# Template evidence tables

## Evidence table of systematic reviews

Table X Evidence table of systematic reviews regarding the diagnosis of pathology or effect of Intervention

|  |  |
| --- | --- |
| Title + study ID (+ref endnote) | |
| Methods |  |
| * Design |  |
| * Source of funding and competing interest | Specify the source of funding: public research funds, government, not governmental organization, healthcare industry or other (give name of organization or corporation) and the presence of declaration of interest (stated/not stated and specify if any) |
| * Search date |  |
| * Searched databases |  |
| * Included study designs | Specify the type of study: RCT, CCT, case control, case series |
| * Number of included studies |  |
| * Statistical analysis | Specify the statistical methods used |
| Patient characteristics |  |
| * Eligibility criteria | State the most relevant inclusion criteria for population (patients and pathology) |
| * Exclusion criteria | State the most relevant exclusion criteria for population (patients and pathology) |
| * Patient & disease characteristics | State the most relevant baseline characteristics |
| Interventions | |
| * Intervention group | Precise details of the interventions for each group (including dose, length, regimen and timing if relevant) |
| * Control group | Precise details of the interventions for each group (including dose, length, regimen and timing if relevant) |
| Results | |
| * Outcome 1 | Summary of the critical and important outcomes within and between groups: effect size (absolute risk reduction, relative risk (reduction), odds ratio) and its precision (p value, CI) |
| * Outcome 2 |  |
| * Outcome 3 |  |
| * Outcome 4 |  |
| * Outcome 5 |  |
| Limitations and other comments |  |
| * Limitations | Comments on limitations of the study (external and internal validity) |

## Evidence tables of intervention studies

Table X Evidence table of intervention studies regarding the effect of Intervention vs Comparator in population

|  |  |
| --- | --- |
| Title + study ID (+ref endnote) | |
| Methods |  |
| * Design | Specify the study design: randomized study, cross sectional study, cohort study, case control study, time series, before and after studies, other; prospective or retrospective study. Precise if it’s the design cited by author(s) |
| * Source of funding and competing interest | Specify the source of funding: public research funds, government, not governmental organization, healthcare industry or other (give name of organization or corporation) and the presence of declaration of interest (stated/not stated and specify if any) |
| * Setting | Number of centres, countries involved, healthcare setting, urban/rural/mixed |
| * Sample size | Give the number of patients needed (= the calculated before protocol) as cited (described) by the author(s) (should clearly report if it is numbers by group or not) and the number of patients actually included |
| * Duration and follow-up | Start and end dates of the study (precise if includes follow up or not), precise inclusion and follow up periods (length rather than dates) |
| * Statistical analysis | Specify the statistical methods used |
| Patient characteristics |  |
| * Eligibility criteria | State the inclusion criteria cited in the paper |
| * Exclusion criteria | State the exclusion criteria cited in the paper |
| * Patient & disease characteristics | Describe baseline characteristics cited in the paper (precise if it is on involved and/or analysed numbers). Highlight discrepancies between groups (i.e. involved and analysed) |
| Interventions |  |
| * Intervention group | Precise details of the interventions for each group (including dose, length, regimen and timing when relevant) |
| * Control group | Precise details of the interventions for each group (including dose, length, regimen and timing when relevant) |
| Results |  |
| * Outcome 1 | Summary of the critical and important outcomes within and between groups: effect size (absolute risk reduction, relative risk (reduction), odds ratio) and its precision (p value, CI) |
| * Outcome 2 |  |
| * Outcome 3 |  |
| * Outcome 4 |  |
| * Outcome 5 |  |
| Limitations and other comments |  |
| * Limitations | Comments on limitations of the study (external and internal validity) |

