STROBE Statement—checklist of items that should be included in reports of observational studies

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|  | Item No. | Recommendation | Page  No. | Relevant text from manuscript |
| **Title and abstract** | 1 | (*a*) Indicate the study’s design with a commonly used term in the title or the abstract | 1 | a case control study |
| (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 1-2 | **METHODS**  Using convenient sampling method, we enrolled 150 young and middle-aged patients with cancer who were admitted to the ICU of our center during the period from July to December 2020. The general data of the patients and PTSD-related indicators were collected. The Impact of Event Scale—Revised (IES-R) was used for assessing PTSD one month after the discharge from the ICU. Binary Logistic regression analysis was performed to assess the independent risk factors for PTSD in these patients.  **RESULTS**  Among these 150 patients, 32 (21.33%) were found to be with PTSD. Binary Logistic regression analysis revealed that factors significantly associated with PTSD among young and middle-aged patients with cancer in ICU included monthly income (OR=0.24, P=0.02), planned transfers (OR=0.208, P=0.019), and Acute Physiology and Chronic Health Evaluation (APACHE II) score (OR=1.171, P=0.003). |
| Introduction | | | |  |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 2-3 | Malignant tumors have become major causes of harm to the health the Chinese residents. In 2015, there were approximately 3.93 million new cancer cases across China, with a significant increase in the incidence rate among individuals aged > 40 years, and with a highest number of cases in those aged 60-64. The diagnosis of a malignant tumor and the accompanying physical and psychological symptoms bring both physical and mental pain to the patients, which may ultimately result in post-traumatic stress disorder (PTSD). PTSD is a long-lasting psychiatric disorder that occurs or is delayed after an individual experiences or witnesses an unusually catastrophic or threatening event. Several studies have shown that tumors have been identified as a source of traumatic stress, and the prevalence of cancer-related PTSD is estimated to range from 7.3% to 15.3%. As young and middle-aged people play crucial roles in families and society, once diagnosed with cancer, they often have to face stress from a variety of aspects including illness, family, work place, and financial burden. Research indicates that young and middle-aged cancer patients suffer more serious emotional pain and often bear greater psychological burden, which leads to increased medical costs and, even worse, risk of suicide. Evidence has shown that cancer patients in intensive care unit (ICU) have more serious mental problems such as anxiety, fear, and loneliness, and the prevalence of PTSD among survivors within the first 6 months after discharge was 25%. Unfortunately, few literatures in China have described PTSD in young and middle-aged patients who have experienced both malignancy development and ICU admission. Here we investigated the occurrence of PTSD and its relevant risk factors in young and middle-aged cancer patients in the ICU, in an attempt to provide new evidence for the development of effective prevention and treatment strategies. |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 3 | Here we investigated the occurrence of PTSD and its relevant risk factors in young and middle-aged cancer patients in the ICU, in an attempt to provide new evidence for the development of effective prevention and treatment strategies. |
| Methods | | | |  |
| Study design | 4 | Present key elements of study design early in the paper | 3 | A case-control study was conducted from September 2020 to December 2020, at the Department of Intensive Care Unit of Tianjin Medical University Cancer Institute and Hospital. |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 3 | A case-control study was conducted from July 2020 to December 2020, at the Department of Intensive Care Unit of Tianjin Medical University Cancer Institute and Hospital. Using convenient sampling method, we enrolled young and middle-aged patients with cancer who were admitted to the ICU of our center. |
| Participants | 6 | (*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up  *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls  *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants | 3-4 | Using convenient sampling method, we enrolled young and middle-aged patients with cancer who were admitted to the ICU of our center during the period from July to December 2020. The inclusion criteria included: a) aged 18 - 65 years; b) with a diagnosis of cancer confirmed by clinical, imaging, and pathological examinations; c) with the ability to communicate; and d) signed informed consent documents and participated in the study voluntarily. The exclusion criteria were: a) patients with severe mental illness or cognitive impairment; b) those with drop-out, withdrawal, or loss to the follow-up; and c) recent sufferings from other major life events or traumatic events. |
| (*b*)*Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed  *Case-control study*—For matched studies, give matching criteria and the number of controls per case | —— | None |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 4-5 | **General information questionnaire**  This self-designed questionnaire covers data including patients' age, gender, marital status, education level, disease diagnosed, disease treatments, and psychosocial factors.  **Impact of Event Scale—Revised**  The Impact of Event Scale—Revised (IES-R) was developed by Weiss and Marmar in 1997 based on the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, 4th edition) criteria and the Horowitz's Impact of Event Scale (IES). It is mostly used to assess the symptoms and severity of PTSD in survivors after critical care. The Chinese version of the IES-R was revised by Guo et al., and has a Cronbach's α coefficient of 0.89. This 22-item scale is divided into three dimensions including intrusion, avoidance, and hyperarousal. For each item, participants respond on a 5-point Likert scale ranging from point 0 “Never” to point 4 “Always”, and a higher score indicates more severe PTSD symptoms. It has a cut-off score of 33: a total score of ≥ 33 denotes positive PTSD symptoms, whereas a total score of <33 indicates negative PTSD symptoms. |
| 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 | 4-5 | Researchers collected general information about patients from the Hospital Information System. The Impact of Event Scale—Revised (IES-R) was developed by Weiss and Marmar in 1997 based on the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, 4th edition) criteria and the Horowitz's Impact of Event Scale (IES). It is mostly used to assess the symptoms and severity of PTSD in survivors after critical care. It has a cut-off score of 33: a total score of ≥ 33 denotes positive PTSD symptoms, whereas a total score of <33 indicates negative PTSD symptoms. |
| Bias | 9 | Describe any efforts to address potential sources of bias | 3-5 | We excluded those who had suffered a recent major life event or traumatic event. All the investigators had passed China’s national counselor level-3 examination and had certain clinical experience and good communication skills. Researchers collected general information about patients from the Hospital Information System and established good patient-consultant relationships during the patient's stay in the ICU. The surveys were conducted after informing the patients of the purpose and values of this survey and obtaining their content. Double data entry was applied to ensure the quality of the responses. |
| Study size | 10 | Explain how the study size was arrived at | 4 | Kendall’s statistic was applied for sample size estimation in this observational study. The sample size was set to be 5 - 10 times greater than the number of variables. Since patients might fail to respond to the survey or get lost during follow-up, an additional 20% of the sample size was added. Thus, the final sample size of this study was determined to be 167 cases. |

