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## Different cerclage for cervical insufficiency: more of the same? A systematic review on perinatal outcomes of pre-conception laparoscopic transabdominal and elective transvaginal cervical cerclage

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### ABSTRACT

**Background.** Cervical cerclage (CC) prevents preterm birth and mid-trimester loss (MTL) in women with cervical insufficiency. While transvaginal cerclage (TVC) is commonly used, laparoscopic abdominal cerclage (LAC) is an alternative for those with anatomical limitations. This systematic review compares pregnancy outcomes between elective TVC and pre-conceptual LAC.

**Materials and Methods.** Following PRISMA guidelines, we conducted a systematic search in PubMed, EMBASE, Scopus, Cochrane Library, and Science Direct in June 2024 using the terms “Elective Cervical cerclage” and “Laparoscopic cerclage”. Studies were included if they involved elective TVC or LAC and reported at least one outcome of interest: delivery < 34 weeks gestation, MTL, infection, or neonatal survival. Non-original and non-English studies were excluded.

**Results.** 13 studies involving 1,259 patients (601 TVC, 658 LAC) were analysed. Delivery ≥ 34 weeks occurred in 71.3-87% of TVC and 71.4-100% of LAC cases. MTL was significantly higher with TVC (6.4% vs 3.4%; p = 0.0055). No significant differences were observed in preterm delivery < 34 weeks (9.7% vs 11.1%; p = 0.053) or complication rates (2.8% vs 1.9%; p = 0.337).

**Conclusions.** While TVC has traditionally been preferred, recent evidence suggests that pre-conceptual LAC may be more effective for women with a history of cervical insufficiency. Further research is necessary to confirm these findings and assess the efficacy of LAC in other high-risk populations.

### INTRODUCTION

Cervical cerclage (CC) represents a successful option available for the management of women at risk for

spontaneous preterm delivery and mid-trimester loss (MTL) caused by cervical insufficiency (CI) [1]. In the first trimester, transvaginal cerclage (TVC) may be performed as a preventive measure (electi-

