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Systematic Review

Extended vs. Standard Pelvic Lymph Node Dissection in Bladder Cancer Patients Undergoing Radical Cystectomy: Systematic Review and Meta-Analysis

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Abstract: Background/Objectives: Pelvic lymph node dissection during radical cystectomy has been established to be important for staging and therapeutic purposes. However, there is uncertainty regarding the optimal extent of nodal dissection. This study aimed to assess the impact of an extended pelvic lymphadenectomy template compared to a standard template in patients with bladder cancer undergoing radical cystectomy. **Methods:** We performed a systematic review and meta-analysis of randomised studies comparing extended pelvic lymph node dissection to standard pelvic lymph node dissection in patients undergoing radical cystectomy. A search of multiple databases was performed up to October 2024. The standard template was defined as including at least the obturator and internal and external iliac nodes. An extended template was defined as a standard template plus the removal of proximal nodal packets. The primary outcomes were overall survival and major Clavien–Dindo complications. **Results:** Two studies encompassing a total of 933 participants met the eligibility criteria. There was no observed improvement in overall survival with extended lymph node dissection compared to limited dissection [HR 0.95, 95%CI 0.66–1.4]. In addition, extended lymph node dissection was associated with an increased risk of grade $\geq$3 Clavien–Dindo complications compared to limited nodal dissection [RR 1.2, 95%CI 1.02–1.37]. There was also an increased risk of lymphoceles requiring intervention with extended lymphadenectomy. **Conclusions:** Extended pelvic lymphadenectomy does not improve oncological outcomes and is associated with increased morbidity compared to a standard template in bladder cancer patients undergoing radical cystectomy.

Keywords: bladder cancer; radical cystectomy; systematic review; lymph node dissection

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1. Introduction

Pelvic lymph node dissection during radical cystectomy for bladder cancer has been recommended in the guidelines because of the diagnostic and oncological benefit it provides [1]. Nodal status is an important factor for bladder cancer staging and provides key prognostic information that can guide future management decisions [2]. However,

radiological imaging alone is not reliable for diagnosing nodal involvement. A recent study of 1104 patients undergoing radical cystectomy found only moderate concordance (65%) between clinical and pathological nodal status [3]. The sensitivity and specificity of conventional imaging modalities to accurately diagnose nodal status was 30% and 84%. Therefore, pelvic lymph node dissection acts as an important staging tool to diagnose lymph node status.

To date, evidence suggests that there is a survival advantage to performing pelvic lymph node dissection. A propensity-matched analysis using the SEER (Surveillance, Epidemiology, and End Results)-Medicare dataset compared patients undergoing radical cystectomy alone to those who also had a pelvic lymph node dissection at the time of their cystectomy and found superior all-cause and cancer-specific mortality in the latter group [4]. Multiple other studies have also supported these findings that nodal dissection improves survival to no pelvic lymph node dissection [5]. The extent of lymph node dissection needed to maximise oncological benefit is not entirely clear from the evidence and still largely debated. The current available evidence is discordant on whether there is any improvement to survival outcomes by extending the proximal boundary of the lymph node dissection to the bifurcation of the aorta or the origin of the inferior mesenteric artery [6]. These studies are largely retrospective, not standardised, and subject to considerable bias that makes their findings uncertain.

We therefore aimed to perform a systematic review and meta-analysis of randomised trials to summarise the best available evidence on extended lymph node dissection templates for patients with high-risk bladder cancer undergoing radical cystectomy. We assessed the impact on oncological outcomes and morbidity. We focussed on patient-important outcomes that can guide decision-making.

2. Evidence Acquisition

The protocol for this review was published in PROSPERO prospectively (CRD42024597964). We included studies of participants with high-risk non-muscle invasive bladder cancer or muscle-invasive bladder cancer undergoing radical cystectomy with pelvic node dissection. Participants were eligible regardless of whether or not they received neoadjuvant chemotherapy. We also did not set any limitations regarding the surgical modality (robotic or open) nor the urinary diversion being undertaken at the time of surgery. We excluded patients who had previous pelvic radiotherapy and those with metastatic disease.

