

Introduction

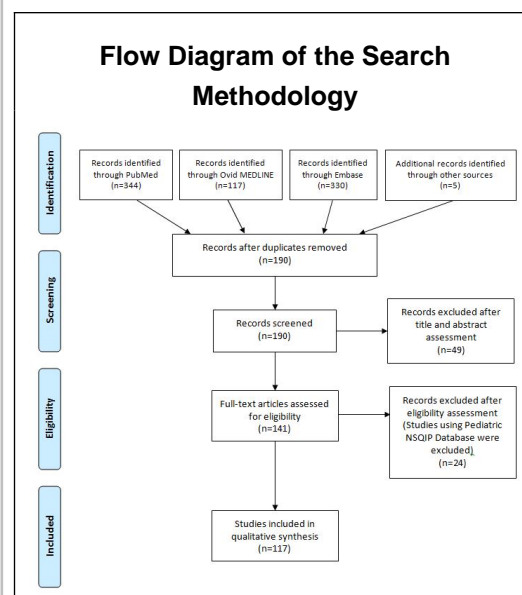
The use of big databases in neurosurgical research has become increasingly more common. However, authors must consider methodological approaches to improve the quality of reporting in these observational studies. Recent studies qualitatively evaluated and commented on the quality of studies utilizing databases and registries. Therefore, we aimed to conduct a qualitative analysis for the studies utilizing ACS-NSQIP, using the criteria recommended by STROBE and RECORD Statements.

Methods

We queried Ovid MEDLINE, EMBASE and PubMed databases for all neurosurgical studies utilizing the ACS-NSQIP. Methodological quality was assessed using The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Criteria, The REporting of studies Conducted using Observational Routinely-collected Health Data (RECORD) Statement and JAMA Checklist to Elevate the Science of Surgical Database Research. For adherence to each item, one point was assigned and total scores were calculated. We also compared the adherence to criteria among papers published in core and non-core journals in neurosurgery according to Bradford's Law.

Results

A total of 117 studies were included in the analysis. Median (IQR) scores for adherence to STROBE Statement, RECORD Statement and JAMA Checklist were 20 (19-21), 9 (8-9) and 6 (5-6), respectively. For STROBE Statement, RECORD Statement and JAMA Checklist; Item 9 (potential sources of bias), Item 13 (supplemental information) and Item 9 (missing data/sensitivity analysis) had the most number of non-adherence among all studies respectively. When comparing core journals vs. non-core journals, no significant difference was found between two groups (STROBE, $p=0.94$; RECORD, $p=0.24$; JAMA checklist, $p=0.60$), including a subgroup analysis done for Spinal Surgery (STROBE, $p=0.13$; RECORD, $p=0.86$; JAMA, $p=0.49$) and Neurosurgical Oncology (STROBE, $p=0.24$; RECORD, $p=0.28$; JAMA, $p=0.47$) subspecialties.



Baseline Study Characteristics

| Variable | NSQIP Papers (n=117) |
|---|--------------------------------|
| Year of Publication, n (%) | |
| 2012 | 1 (0.90) |
| 2013 | 1 (0.90) |
| 2014 | 10 (8.55) |
| 2015 | 18 (15.4) |
| 2016 | 39 (33.3) |
| 2017 | 30 (25.6) |
| 2018 | 1 (15.4) |
| Journals, n (%) | |
| Spine | 23 (19.7) |
| World Neurosurgery | 17 (14.5) |
| Journal of Neurosurgery | 15 (12.8) |
| The Spine Journal | 10 (8.55) |
| Journal of Clinical Neuroscience | 9 (7.69) |
| Neurosurgery | 7 (5.98) |
| Clinical Neurology and Neurosurgery | 5 (4.27) |
| Neurosurgical Focus | 5 (4.27) |
| Journal of Neurooncology | 4 (3.42) |
| Journal of Neurosurgery (Spine) | 3 (2.56) |
| Cancer | 2 (1.71) |
| Global Spine Journal | 2 (1.71) |
| Neurological Research | 2 (1.71) |
| Surgical Neurology International | 2 (1.71) |
| Acta Neurochirurgica | 1 (0.90) |
| American Journal of Surgery | 1 (0.90) |
| Clinical Orthopedics and Related Research | 1 (0.90) |
| Clinical Spine Surgery | 1 (0.90) |
| Journal of Neurosurgical Anesthesiology | 1 (0.90) |
| Journal of Otorhinolaryngology Head and Neck Surgery | 1 (0.90) |
| Journal of the American College of Surgeons | 1 (0.90) |
| Neurosurgical Review | 1 (0.90) |
| Otology & Neurology | 1 (0.90) |
| Seminars in Thrombosis and Hemostasis | 1 (0.90) |
| Microsurgery | 1 (0.90) |
| STROBE Score, out of 22, median (IQR) | 20 (19-21) |
| RECORD Score, out of 10, median (IQR) | 9 (8-9) |
| JAMA Score, out of 7, median (IQR) | 6 (5-6) |
| STROBE Criteria | Number of Nonadherences |
| Address source of bias, n (%) | 66 (56.4) |
| Discuss external validity, n (%) | 49 (41.9) |
| Statement of specific objectives, n (%) | 22 (18.8) |
| RECORD Statement | Number of Nonadherences |
| Include supplemental information, n (%) | 79 (67.5) |
| Discuss data cleaning methods, n (%) | 40 (34.2) |
| Provide validation of population selection, n (%) | 29 (24.8) |
| JAMA Checklist | Number of Nonadherences |
| Discuss missing data, n (%) | 59 (50.4) |
| Statement of compliance with IRB, n (%) | 46 (39.3) |
| Report inclusion, exclusion, and outcome variables, n (%) | 30 (25.6) |

