the paper is about. Moreover, a reader should decide whether or not to study a full article based on the abstract, due to limited time in combination with the numerous publications [25]. The main reason for investigating a possible relationship is to demonstrate whether the reporting quality of abstracts is indicative of the reporting quality of the observational studies, and not to infer the STROBE compliance of the abstracts. The correlation was estimated by parametric and non-parametric methods. Both tests identified a moderate to strong positive correlation which was statistically significant. According to the literature, the standardization of presentations and the reporting quality of conference abstracts [26] have been attempted through the

implementation of several criteria. To our knowledge, no previous study has examined the correlation between the STROBE compliance of both abstracts and full-texts.

We additionally attempted the estimation of the relationship between STROBE adherence and journal ranking. IF is considered a marker of journal quality and consequently, article quality [27]. The correlation was examined by parametric and non-parametric methods, both of which were indicative of weak correlation. The intrinsic weaknesses of the journal impact factor as a quality indicator [28, 29] have been established. One the shortcomings of the impact factor (IF), a ratio calculated by Thomson Reuters (formerly Thomson Scientific) for many journals each year, is that the numerator of the ratio includes all citations to pieces published in a journal during a 2-year period, whereas the denominator includes only the number of original research reports and other substantive papers published during the same period. Our study failed to confirm its association with good publication practice as found in previous studies [30, 31].

Poorolajal et al, [32] assessed the reporting quality of cohort studies published in six prestigious scientific medical journals that generally accept the well-done and well-written studies to explore to what extent the items in the (STROBE) checklist were addressed. An overall adherence of almost 69.3% of the items and sub-items in STROBE checklist was estimated. In our study, the mean STROBE adherence was calculated at 65.43%. The design and the division of the 22 items into sub-items, which were evaluated in that study, were not comparable with those of our study. However the results are similar.

Our results are consistent with other studies assessing deficiencies in reporting of individual STROBE items such sample size, use of flow diagram and reporting of missing data [33-35]. Langan et al[33] assessed the reporting quality of observational studies in dermatology and concluded that the key areas that were infrequently reported were sample size calculations, missing data , losses to follow-up , and statistical methods, whereas the reporting of participant details was sufficient in cohort studies. Muller et al [35] estimated the reporting of STROBE in sexual health and in their survey they indicated that the methods of follow-up, the number of participants completing follow-up and the approach chosen to address loss to follow-up were insufficiently addressed; nonetheless over 90% of reports included a clear description of the inclusion criteria.

To our knowledge, this is the first study to assess the reporting quality of observational studies on the prognostic factors in chronic headache. One of the strengths of the study is the division of certain STROBE items in sub-items in order to create a more accurate reporting tool. Most importantly, there is a balance between the studies published before and after the STROBE statement was issued. Possible limitations include the limited number of studies evaluated, which might increase random error and a poor internal validity as the selection and evaluation processes were performed by only one reviewer. The result of the present survey demonstrates the quality of the reporting of cohort studies, therefore it is not prudent to generalize this result to other forms of observational studies (case-control and cross-sectional).

This study concludes that reporting quality of observational cohort studies is moderate. Hence the need for improvement is highlighted. The STROBE statement recommendations

are not prescriptions for setting up or conducting studies, nor do they dictate methodology or mandate a uniform presentation. Nonetheless, they aim in optimizing planning of observational studies, and aspire to guide peer reviewers and editors in their evaluation of manuscripts.

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