We compared extended pelvic lymph node dissection to a standard template. We defined the extended template as standard lymph node dissection, including at least the obturator and internal and external iliac nodes, plus extended dissection to at least the aortic bifurcation (common iliac, presacral, paracaval, and interaortocaval nodes and could extend to include the para-aortal nodes up to the inferior mesenteric artery). The standard template was defined as including at least the obturator and internal and external iliac nodes.

This review focussed on outcomes that are important to patients. The primary outcomes of this review were as follows:

- Overall survival defined as the time from radical cystectomy to death by any cause.
- Major complications defined as any grade $\geq$3 Clavien–Dindo complications within 90 days of surgery.

The secondary outcomes of interest were as follows:

- Disease-free survival defined as the time from radical cystectomy to disease recurrence, as determined by the investigator through clinical radiological and/or pathological information.

- Cancer-specific survival defined as the time from radical cystectomy to death caused by bladder cancer, as determined by the investigator.
- Lymphoceles requiring intervention, defined as lymphoceles requiring drainage using any method, including percutaneous or surgical (Clavien grade ≥ 3).

We only included randomised studies in this systematic review and excluded all non-randomised publications.

2.1. Search and Study Selection

We performed a detailed search of multiple databases, including MEDLINE, EMBASE, ScienceDirect, Cochrane Libraries, HTA database, and Web of Science, up to October 2024. Citations of included papers were tracked and reference lists were cross-checked to ensure all relevant records were included. We placed no restrictions on language nor date of publication.

In accordance with the Cochrane Handbook of Systematic Reviews [7], abstract screening, full-text review, and data extraction were performed by two independent authors (J.S. and P.S.). A senior author (N.S.) reviewed and resolved any disagreements.

2.2. Statistical Analysis

We performed statistical analysis according to the recommendations of the Cochrane Handbook for Systematic Reviews [8]. Time-to-event outcomes were pooled using generic inverse variance methods. Dichotomous outcomes were combined using the Mantel–Haenszel method. Random effect models were used for all analyses. Study heterogeneity was assessed using the I^2 statistic and classified according to the Cochrane guidance: not important (0–40%), moderate (30–60%), substantial (50–90%), or considerable (75–100%) [8].

2.3. Risk of Bias

A critical appraisal of studies was carried using the risk-of-bias (RoB) tool 2.0 for randomised trials [9].

3. Evidence Synthesis

The results of the search and study selection are outlined in the PRISMA diagram (Figure A1). There were 2069 results retrieved from the search strategy, of which 12 had their complete texts assessed for eligibility. We included two randomised trials, which encompassed 993 participants in total [10,11]. The details of the included trials are outlined in Table 1. The median number of nodes excised in the standard templates in the two included trials were 19 and 24 compared to 31 and 39 in the extended template arms. The extended template in the LEA (Eingeschrankte vs. Ausgedehnte Lymphadenektomie) study comprised the standard template plus bilateral deep obturator fossa, common iliac, presacral, paracaval, interaortocaval, and para-aortal nodes up to the inferior mesenteric artery. However, in the SWOG (Southwest Oncology Group) trial, the extended template comprised the standard template plus the common iliac nodes, the presciatic region (fossa of Marcille), the presacral space, the region anterior to the left common iliac vein, and the medial to the common iliac arteries, up to the bifurcation of the aorta.

Table 1. Characteristics of included studies.

Study	**LEA [10]**		**SWOG [11]**	
Year	**2019**		**2024**	
Dissection method	sLND	eLND	sLND	eLND
Sample size	203	198	300	292