Comparison of Core Journals with Non-core Journals

| Items | Non-adherence, No. of studies/ Total No. (%) | | p-value |
|---|--|-----------------------|--------------|
| | Core Journals in Neurosurgery (n=45) | Other Journals (n=72) | |
| STROBE Criteria (Out of 22) | | | |
| Statement of specific objectives, n (%) | 7 (15.6) | 15 (20.8) | 0.48 |
| Address sources of bias, n (%) | 27 (60.0) | 39 (54.2) | 0.54 |
| Discuss external validity, n (%) | 21 (46.7) | 28 (38.9) | 0.41 |
| RECORD Criteria (Out of 10) | | | |
| Provide validation of population selection, n (%) | 11 (24.4) | 18 (25.0) | 0.95 |
| Discuss data cleaning methods, n (%) | 16 (35.6) | 24 (33.3) | 0.81 |
| Include supplemental information, n (%) | 28 (62.2) | 51 (70.8) | 0.33 |
| JAMA Checklist (Out of 7) | | | |
| Statement of compliance with IRB, n (%) | 25 (55.6) | 21 (29.2) | 0.005 |
| Report inclusion, exclusion, and outcome variables, n (%) | 9 (20.0) | 21 (29.2) | 0.27 |
| Discuss missing data, n (%) | 21 (46.7) | 38 (52.8) | 0.52 |
| Total Criteria Scores | | | |
| STROBE Score, median (range) | 20 (19-21) | 20 (19-21) | 0.40 |
| RECORD Score, median (range) | 9 (8-9) | 8.5 (8-9) | 0.18 |
| JAMA Checklist, median (range) | 6 (5-7) | 6 (5-6) | 0.88 |

Conclusions

Increase in concerns about the utilization of national registries lead to critical analyses of these papers. In our review, it is found that, except for specific criteria according to STROBE and RECORD criteria, most of the studies show a good reporting quality overall. For further evaluation of utilization of national registries and databases, studies utilizing other databases should be assessed quantitatively as well.

Discussion

Improvements in the in big data research will clearly help us better understand and interpret the information provided to us through large databases and registries. This process should involve all parties involved in research, including the journals. Adherence to reporting guidelines needs to be included during article submission and assessed during the reviewing process. Secondly, adherence to reporting quality criteria for other databases, such as Quality Outcomes Database¹³⁴, The Nationwide Readmissions Database¹³⁵, The National Cancer Database¹³⁶ and The Surveillance, Epidemiology, and End Results Program¹³⁷ should be performed. This is especially a concern with administrative database where established research has shown that complications are not accurately captured and reported compared to registry data.¹³⁸ Even though well-defined and categorized, STROBE Statement, RECORD Statement and JAMA Checklist are not specific to neurosurgery. Therefore, specific guidelines for neurosurgery should be established. This is particularly applicable to our specialty given the relative lack of neurosurgical databases. As seen in our analysis, high proportion of studies utilizing ACS-NSQIP lacked statement of specific hypotheses. In many instances, these databases are mined in the absence of a priori hypothesis. Studies utilizing databases should have a specific hypothesis for a specific clinical question.