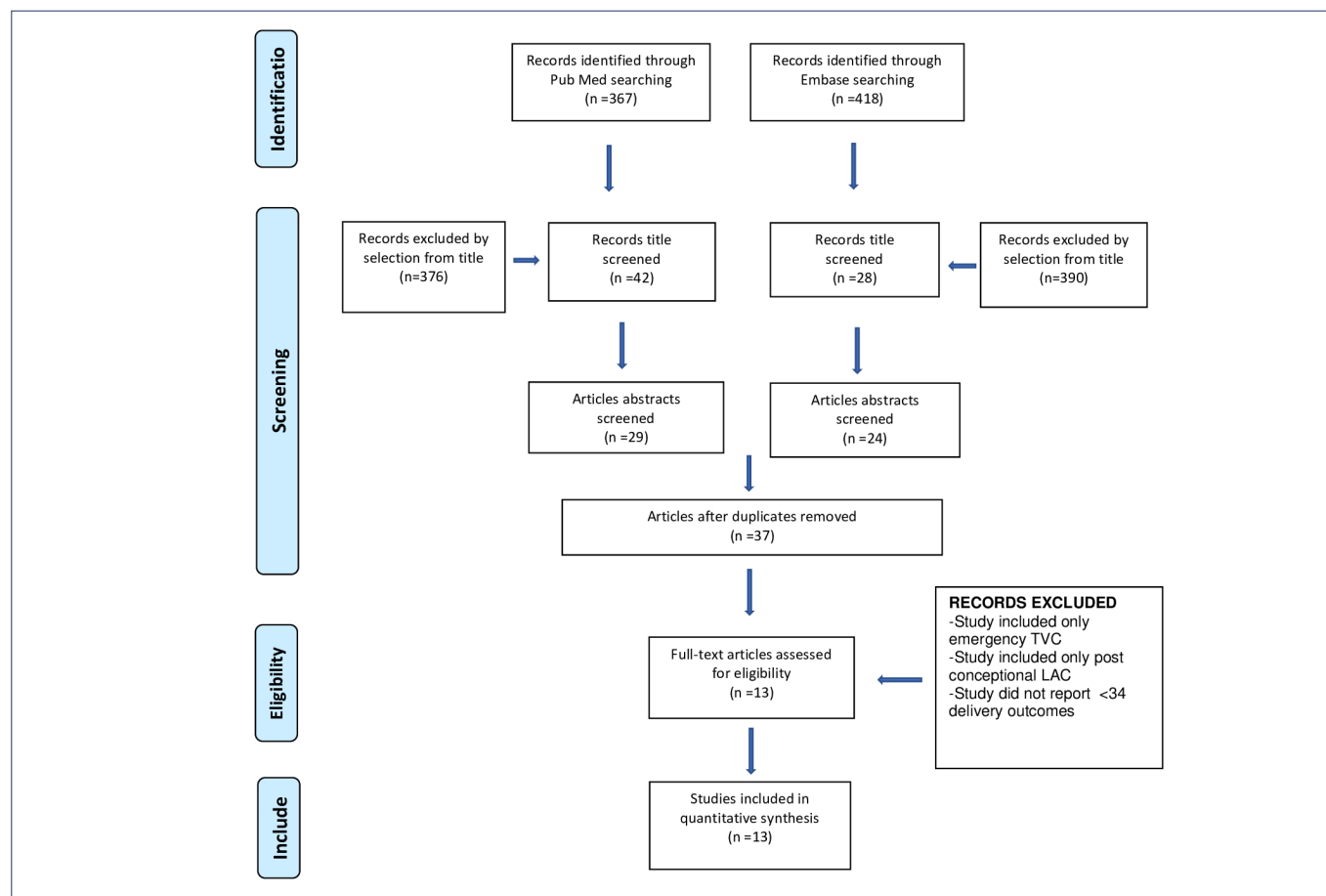


Figure 1. PRISMA flow diagram.

ve) if clinical history indicates a risk of mid-trimester loss or low cervical resistance, such as CI or a history of cervical cerclage placement in a previous pregnancy. This procedure may also be required for a short cervix (25mm) or cervical shortening found on ultrasound. There is also a possibility of placing an emergency cervical suture in women who already have a dilated cervix with membranes bulging without any signs of labour, infection, or heavy bleeding [2].

An alternative strategy could be represented by transabdominal cerclage. It is considered for women who had cervical insufficiency or anatomy that excluded a transvaginal cerclage [3]. Compared to the vaginal approach, the abdominal approach is considered to provide greater mechanical support to the cervix by placing the suture at or slightly above the internal ostium. In order to minimize surgical discomfort, a laparoscopic procedure can be performed [4].

Our systematic review aimed to compare the pregnancy outcomes between elective TVC and preconceptional laparoscopic abdominal cerclage (LAC) in patients with cervical insufficiency.

## MATERIALS AND METHODS

The methods for this study were specified a priori based on the recommendations in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [5]. The present work has been categorized on the PROSPERO International Prospective Register of Systematic Reviews as ID CRD42024558592.

### Search method

In June 2024, we performed a systematic search for articles in PubMed Database, Embase, Cochrane Library, Science Direct, and Scopus Database, adopting the string “Elective Cervical cerclage” and “Laparoscopic cerclage”. We provided no restriction on the country and year of publication and considered English-published articles (Figure 1).

### Study selection

Study selection was made independently by E.B. and M.C.S. In case of discrepancy, C.R. decided on inclusion or exclusion. Inclusion criteria were: 1) studies that included patients undergoing elective

TVC or LAC; 2) articles reporting at least one outcome of interest: delivery < 34 weeks of gestation, mid-trimester loss, number of infections and chorioamnionitis and neonatal survival rate; 3) peer-reviewed articles published originally. We excluded non-original studies, preclinical trials, animal trials, abstract-only publications, and articles in languages other than English.

An email request was sent to the authors of studies that were only available as abstracts in order to obtain data from them.

We mentioned the studies selected and all reasons for exclusion in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart (**Figure 1**). We assessed all included studies regarding potential conflicts of interest.

### Data extraction

G.C. and M.C.D.D. extracted data for all relevant series and case reports. They extracted data on the number of pregnancies achieved, the number of deliveries beyond 34 weeks of gestation, the number of deliveries before 34 weeks of gestation, mid-trimester loss (MTL), the number of infections and chorioamnionitis, and the neonatal survival rate.

The number of pregnancies was defined as an absolute number. The number of deliveries beyond 34 weeks' gestation and before 34 weeks' gestation was defined as the ratio of live-birth deliveries to the total number of pregnant patients. The MTL rate was defined as the ratio of patients who underwent pregnancy loss between 12 and 24 weeks' gestation. The infections and chorioamnionitis rate was defined as the infections and chorioamnionitis ratio of the total number of pregnancies. The neonatal survival rate was the ratio to the total number of pregnancies.