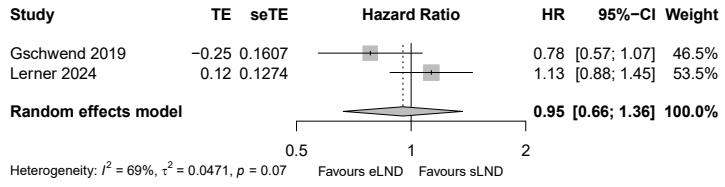
Table 1. *Cont.*

Study	LEA [10]		SWOG [11]	
Number of nodes taken	19 (12–26)	31 (22–47)	24 (6–61)	39 (15–94)
Year	**2019**		**2024**	
FU (months)	58.4	58.4	73.2	73.2
Age (yr)	68 (61–73)	67 (59–74)	68 (38–90)	69 (37–92)
Neoadjuvant chemotherapy	Excluded	Excluded	170 (57)	166 (57)
Adjuvant chemotherapy	30 (15)	28 (14)	33 (11)	32 (11)
T-stage				
pT1	24 (12)	31 (16)	NA	NA
pT2	81 (40)	88 (44)	213 (71)	208 (71)
pT3	68 (34)	63 (32)	87 (29)	84 (29)
pT4	30 (15)	16 (8.1)		
N-stage				
pNx	0	2 (1)	NA	NA
pN0	147 (72)	152 (77)	229 (76)	217 (74)
pN+	56 (28)	44 (22)	NA	NA
pN1	15 (7.4)	14 (7.1)	36 (12)	34 (12)
pN2	41 (20)	29 (15)	31 (10)	20 (7)
pN3	0	1 (0.5)	4 (1)	21 (7)

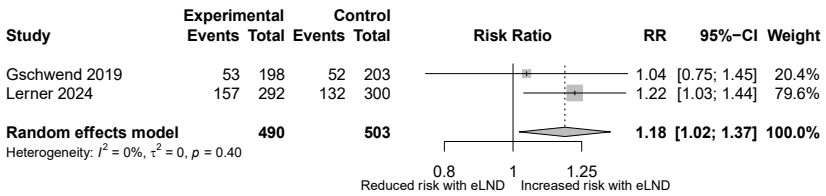
Abbreviations: eLND = extended lymph node dissection. FU = follow-up. LEA = Eingeschränkte vs. Ausgedehnte Lymphadenektomie. NA = not applicable. sLND = standard lymph node dissection. SWOG = Southwest Oncology Group. yr = years.

3.1. Primary Outcomes

Both included studies reported on the primary outcomes of interest. The 5-year overall survival in the standard lymphadenectomy arm was reported to be 63% in most recent study. There was no observed improvement in overall survival with extended lymph node dissection compared to limited dissection [pooled HR 0.95, 95%CI 0.66 to 1.4] (Figure 1A). There was significant heterogeneity observed in this analysis [I^2 = 69%].



(**A**)



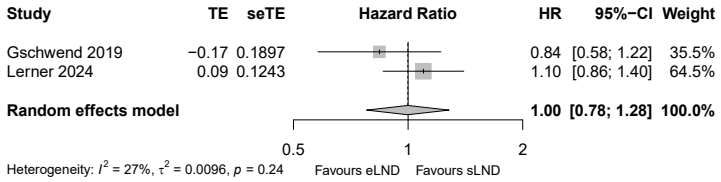
(**B**)

Figure 1. Forest plot of primary outcomes: (**A**) overall survival and (**B**) major complications. The gray diamond represents the summary effect and the dotted line is the point pooled effect [10,11]. eLND—extended lymph node dissection, sLND—standard lymph node dissection.

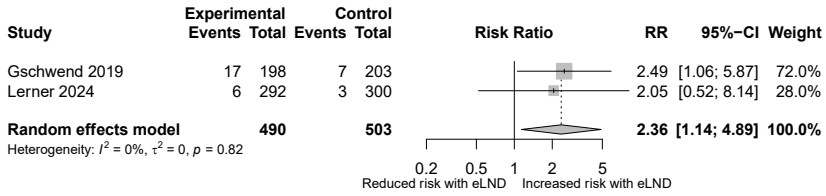
Extended lymph node dissection was associated with an increased risk of grade ≥3 Clavien–Dindo complications compared to limited nodal dissection [RR 1.2, 95%CI 1.02 to 1.37] (Figure 1B). There was no significant heterogeneity observed [I^2 = 0%]. The most common grade ≥3 Clavien–Dindo complications with an incidence of >5% reported by the SWOG S1011 trial included anaemia at 18% and 15%, urinary tract infection at 9% and 9%, and sepsis at 5% and 7% for standard lymphadenectomy and extended lymphadenectomy, respectively. The frequencies and specific types of complications that occurred in patients experiencing grade ≥3 Clavien–Dindo complications in the LEA trial were not reported by the authors.