## Evidence tables of diagnostic studies

Table Evidence table of diagnostic studies regarding the diagnosis of pathology with test 1

|  |  |
| --- | --- |
| Title + study ID (+ref endnote) | |
| Methods |  |
| * Design | Specify the study design: randomized study, cross sectional study, cohort study, case control study, time series, before and after studies, other; prospective or retrospective study. Precise if it’s the design cited by author(s) |
| * Source of funding and competing interest | Specify the source of funding: public research funds, government, not governmental organization, healthcare industry or other (give name of organization or corporation) and the presence of declaration of interest (stated/not stated and specify if any) |
| * Setting | Number of centres, countries involved, healthcare setting, urban/rural/mixed |
| * Sample size | Give the number of patients needed (= the calculated before protocol) as cited (described) by the author(s) (should clearly report if it is numbers by group or not) and the number of patients actually included |
| * Time interval between tests | Specify if any |
| * Statistical analysis | Specify the statistical methods used |
| Patient characteristics |  |
| * Eligibility criteria | State the inclusion criteria cited in the paper |
| * Patient characteristics | Describe baseline characteristics cited in the paper (precise if it is on involved and/or analysed numbers). Highlight discrepancies between groups (i.e. involved and analysed) |
| * Prevalence of disease | State the prevalence estimation of the disease in the general population |
| Interventions |  |
| * Index test(s) | Describe the evaluated test(s):   * What (including the provider’s name if applicable), by whom and how, when * Cut-offs, categories of results * Blinding (investigator) to clinical information and/or to index test results, if applicable |
| * Reference standard | Describe the reference standard test:   * What (including the provider’s name if applicable), by whom and how, when * Cut-offs, categories of results * Blinding (investigator) to clinical information and/or to index test results, if applicable |
| Results |  |
| * Outcome 1 | Summary of the critical and important outcomes within and between groups: effect size (absolute risk reduction, relative risk (reduction), odds ratio) and its precision (p value, CI); diagnostic accuracy (Se, Sp, PPV, NPV, DOR, AUC, LR+, LR‑) and its precision (p value, CI) |
| * Outcome 2 |  |
| * Outcome 3 |  |
| * Outcome 4 |  |
| * Outcome 5 |  |
| Limitations and other comments |  |
| * Limitations | Comments on limitations of the study (external and internal validity) |

## Evidence tables of prognostic studies

Table X Evidence table of prognostic studies regarding the effect of Intervention vs Comparator in population

|  |  |
| --- | --- |
| Title + study ID (+ref endnote) | |
| Methods |  |
| * Design | Specify the study design: randomized study, cross sectional study, cohort study, case control study, time series, before and after studies, other; prospective or retrospective study. Precise if it’s the design cited by author(s) |
| * Source of funding and competing interest | Specify the source of funding: public research funds, government, not governmental organization, healthcare industry or other (give name of organization or corporation) and the presence of declaration of interest (stated/not stated and specify if any) |
| * Setting | Number of centres, countries involved, healthcare setting, urban/rural/mixed |
| * Sample size | Give the number of patients needed (= the calculated before protocol) as cited (described) by the author(s) (should clearly report if it is numbers by group or not) and the number of patients actually included |
| * Duration and follow-up | Start and end dates of the study (precise if includes follow up or not), precise inclusion and follow up periods (length rather than dates) |
| * Statistical analysis | Specify the statistical methods used |
| Patient characteristics |  |
| * Eligibility criteria | State the inclusion criteria cited in the paper |
| * Exclusion criteria | State the exclusion criteria cited in the paper |
| * Patient & disease characteristics | Describe baseline characteristics cited in the paper (precise if it is on involved and/or analysed numbers). Highlight discrepancies between groups (i.e. involved and analysed) |
| Interventions |  |
| * Exposure | Precise details on the exposure for each group |
| * Confounders | Precise details on the confounders for each group |
| Results |  |
| * Outcome 1 | Summary of the critical and important outcomes within and between groups: effect size (absolute risk reduction, relative risk (reduction), odds ratio) and its precision (p value, CI) |
| * Outcome 2 |  |
| * Outcome 3 |  |
| * Outcome 4 |  |
| * Outcome 5 |  |
| Limitations and other comments |  |
| * Limitations | Comments on limitations of the study (external and internal validity) |