However, the lack of information and different criteria for each paper hindered this activity.

### Heterogeneity

Although our analysis applied standard methods for pooling results, potential heterogeneity across studies must be acknowledged. Differences in clinical inclusion criteria (*e.g.*, patient age ranges, disease severity, or comorbidity profiles), variations in treatment protocols, and inconsistent definitions or measurements of outcomes may have introduced heterogeneity. Furthermore, the duration of follow-up and the setting (single *vs* multicentre studies) could also contribute to between-study variability.

### Quality assessment

We assessed the included studies' quality using the Newcastle–Ottawa scale (NOS) [6]. This assessment scale uses three broad factors (selection, comparability, and exposure), with the scores ranging from 0 (lowest quality) to 8 (best quality). Two authors (V.C. and C.S.) independently rated the study's quality. Any disagreement was subsequently resolved by discussion or consultation with C.R. Discrepancies were resolved through discussion and consensus among the three reviewers. If consensus could not be reached initially, the decision of the third reviewer was considered final. We reported the NOS Scale in **Appendix A**.

### Statistic consideration

The nominal variables were expressed as absolute frequency and percentages and compared using Fisher's exact and Chi-square tests, according to their distribution. Continuous variables were expressed as median. No comparison between continuous variables was planned.

Patients were divided according to technique into TVC and LAC.

The null hypothesis of our study was that there was no difference in the prevalence of the MLT between patients who underwent TVC or LAC ( $H_0: p_1 = p_2$ ;  $H_1: p_1 - p_2 \neq 0$  two-sides). Secondary outcomes were the same evaluation for births before 34 gw and any complication related to the technique. All statistical investigations were performed using R software and R Studio vers. 2023.12.1 + 402.

### Declaration of generative AI

Grammar correction tools (Grammarly, Inc.) were used to improve the quality of English and readability. The technology was used under human oversight and control.

## RESULTS

### Studies characteristics

After the database search, 785 articles matched the search criteria. After removing records with no full text, duplicates, and wrong study designs (*e.g.*, reviews), 37 were eligible. Of those, 13 matched the inclusion criteria and were included in the systematic review. Those data are summarized in **Table 1**. An analysis of 5 retrospective articles examined elective TVC placed in the first trimester ba-

Table 1. Characteristics of included studies.

| Authors, year of publication | Country     | Study design                                | Period of enrolment | No. of participants | Cervical insufficiency treatment (LAC/elective TVC) | Inclusion criteria   |
|------------------------------|-------------|---|---------------------|---------------------|---|--|
| To M.S. 2002                 | UK          | Retrospective monocentric study             | 1995-2000           | 41                  | TVC   | Singleton pregnancies who had at least one previous spontaneous delivery at 16-33 weeks of gestation   |
| Liddell H.S. 2008            | New Zealand | Retrospective monocentric study             | 1998-2003           | 11                  | LAC   | Cervical incompetence and/or a short or absent cervix after cervical surgery MTL, cervical surgery   |
| Burger N. B. 2012            | Netherlands | Retrospective multicentre cohort study      | 1997-2011           | 56                  | LAC   | Cervical surgery; previous failed TVC  |
| Riiskjaer M. 2012            | Denmark     | Prospective observational monocentric study | 2004-2011           | 52                  | LAC   | Cervical incompetence and/or a short or absent cervix after cervical surgery. PPROM. Preterm delivery or contractions.   |
| Gluck O. 2016                | Israel      | Retrospective monocentric cohort study      | 2006-2014           | 154                 | TVC   | MTL, preterm loss, cervical incompetence and/or a short or absent cervix after cervical surgery  |
| Huang X. 2016                | China       | Prospective observational monocentric study | 2010-2015           | 100                 | LAC   | Prior midtrimester loss; failed TVC  |
| Ades A. 2018                 | Australia   | Prospective observational study             | 2007-2017           | 225                 | LAC   | diagnosis of cervical insufficiency based on previous obstetric history and/ or a short or absent cervix   |
| Wei 2018                     | China       | Retrospective monocentric study             | 2009-2015           | 276                 | TVC   | MTL, cervical surgery  |
| Saridogan E. 2019            | England     | Prospective observational monocentric study | 2004-2017           | 54                  | LAC   | Cervical surgery; previous failed TVC  |
| Yüksel Şimşek S. 2020        | Turkey      | Retrospective monocentric study             | 2012-2019           | 48                  | TVC   | History of cervical insufficiency in previous pregnancy  |
| Tian S. 2020                 | China       | Retrospective monocentric study             | 2014-2018           | 135                 | LAC   | History of >2 s-trimester pregnancy losses or preterm delivery or contractions <34 weeks. Singleton pregnancy. Cervical incompetence and/or a short or absent cervix |
| Tian S. 2020                 | China       | Retrospective monocentric study             | 2014-2018           | 82                  | TVC   | History of >2 s-trimester pregnancy losses or preterm delivery or contractions <34 weeks. Singleton pregnancy. Cervical incompetence and/or a short or absent cervix |
| Abdulrahman N. 2024          | Netherlands | Retrospective multicentre cohort study      | 1997-2007           | 250                 | LAC   | Cervical incompetence and/or a short or absent cervix after cervical surgery; previous failed vaginal cerclage   |