3.2. Secondary Outcomes

The 5-year disease-free survival in the standard lymphadenectomy arm was 60% in the SWOG S1011 trial [11]. We did not observe an improved disease-free survival with extended lymphadenectomy compared to a standard template [pooled HR 1.0, 95%CI 0.8 to 1.3] (Figure 2A). There was a minor heterogeneity observed in this analysis [I^2 = 27%].



(**A**)



(**B**)

Figure 2. Forest plot of secondary outcomes: (**A**) disease-free survival and (**B**) lymphoceles requiring intervention. The gray diamond represents the summary effect and the dotted line is the point pooled effect [10,11]. eLND—extended lymph node dissection, sLND—standard lymph node dissection.

Cancer-free survival was only reported in one of the included studies [10]. There was no improvement observed in this outcome with extended lymphadenectomy [pooled HR 0.7, 95%CI 0.5 to 1.1].

The incidence of lymphoceles that required intervention in the included studies ranged from 1% to 3% with the standard lymphadenectomy templates. Extended lymph node dissection templates increased the risk of lymphoceles requiring intervention compared to a standard template [pooled HR 2.4, 95%CI 1.1 to 4.9] (Figure 2B). There was no significant heterogeneity observed [I^2 = 0%].

3.3. Risk of Bias

Risk of bias judgements are summarised Figure A2. The randomisation and allocation concealment of both trials was performed adequately and judged to be at low risk of bias. There was also low risk of bias for missing outcome data because the attrition rate was low and the analyses in both trials were performed with an intention-to-treat method. Both trials were open label studies where neither the participants nor personnel were blinded and, therefore, there may be some concerns regarding bias regarding outcome

measurements. We were unable to assess publication bias due to the limited number of trials that met the eligibility criteria.

4. Discussion

This study summarises the most up-to-date and highest quality evidence on the oncological benefit of extending lymph node dissection templates beyond the bifurcation of the common iliac artery in patients undergoing radical cystectomy for high-risk bladder cancer. We pooled the data from two randomised studies of nearly 1000 participants and found that there was no improvement in survival outcomes with an extended lymphadenectomy template compared to a standard template. In addition, an extended lymph node dissection results in harm to the patient with an 18% higher risk of major Clavien–Dindo complications (grade $\geq$ 3) and more than doubles the incidence of lymphoceles that require intervention. These findings strongly suggest that the extent of lymphadenectomy should be limited to the standard template in order to minimise harm while maintaining oncological control. This is in contrast to previous pooled analyses that reported that extended lymph node dissection improves five-year recurrence-free survival (HR 1.6, 95%CI 1.3 to 2.1) [12]. This study also found that the complication rates were not increased with extended nodal dissection. However, the studies included in the systematic review by Mandel et al. were non-randomised and mostly retrospective and were therefore subject to confounders.

Current EAU (European Association of Urology) guidelines states that "there are data to support that extended vs. standard LND (lymph node dissection) improves survival after RC (radical cystectomy)". A systematic review in 2014 that included twenty-three studies and nearly 20,000 participants found that the impact of extended lymph node dissection was not clear [6]. Only one of the included studies comparing standard to extended lymph node dissection performed multivariable analysis that found that an extended template was an independent predictor of disease-free and cancer-specific survival [13]. This was, however, a retrospective study and did not include patients that had undergone neoadjuvant chemotherapy, which would be considered to be the standard of care in contemporaneous practice. The Cochrane review on the topic, which only included the single Gschwend et al. randomised trial, concluded that extended lymph node dissection may reduce overall survival and cancer-specific survival but this review does not include the contemporary SWOG trial [14]. Furthermore, a single-centre, prospective analysis of patients undergoing radical cystectomy in Mansoura, Egypt, found that increasing the lymph node template to the inferior mesenteric artery resulted in improved 5-year disease-free survival [15]. In contrast, a retrospective, cohort study of 78 patients from a single-centre in India undergoing radical cystectomy and pelvic lymph node dissection found that extending the nodal template increased the nodal yield but did not have any effect on survival [16]. The median nodal yield in this study was only 16 in the extended group, which is lower than that in comparative studies and may suggest that the quality of nodal dissection is lacking, despite the acknowledgment of these issues and the use of nodal yield to assess quality. Taken together, the studies included in the 2014 systematic review are predominantly retrospective and at risk of significant bias, and thus, the findings are likely to be uncertain and not reliable [6].

