Journal Club Worksheet

CRITICAL APPRAISAL WORKSHEET

Type of Study: Randomized Controlled Trial

**Article:** Walsh, M., Merkel, P. A., Peh, C. A., Szpirt, W. M., Puéchal, X., Fujimoto, S., ... & Jayne, D. R. (2020). Plasma exchange and glucocorticoids in severe ANCA-associated vasculitis. New England Journal of Medicine, 382(7), 622-631.

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| **What is a randomized controlled trial?**  “An experiment in which two or more conditions are compared by randomly allocating participants to one of at least two groups (usually, one group receives an intervention or treatment, and the other – the ‘control group’ – receives no intervention or an alternative intervention), and then testing the effects. RCTs can have more than two groups (e.g. two treatment groups and one control group). RCTs are considered one of the most reliable research designs, because random allocation helps to reduce the risk that the effects of the intervention might have been due to some form of bias.”  Source: Department of Social Policy and Intervention > Centre for Evidence-Based Intervention > Research designs. (2017). Cebi.ox.ac.uk. Retrieved 10 December 2017, from http://www.cebi.ox.ac.uk/for-practitioners/research-designs.html |

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| 1. What question did the study ask? Rewrite it below in a PICO format |
| Patient population:  Intervention:  Control:  Outcome:  What phase trial is this? Circle one   * Phase I: Is it Safe? * Phase II: Does it Work? * Phase III: Is it as good, or better than existing standards? * Phase IV: Long term side effects? |
| **2. Was the assignment of the patients to treatments randomised?** |
| **Ideally the study should:** Use centralised computer randomisation in multi-centred trials. Smaller trials may use an independent person (e.g, the hospital pharmacy) to “police” the randomization. |
| **Did this study do this? (circle one): Yes No Unclear**  **Comment:** |
| 3. Were the groups similar at the start of the trial? |
| Ideally the study should: Have similar intervention and control groups at the beginning of the trial if the randomisation was successful. There should be some indication of whether the differences between groups are statistically significant (i.e. p values) |
| **Did this study do this? (circle one): Yes No Unclear**  Comment: |
| 4. Aside from the allocated treatment, were the groups treated equally? |
| **Ideally the study should**: treat the intervention and control group the same apart from the intervention. |
| **Did this study do this? (circle one) Yes No Unclear**  **Comment:** |
| 5. Were all patients who entered the trial accounted for? – and were they analysed in the groups to which they were randomised? |
| **Ideally the study should:** minimize loss to follow-up. Preferably less than 20%. However, if few patients have the outcome of interest, then even small losses to follow-up can bias the results. Patients should also be analysed in the groups to which they were randomised or “intention-to-treat analysis”. |
| **Did this study do this? (circle one) Yes No Unclear**  **Comment:** |
| 6. Were measures objective? Or were the patients and clinicians kept blind to which treatment was being received? |
| **Ideally the study should:** be double-blinded – that is both patients and investigators are unaware of treatment allocations. If the outcome is objective (e.g. Death) then blinding is less critical. If the outcome is subjective (e.g. symptoms or function) then blinding the outcome assessor is critical. |
| **Circle one: Yes No Unclear**  **Comment:** |
| **7. Will the results help me in caring for my patient?** |
| The questions that you should ask before you decide to apply the results of the study to your patient are:   * Is my patient so different to those in the study that the results cannot apply? * Is the treatment feasible in my setting? * Will the potential benefits of treatment outweigh the potential harms of treatment for my patient? |
| **Circle one: Yes No Unclear**  **Comment:** |