TVC: transvaginal cervical cerclage; LAC: laparoscopic abdominal cerclage.

sed on the patient's obstetric history or anatomical characteristics [7-11].

A total of 8 studies evaluated pre-conceptional LAC placement based on the patient's previous obstetric history or anatomy criteria [12-18]. There were 4 retrospective studies and 4 prospective studies in this group.

**Table 1** summarizes the publication year range, the studies' design, the number of participants, and the type of treatment (elective TVC or pre-conceptional LAC).

The publication years ranged from 2002 to 2024 [7-18].

In total, 1,259 patients who performed cerclages were included in this review: 601 were treated with elective TVC and 658 were treated with pre-conceptional LAC.

### Outcomes

In the elective TVC studies group, 601 patients were treated. 532 pregnancies were followed up, and the percentage of delivery beyond 34 week gestation ranged from 71.3% to 87%. In the pre-conceptional LAC studies group, 658 patients were treated, and 549 pregnancies were achieved. The percentage of

Table 2. Pregnancy outcomes of LAC and TVC.

| Authors, year of publication | Country     | Pregnancies achieved | MTL (%) | Preterm delivery < 34 weeks | Delivery > 34 weeks | Infections and chorioamnionitis | Neonatal survival (%) | Cervical treatment (LAC/ elective TVC) |
|------------------------------|-------------|----------------------|---------|-----------------------------|---------------------|---------------------------------|-----------------------|--|
| To M.S. 2002                 | UK          | 41                   | 2.4%    | 14.6%                       | 85.4%               | NA                              | NA                    | TVC                                    |
| Liddell H.S. 2008            | New Zealand | 10                   | 0%      | 0%                          | 100%                | NA                              | 100%                  | LAC                                    |
| Burger N. B. 2012            | Netherlands | 35                   | 8.6%    | 5.7%                        | 71.4%               | 0%                              | 90%                   | LAC                                    |
| Riiskjaer M.2012             | Denmark     | 45                   | 11%     | 13%                         | 82.5%               | NA                              | NA                    | LAC                                    |
| Gluck O. 2016                | Israel      | 154                  | 2.5%    | 2.59%                       | 81.8%               | 1.29%                           | NA                    | TVC                                    |
| Huang X. 2016                | China       | 85                   | 3.7%    | 20%                         | 76.4%               | NA                              | 96.4%                 | LAC                                    |
| Ades A. 2018                 | Australia   | 121                  | 1.6%    | 12.4%                       | 79.7%               | 1.3%                            | 98.4%                 | LAC                                    |
| Wei 2018                     | China       | 257                  | 7.2%    | 5.1%                        | 87%                 | NA                              | 91.8%                 | TVC                                    |
| SaridoganE. 2019             | England     | 42                   | 4,7%    | 14%                         | 83%                 | NA                              | 97%                   | LAC                                    |
| Yüksel Şimşek S. 2020        | Turkey      | 48                   | NA      | 20.8%                       | 79.2%               | 2.1%                            | NA                    | TVC                                    |
| Tian S.2020                  | China       | 74                   | NA      | NA                          | 94.6%               | 0%                              | 97.3%                 | LAC                                    |
| Tian S. 2020                 | China       | 80                   | NA      | NA                          | 71.3%               | 6.3%                            | 83.8%                 | TVC                                    |
| Abdulrahman N. 2024          | Netherlands | 137                  | 18.3%   | 9,6%                        | 90.4%               | 2.5%                            | 96.2%                 | LAC                                    |

TVC: transvaginal cervical cerclage; LAC: laparoscopic abdominal cerclage; MTL: Mid trimester loss.

delivery beyond 34 weeks gestation ranged from 71.4% to 100%.