Aside from a lack oncological benefit, extended lymph node dissection has been observed to increase the harms experienced by patients. Lymph node dissection can be technically challenging because it involves dissection along large vessels that are at risk of damage and significant bleeding. Therefore, it is understandable that extending the dissection proximally along even larger vessels increased the risk of major Clavien–Dindo grade $\geq$3 complications. A number of prostate cancer studies have also reported that extended pelvic lymph node dissection templates results in a higher risk of lymphoceles

and prolongs hospital stay [17,18]. Although our review did not directly assess the risk of thromboembolic events, extended lymph node dissection has been associated with an increased risk. Given the additional morbidity of an extended template, the benefits would need to be significant to justify its use, which the current evidence suggests not to be the case. There may be a subgroup of patients that may still benefit from an extended lymph node dissection but the challenge is to identify these patients and this could be aided by new technologies, such as indocyanine green fluorescence or FDG-PET (18F-fluorodeoxyglucose-positron emission tomography) [19,20].

There are limitations to this systematic review that need to be considered when interpreting its results. Only two randomised controlled trials were identified and neither of the included studies were designed nor adequately powered to detect a difference in overall survival and therefore even the pooled results may be statistically underpowered. Both studies were powered for their primary outcome, which was recurrence-free survival. The overall survival analysis also had considerable statistical heterogeneity that we could not fully explain and may be due to differences in the characteristics of patients or studies; for example, the proportion of patients with T1 disease or those that received neoadjuvant chemotherapy. Given the small number of included trials, I^2 may also be an unreliable measure of statistical heterogeneity. Random effects models partly mitigate the observed heterogeneity, and the pooled overall survival results should therefore be interpreted with caution due to over-interpretation risk. The included studies were performed at centres of excellence by experienced surgeons and the results may therefore not be generalisable to the wider community. Even in the standard lymphadenectomy template arm, the median node count in the two studies were 19 and 24 nodes. This is considerably higher than other reports in the literature of median nodes removed at the time of radical cystectomy [21]. Furthermore, as we did not set limitations regarding the surgical modality or approach for urinary diversion, we were unable to account for the possible influence of surgical approach on the results in terms of complications. Moreover, subgroup analysis according to chemotherapy status, sex, type of chemotherapy or immunotherapy, and specific stage was not performed in this study as there were insufficient data to do so; however, these factors should be considered in the clinical application of the current findings. Future studies comparing these subgroups may enable investigation into the potential differential outcomes of extended versus standard lymphadenectomy across different patient subgroups.

5. Conclusions

Overall, the pooled data from two high-quality randomised studies suggest that extended lymph node dissection templates, performed more proximally than the common iliac artery bifurcation, confers no oncological benefit in patients with high-risk bladder cancer undergoing radical cystectomy. Additionally, extended nodal dissection increases the risk of harm to the patient, including major Clavien–Dindo complications and lymphoceles that require intervention.