### Example of evidence table of intervention study

|  |  |
| --- | --- |
| The American College of Surgeons Oncology Group Z0011 trial, addressed by: Lucci 2007, Giuliano 2010, Giuliano 20113 | |
| Methods |  |
| * Design | RCT |
| * Source of funding and competing interest | National Cancer Institute |
| * Setting | Multicenter |
| * Sample size | N=891 |
| * Duration | Patient enrollment from May 1999 to December 2004. Targeted enrolment was 1900 women with final analysis after 500 deaths, but the trial closed early because mortality rate was lower than expected. |
| * Follow-up | Patients were assessed for disease recurrence by history and physical examination (every 6 months for the first 36 months and yearly thereafter) and annual mammography. Other testing was based on symptoms and investigator preference. Median follow-up of 6.3 years (last follow-up, March 4, 2010) |
| * Statistical analysis |  |
| Patient characteristics |  |
| * Eligibility criteria | women with clinical T1-T2 invasive breast cancer, no palpable adenopathy, and 1 to 2 SLNs containing metastases identified by frozen section, touch preparation, or hematoxylin-eosin staining on permanent section. |
| * Exclusion criteria | women were excluded if they were pregnant or lactating, were treated with neoadjuvant chemo or hormonal therapy, had bilateral breast cancer, multicentric disease, a history of ipsilateral axillary surgery, prepectoral implants, or medical contraindications to ALND. Patients with matted nodes or gross extranodal disease at the time of SLND were excluded as were patients with 3 or more involved SLNs. |
| * Patient & disease characteristics | Group 1: n= 436; Group 2: n= 420   * Median age (range): 56 (24-92) vs. 54 (25-90); * Clinical T stage: T1: 284 (67.9%) vs. 303 (70.6%), T2: 134 (32.1%) vs.126 (29.4%) * Micrometastases in SLNs: 164/366 (44.8%) vs. 137/365 (37.5%)   The characteristics were well balanced between the 2 groups (T stage, tumour size, receptor status for estrogen and progesterone, LVI, loom- Richardson score, tumour type). |
| Interventions |  |
| * Intervention group (1) | **Group 1**: Sentinel lymph node dissection (SLND) only (no further axillary surgery)  SLND was performed with isosulfan blue, a radiopharmaceutical or both. All patients underwent breast conservation therapy and whole breast irradiation. |
| * Control group (2) | **Group 2** : SLND and axillary lymph node dissection (ALND)  SLND was performed with isosulfan blue, a radiopharmaceutical or both. All patients underwent breast conservation therapy and whole breast irradiation. |
| Results |  |
| * Overall survival | Median follow-up of 6.3years with a noninferiority margin of a 1-sided hazard ratio of less than 1.3 indicating that SLND alone is non-inferior to ALND)  Group 1: 42 deaths vs Group 2: 52 deaths  HR = 0.79 (90% CI 0.56 to 1.10), which did not cross the pre-specified boundary of 1.3  *NOTE: a 2-sided 90% CI corresponds to a 1-sided significance level of 0.05. If the 90% CI for the HR was below 1.3, this would indicate that patients undergoing SLND alone do not have an unacceptably worse overall survival than patients undergoing SLND plus ALND.* |