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| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 4-5 | It has a cut-off score of 33: a total score of ≥ 33 denotes positive PTSD symptoms, whereas a total score of <33 indicates negative PTSD symptoms. |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | 5 | All the statistical analyses were performed using the SPSS 19.0 software package (IBM Corporation, Somers, NY, USA). All tests were two-sided, and a P value of < 0.05 was considered statistically significant. The measurement data are expressed as mean ± standard deviation (±SD) or medians/quartiles. The independent t test for two samples was used for the comparisons of normally distributed measurement data, and the rank sum test was used for non-normally distributed ones. Count data are described by frequency and rate, and intergroup comparisons were performed by chi-square test or Fisher's exact test. Risk factors for PTSD in young and middle-aged cancer patients in the ICU were firstly screened using univariate analysis, and then the significant variables were included in a binary Logistic regression model for further analysis. The forest plots were created using GraphPad Prism 8.0 software (GraphPad Software Inc., San Diego, CA, USA). |
| (*b*) Describe any methods used to examine subgroups and interactions | —— | None |
| (*c*) Explain how missing data were addressed | —— | None |
| (*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed  *Case-control study*—If applicable, explain how matching of cases and controls was addressed  *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy | —— | Not applicable |
| (*e*) Describe any sensitivity analyses | —— | None |
| 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 | 6 | A total of 169 patients were included in this study, among whom 150 patients entered the final analysis. |
| (b) Give reasons for non-participation at each stage | 6 | Nineteen patients were ruled out due to the following reasons: loss to telephone follow-up (n=6); died after discharge (n=6); lost after transfer to other hospitals (n=4); and withdrew voluntarily during the study period (n=3). |
| (c) Consider use of a flow diagram | —— | None |
| Descriptive data | 14\* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 6-7 | See Table1. |
| (b) Indicate number of participants with missing data for each variable of interest | —— | None |
| (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) | —— | Not applicable |
| Outcome data | 15\* | *Cohort study*—Report numbers of outcome events or summary measures over time | —— | Not applicable |
| *Case-control study—*Report numbers in each exposure category, or summary measures of exposure | 6-7 | See Table1. |
| *Cross-sectional study—*Report numbers of outcome events or summary measures | —— | Not applicable |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 8-9 | With the occurrence of PTSD as the dependent variable, the factors that were statistically significant in the univariate analysis were assigned as independent variables. An unconditional binary multivariate Logistic regression analysis was performed, as shown in Table 2. |
| (*b*) Report category boundaries when continuous variables were categorized | —— | None |
| (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | —— | None |

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| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | —— | None |
| Discussion | | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 8-9 | Results of regression analysis  Binary Logistic regression analysis showed that monthly income, APACHEII score, and planned transfers were risk factors for PTSD in young and middle-aged cancer patients in the ICU. |
| 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 | 11 | There are some limitations in this study. First, as asingle-center study, its findings may not represent the clinical characteristics of the cancer patients in ICUs at hospitals of different levels in different regions. Second, long-term follow-up was not carried out due to the limited study period, and some risk factors were not analyzed. Third, limited by the budget, we followed up our patients only via telephone, and no customized clinical interviews on PTSD diagnosis by clinical professionals were arranged. In future, we will further screen PTSD patients by this method in multi-center large-sample studies. |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 12 | It was found in our study that low monthly income, unplanned transfers, and increased APACHE II score were the risk factors for PTSD in young and middle-aged cancer patients in the ICU. Early identification and effective preventive interventions may help to reduce the occurrence of PTSD and improve the quality of life in this population. |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 11 | As a single-center study, its findings may not represent the clinical characteristics of the cancer patients in ICUs at hospitals of different levels in different regions. |
| 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 | —— | None |

\*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.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.