Original Research

Submissions categorized as Original Research describe substantive, well-controlled research projects. They are to be organized as follows:

Abstract: Structured abstract (400 words or less), as directed by the CONSORT extension for abstracts followed by 4 to 6 carefully chosen keywords for indexing.

The abstract should be formatted as follows:

**Purpose:** Briefly provides the frame of reference for the reader and identifies the knowledge gap that the article seeks to address; clearly states the purpose of the research; and identifies the scientific hypotheses and questions being asked.

**Methods:** Succinctly outlines study methodology, including detailed study design, exclusion and inclusion criteria, statistical approaches, and adverse event assessment methodology.

**Findings:** Includes study demographics, adverse events, principle data and outcomes, and statistical analyses.

**Implications:** Covers any limitations or problems in interpretation or generalization from the study findings as well as implications and future directions; must be strictly limited to what can be supported directly by the Findings, and what was identified in the Purpose section.

**Study registry identification number should be included immediately following the Conclusions section of the abstract.**

Body of Manuscript

Introduction: State the objectives of the work and provide an adequate background; avoid a detailed literature survey or a summary of the results.

Patients and methods: Provide sufficient detail to allow the work to be replicated by others. Methods already published should be indicated by a reference: only relevant modifications should be described. For work involving human subjects, inclusion/exclusion criteria, study design, and randomization procedures should be included here, as well as clear indication of IRB-approval or waiver, and details of patient consent (or assent of youth and children). Appropriate statistical analyses should be described in detail and cited, with a priori significance thresholds clearly indicated.

Results: Results should be clear and concise. The study population should be described here, including demographic characteristics of subjects. All numeric data should be reported with descriptive and/or inferential statistical test results (including exact p-values if available).

Discussion: This should explore the significance of the results of the work, not repeat them. Authors should also address any limitations of the study design or statistically indeterminate results here. A
combined Results and Discussion section is often appropriate. Avoid extensive citations and discussion of published literature.

Conclusions The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion section. Conclusions should be strictly limited to what can be supported directly by the Results, and what was sought in the Objective.

Acknowledgements

Conflict of Interest statement

Appendices If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc. Please note that there are no text or graphic limits imposed on original research manuscripts.

Units: Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

Essential Title Page Information

• Title. The title should be concise but descriptive, include the study design and population studied, and avoid reporting results or conclusions. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.

• Author names and affiliations. Where the family name may be ambiguous (e.g., a double name), please indicate this clearly. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name, and, if available, the e-mail address of each author.

• Corresponding author. Clearly indicate who will handle correspondence at all stages of refereeing and publication, as well as post-publication. Ensure that telephone and fax numbers (with country and area code) are provided in addition to the e-mail address and the complete postal address. Contact details must be kept up to date by the corresponding author.

• Present/permanent address. If an author has moved since the work described in the article was done, or was visiting at the time, a "Present address" (or "Permanent address") may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main affiliation address. Superscript Arabic numerals are used for such footnotes.