| * 5-year overall survival | Group 1 92.5% vs Group 2 91.8%  HR (adjusted for adjuvant therapy (chemotherapy, endocrine therapy, and/or radiation therapy) and age) = 0.87 (90% CI 0.62 to 1.23) |
| * 5-year disease-free survival | Group 1: 83.9% vs Group 2: 82.2%  HR (unadjusted) = 0.82 (95% CI 0.58 to 1.17)  HR (adjusted for adjuvant therapy (chemotherapy, endocrine therapy, and/or radiation therapy) and age) = 0.88 (95% CI 0.62 to 1.25) |
| * Local/regional recurrence | *Local recurrence after median follow-up of 6.3 years*:  Group 1: 8/436 (1.8%) vs Group 2: 15/420 (3.6%)🡪RR= 0.51 (95% CI 0.22 to 1.20)  *At 5 years:*  Group 1: 7/436 (1.6%) vs Group 2: 13/420 (3.1%)🡪 RR= 0.52 (95% CI 0.21 to 1.29)  *Regional recurrences in ipsilateral axilla*:  Group 1: 4/436 (0.9%) vs Group 2: 2/420 (0.5%)🡪RR= 1.93 (95% CI 0.35 to 10.46)  Median time of local recurrence-free survival and regional recurrence-free survival was not reached in either group and did not differ between the arms.  *5-year locoregional recurrence–free survival*  Group 1: 96.7% vs Group 2: 95.7% (P=0.28).  Recurrence in ‘Treatment received’ sample\*:  *Locoregional recurrence*:  Group 1: 12/425 (2.8%) vs Group 2: 16/388 (4.1%)🡪 RR= 0.68 (95% CI 0.33 to 1.43)  *Local recurrence*:  Group 1: 8/425 (1.9%) vs Group 2: 14/388 (3.6%)🡪 RR= 0.52 (95% CI 0.22 to 1.23)  *Regional recurrence*:  Group 1: 4/425 (0.9%) vs Group 2: 2/388 (0.5%)🡪 RR= 1.83 (95% CI 0.34 to 9.91) |
| * Arm morbidity | *Wound infections at 30 days*  Group 1: 11/371 vs Group 2: 31/373🡪 RR= 0.36 (95% CI 0.18 to 0.70)  *Axillary seromas at 30 days*  Group 1: 21/371 vs Group 2: 53/373🡪 RR= 0.40 (95% CI 0.25 to 0.65)  *Axillary paresthesias*  At 30 days:  Group 1: 43/371 vs Group 2: 174/373🡪 RR= 0.25 (95% CI 0.18 to 0.34)  At 6 months:  Group 1: 35/288 vs Group 2: 146/335🡪 RR=0.28 (95% CI 0.20 to 0.39)  At 12 months:  Group 1: 24/268 vs Group 2: 113/287🡪 RR= 0.23 (95% CI 0.15 to 0.34)  *Lymphedema (reported subjectively)*  At 6 months:  Group 1: 19/339 vs Group 2: 27/327🡪 RR= 0.68 (95% CI 0.39 to 1.20)  At 12 months:  Group 1: 16/268 vs Group 2: 37/288🡪 RR= 0.46 (95% CI 0.26 to 0.82)  After 12 months:  Group 1: 14/253 vs Group 2: 52/272 🡪 RR= 0.29 (95% CI 0.16 to 0.51)  *Lymphedema (by arm measurements)*  At 30 days:  Group 1: 17/272 vs Group 2: 23/255🡪 RR= 0.69 (95% CI 0.38 to 1.27)  At 6 months:  Group 1: 21/271 vs Group 2: 29/270🡪 RR= 0.72 (95% CI 0.42 to 1.23)  At 12 months:  Group 1: 14/226 vs Group 2: 26/242🡪 RR = 0.58 (95% CI 0.31 to 1.08)  *Brachial plexus injury (BPI)*  “Eighteen BPIs were reported originally, but after each injury was re-evaluated, it was discovered that 10 would have been more accurately classified as axillary paresthesias. Three BPIs occurred after SLND alone, but all of these had resolved at last follow-up, as had 88% of all BPIs.” |
| * Quality of life | Not addressed |
| Limitations and other comments | |
| * Limitations | Thirty-two women in the ALND group did not have ALND and 11 women in the SLND-alone group had ALND. Therefore, the treatment-received sample consisted of 388 women who indeed did receive ALND and 425 women who indeed did receive SLND alone. The primary analyses were performed on the intent-to-treat sample, and all were repeated for the treatment received sample. Both analyses yielded similar results with no significant change in results. |