10 articles presented data on losses in the mid-trimester (between 14 and 27 weeks of pregnancy); specifically, mid-trimester loss ranged from 2.4% to 7.8% in the TVC group and from 0% to 8.6% in the LAC group.

7 articles reported the overall complication rate regarding wound infections, chorioamnionitis, and intra-operative injury; TVC group complications ranged from 1.2% to 6.3% and LAC group complications ranged from 0% to 2.5%. Only nine studies presented neonatal survival data, specifically: two studies of TVC group and seven studies of LAC group. A neonatal survival rate of 90%-100% was observed in the LAC group, compared to an average of 83.8%-91% in the TVC group. Data are summarized in Table 2.

**Analysis of the data**

Rearranging all the data reported in the literature, we compared the two techniques regarding MTL, < 34 gw deliveries, and complication rate (CR).

Concerning MTL, data were obtainable for 924 patients (456 TCV and 468 LAC). The TVC technique showed a higher rate of MTL (6.4% vs 3.4%; p = 0.0055). Regarding delivery previous than 34 gw, in a sample of 1123 patients (524 TVC vs 483 LAC), each technique failed to show itself superior to the other (9.7% in TVC vs 11.1% in LAC; p = 0.053). Finally, CR information was obtainable for only 614 patients (282 who underwent TVC and 332 LAC);

no statistically significant difference was observed in the two groups (CR 2.8% vs 1.9%; p = 0.337). Those data are summarized in Table 3.

**DISCUSSION**

**Data discussion**

It is difficult to find one technique that is clearly superior to the other. Our study failed to show a statistically significant difference in reducing preterm deliveries. However, it did show a trend (p = 0.053), with a very slight advantage in favour of TVC (9.7% vs 11.1%). On the other hand, this finding can be interpreted in terms of ‘non-inferiority’, showing that both techniques are effective about 9 times out of 10, with an extremely low-risk profile of complications (2.8% and 1.9%). Our systematic review shows that both elective TVC and pre-conceptual LAC are effective in reducing the incidence of preterm birth before 34 weeks gestation

Table 3. Analysis of the data reported in the literature.

| Outcome                  | TVC (%)  | LAC (%)   | P-value° |
|--------------------------|----------|-----------|----------|
| MLT+                     | 29 (6.4) | 16 (3.4)  | 0.0055   |
| Preterm delivery <34 gw+ | 56 (9.7) | 60 (11.1) | 0.053    |
| CR+                      | 8 (2.8)  | 6 (1.9)   | 0.337    |

TVC: transvaginal cerclage; LAC: laparoscopic abdominal cerclage; MTL: Mid trimester loss; gw: gestational weeks; CR: Complication Rate; °chi-squared test; +Data available for a proportion of patients.

in women at risk. However, due to the inclusion criteria of the individual studies, effect sizes may have varied.

According to our research, we found no comparative studies between pre-conceptual LAC and elective TVC, except in Tian *et al.*, in which patients with a history of cervical insufficiency, prophylactic LAC appears to have a better pregnancy outcome than elective TVC [11].

However, the data reported for both techniques appear superimposable even without comparative studies. This could mean that the very concept of 'cerclage' is effective against cervical incontinence, and the mode of placement and time of planning have little effect on the final outcome.

#### *Comparison with existing literature*

Several techniques can be considered for TVC. Previous research has found that pregnancy outcomes were similar in Shirodkar and McDonald cerclages [19, 20].

Conversely, with fewer complications and less damage, laparoscopic abdominal cerclage is as effective and perhaps even better than open abdominal cerclage, so it gradually replaced open abdominal cerclage as a primary surgical technique [21]. Despite this, the LAC shows a lower incidence of infections and faster patient relief [11]. Also, in our review, the lowest infection rate occurred in the LAC group, even though we were unable to report statistical significance. In addition, previous retrospective studies have shown that the two approaches have a superimposable rate of preterm deliveries while maintaining superimposable clinical outcomes of complications and hospitalizations [22].