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Appendix A

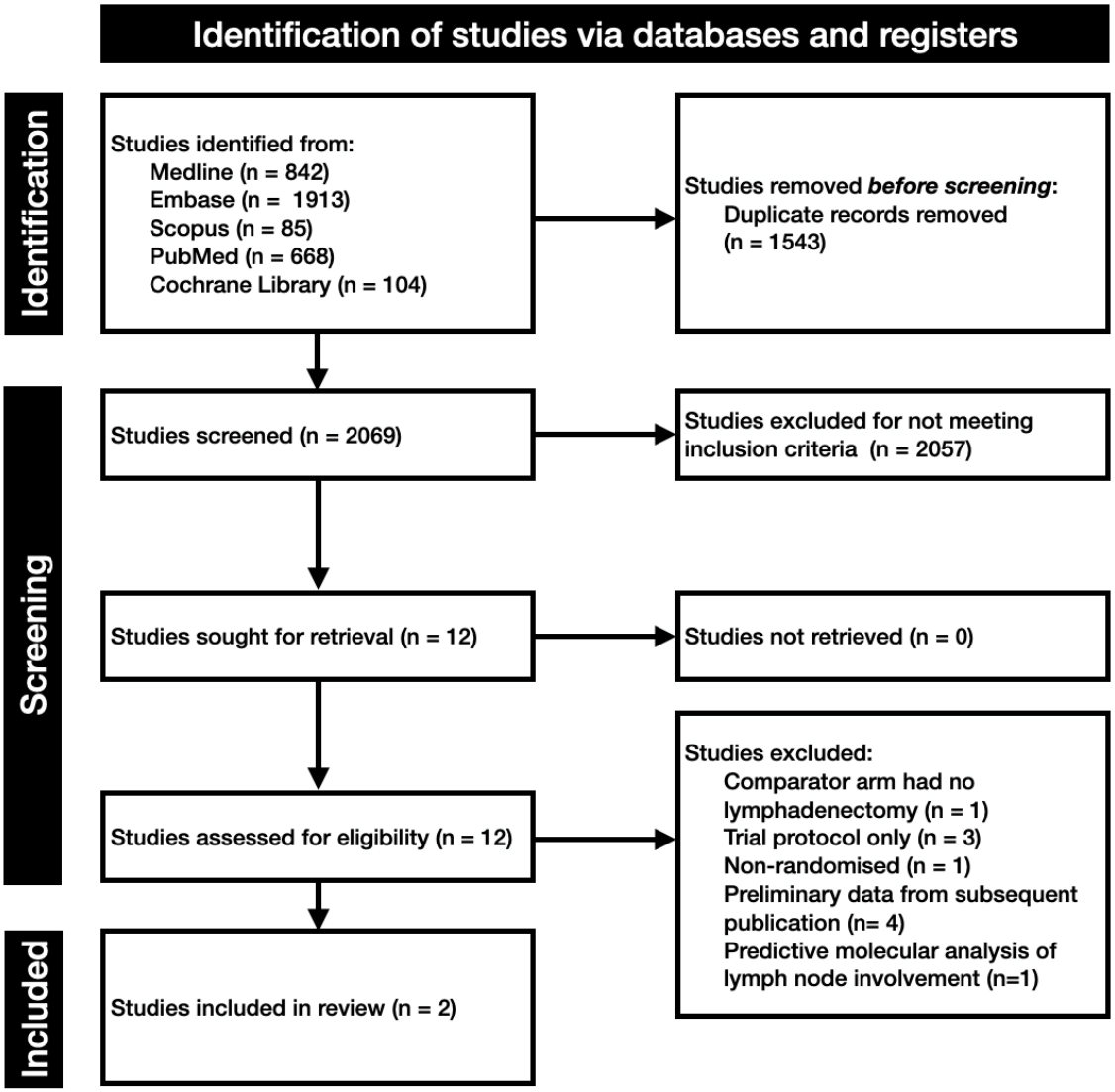


Figure A1. PRISMA diagram of study selection.

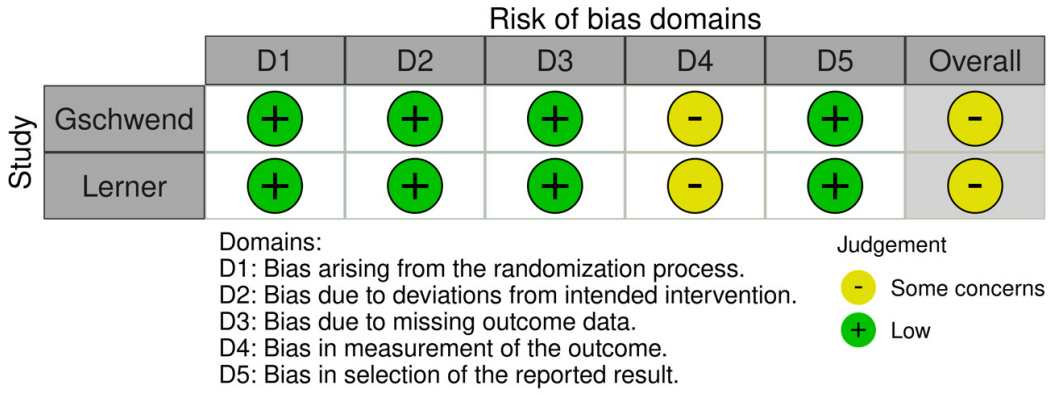


Figure A2. Risk of bias.

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