Supplementary Table 1. Modified Newcastle-Ottawa Scale for single-arm cohort studies

|  |  |  |  |
| --- | --- | --- | --- |
| **Study** | **Selection** | **Outcome** |  |
| **Representative of the exposed cohort** | **Ascertainment of exposure** | **Demonstration that the current outcome of interest was not present at start of study** | **Assessment of Outcome** | **Was follow-up long enough for outcomes to occur** | **Adequacy of follow up of cohorts** | **Quality Score (/6)** |
| Bestourous 2020 | 1 | 1 | 1 | 1 | 1 | 1 | 6 |
| Pomerantz 2018 | 0 | 1 | 1 | 1 | 1 | 1 | 5 |
| Steffen 2018 | 1 | 1 | 1 | 1 | 1 | 1 | 6 |
| Suurna 2021 | 1 | 1 | 1 | 1 | 1 | 1 | 6 |
| Woodson 2016 | 1 | 1 | 1 | 1 | 1 | 1 | 6 |

Supplementary Table 2. Quality Assessment Tool for Before-After (Pre-Post) Studies with No Control Group

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study | D1 | D2 | D3 | D4 | D5 | D6 | D7 | D8 | D9 | D10 | D11 | D12 | Quality Rating |
| Kezirian 2014 | Yes | Yes | Yes | Cannot determine | No | Yes | Yes | No | Yes | Yes | Yes | Not applicable | Fair |

D1: Was the study question or objective clearly stated?
D2: Were eligibility / selection criteria for the study population prespecified and clearly described?

D3: Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?

D4: Were all eligible participants that met the prespecified entry criteria enrolled?

D5: Was the sample size sufficiently large to provide confidence in the findings?

D6: Was the test/service/intervention clearly described and delivered consistently across the study population?

D7: Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?

D8: Were the people assessing the outcomes blinded to the participants' exposures/interventions?

D9: Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?

D10: Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?

D11: Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?

D12: If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.) did the statistical analysis take into account the use of individual-level data to determine effects at the group level?

Supplementary Table 3. Joanna Briggs Institute Checklist for case series

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | D1 | D2 | D3 | D4 | D5 | D6 | D7 | D8 | D9 | D10 | **Total Score (/10)** |
| Arens 2021 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 1 | 0 | 1 | 7 |
| Patel 2022 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 3 |
| Taylor 2023 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 8 |
| Urban 2023 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 4 |
| Vasconcellos 2019 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 8 |

D1: Were there clear criteria for inclusion in the case series?

D2: Was the condition measured in a standard, reliable way for all participants included in the case series?

D3: Were valid methods used for identification of the condition for all participants included in the case series?

D4: Did the case series have consecutive inclusion of participants?

D5: Did the case series have complete inclusion of participants?

D6: Was there clear reporting of the demographics of the participants in the study?

D7: Was there clear reporting of the clinical information of the participants?

D8: Were the outcomes or follow-up results of cases clearly reported?

D9: Was there clear reporting of the presenting sites'/clinics' demographic information?

D10: Was statistical analysis appropriate?

Supplementary Table 4. Joanna Briggs Institute Checklist for case reports

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **D1** | **D2** | **D3** | **D4** | **D5** | **D6** | **D7** | **D8** | **Total Score (/8)** |
| Deep 2019 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 6 |
| Macielak 2021 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 1 | 4 |
| Tabatabai 2018 | 0 | 0 | 1 | 1 | 1 | 1 | - | 1 | 5 |

D1: Were the patient's demographic characteristics clearly described?

D2: Was the patient's history clearly described and presented as a timeline?

D3: Was the current clinical condition of the patient on presentation clearly described?

D4: Were diagnostic tests or assessment methods and the results clearly described?

D5: Was the intervention(s) or treatment procedure(s) clearly described?

D6: Was the post-intervention clinical condition clearly described?

D7: Were adverse events (harms) or unanticipated events identified and described?

D8: Does the case report provide take away lessons?

Supplementary Table 5. Percentage of patients that underwent explantation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study | Study type | Total patients in study | Total patients that underwent explantation / revision / replacement | Percentage of patients that underwent explantation / revision / replacement, % |
| Kezirian 20148 | Single-arm controlled trial | 31 | 6 | 19.4 |
| Pomerantz 201810 | Retrospective cohort abstract | 10 | 2 | 20 |
| Steffen 201811 | Prospective cohort | 60 | 1 | 1.7 |
| Suurna 202112 | Prospective cohort | 823 | 1 | 0.1 |
| Woodson 201617 | Prospective cohort | 116 | 3 | 2.6 |