#### *Clinical implication*

Given the overlap in neonatal outcomes in the two study groups, the 'non-inferiority' of one technique over the other should be understood as greater clinical manoeuvrability. While vaginal techniques are easier to perform, preconception treatment could lead to equal results by avoiding anxiety and worry in patients at risk of premature birth or mid-trimester loss. On the other hand, the effects of vaginal surgery are reassuring, making it possible to treat even patients who were not selected in the pre-conceptual phase as candidates for cervical cerclage. Finally, the high neonatal survival rate makes the two techniques optimal for the management of the risk of premature birth in cases of cervical-histomy insufficiency.

#### *Strength and limitation*

Our study found its strength in the systematic nature of the research, which covered everything published on the subject without date or research group limitations. The construction of a NOS scale gave due qualitative weight to the individual studies. On the other hand, a limitation was the complete absence of direct comparative studies, which made a quantitative analysis impossible. Another limitation is the absence of data on the management and timing of cerclage removal in non-pregnant patients, which was not addressed in our analysis. Dedicated studies are required to explore this specific clinical question. Further studies of a prospective nature aimed at a direct comparison will be necessary to settle the differences between the two techniques.

## CONCLUSIONS

TVC has been considered the traditional approach. Studies have demonstrated that TVC is associated with fewer complications and a similar neonatal survival rate than laparoscopic approaches [3, 20]. Nevertheless, other studies have suggested that laparoscopic cerclage may be more effective than transvaginal cerclage in patients with a history of transvaginal cerclage failure. Regarding which approach should be considered first, there is still a debate. As a result of our study, LAC may be beneficial for women who have previously failed vaginal cerclages, but further research is necessary to confirm its efficacy in other high-risk groups.

## COMPLIANCE WITH ETHICAL STANDARDS

#### *Authors' contributions*

CR: Methodology, conceptualization. EB: Data curation, writing – original draft, writing – review & editing. MCS: Data curation, writing – original draft. GA: Formal analysis. GC: Data curation. MCDD: Conceptualization. CS: Methodology. VC: Validation.

#### *Funding*

None.

#### *Study registration*

The present work has been categorized on the PROSPERO International Prospective Register of Systematic Reviews as ID CRD42024558592.

**Declaration of interests**

The authors declare that they have no conflict of interests.

**Ethical approval**

N/A. This study is a systematic review of previously published data and did not involve the collection of new data from human participants.

**Informed consent**

No individual patient data were collected or reported in this study.

**Data sharing**

Data are available under reasonable request to the corresponding author.

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## APPENDIX A. Newcastle-Ottawa scale (NOS).

| Study                   | Representativeness of the exposed cohort (1) | Selection of the non-exposed cohort (1) | Item & score                  |  |   |                           | Was follow up long enough for outcomes to occur (1) | Adequacy of follow up of cohorts (1) |
|-------------------------|--|---|-------------------------------|--|---|---------------------------|---|--------------------------------------|
|                         |  |   | Ascertainment of exposure (1) | Demonstration that outcome of interest was not present at start of study (1) | Compare ability of cohorts on the basis of the design or analysis (2) | Assessment of outcome (1) |   |                                      |
| To M.S. et al 2002      | 1  | 1                                       | 1                             | 1  | 2   | 1                         | 1   | 1                                    |
| Liddell H.S. et al 2008 | 1  | 0                                       | 1                             | 1  | 2   | 1                         | 1   | 1                                    |
| Burger N. B. 2012       | 1  | 1                                       | 1                             | 1  | 2   | 1                         | 1   | 1                                    |
| Riiskjaer M. 2012       | 1  | 1                                       | 1                             | 1  | 2   | 1                         | 1   | 1                                    |
| Gluck O. 2016           | 1  | 1                                       | 1                             | 1  | 2   | 1                         | 1   | 1                                    |
| Huang X. 2016           | 1  | 1                                       | 1                             | 1  | 2   | 1                         | 1   | 1                                    |
| Ades A. 2018            | 1  | 1                                       | 1                             | 1  | 2   | 1                         | 1   | 1                                    |
| Wei 2018                | 1  | 1                                       | 1                             | 1  | 2   | 1                         | 1   | 1                                    |
| Saridogan E. 2019       | 1  | 1                                       | 1                             | 1  | 2   | 1                         | 1   | 1                                    |
| Yüksel Şimşek S. 2020   | 1  | 1                                       | 1                             | 1  | 2   | 1                         | 1   | 1                                    |
| Tian S. 2020            | 1  | 1                                       | 1                             | 1  | 2   | 1                         | 1   | 1                                    |
| Abdulrahman N. 2024     | 1  | 1                                       | 1                             | 1  | 2   | 1                         | 1   | 1                                    |