CRITICAL REVIEW FORM: THERAPY ARTICLES

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Citation: Brockow et al., – Effect of a structured educational intervention on knowledge and emergency management in patients at risk for anaphylaxis. Ann Emerg Med. 2015 Oct;66(4):381-9.

Study Objective: To determine effect of an educational intervention on patient and caregiver knowledge, anxiety, and emergency management competence in anaphylaxis

Study Methodology: Multicenter randomized control trial in which an interventional group was given a structured educational intervention (divided into x2 3-h educational modules) and the control group was given only standard EpiPen training. Study occurred in ten "centres" with long-term experience in the diagnosis and treatment of anaphylaxis in Germany recruited caregivers of children and adults at risk of anaphylaxis who carried an epinephrine auto-injector. Patients were previously diagnosed by an allergist using World Allergy Organization (WAO) criteria.

GUIDE	COMMENTS	
I. Are the results valid? Yes – there was a significant improvement in outcomes in regards to knowledge on anaphylaxis and emergency management competence in both intervention groups compared to control group		
A. Did experimental and control groups begin the study with a similar prognosis	Yes. Table 1. Aside from a mean difference in age 37.5 vs 34.5 yrs. (P=.05) there were no significant differences	
1. Were patients randomized?	Yes. However authors do not provide any details regarding how randomization occurred	
2. Was randomization concealed (blinded)? In other words, was it possible to subvert the randomization process to ensure that a patient would be "randomized" to a particular group?	Uncertain. Once randomized centrally (Institute of Medical Psychology) no mention of concealment of randomization so hard to say if this process could have been corrupted.	
3. Were patients analyzed in the groups to which they were randomized?	Yes. The authors used <u>intention-to-treat analysis</u> and "For the analyses, values of the lost caregiver and patients were estimated using 'last observation carried forward (LOCF)'.	
4. Were patients in the treatment and control groups similar with respect to known prognostic factors?	There was no significant difference between intervention and control groups in severity of anaphylaxis.	
5. Were patients aware of group allocation?	Yes.	

6. Were clinicians aware of group allocation?	Yes. Clinicians involved in the structured patient education had to undergo 30h training course for eligibility to teach.
7. Were outcome assessors aware of group allocation?	Yes. Allergist trainers rating skills before and after intervention were not blinded to intervention allocation.
8. Was follow-up complete?	Yes. There was a small attrition rate 17/193 (8%). Data analyses did not note changes in significance of results for outcome measures even if patient who dropped out were excluded.
What are the results ?	
How large was the treatment effect? (Table 4)	 Cohort: 95 caregivers of children 98 adults with previous episodes of anaphylaxis Baseline values for knowledge, emergency management, anxiety and depression were NOT statistically significant. Caregiver Group: difference from control after interventions: Knowledge: 3.16 (CI 2.50; 3.82) vs. 0.65 (0.04; 1.34) Emerg. Mgt: 8.57 (7.46; 9.69) vs. 1.20 (0.03; 2.38) Anxiety: 1.87 (2.58; 1.15) vs. 0.74 (1.46; 0.02) Depression: N/S NNT's (1/ARR): Knowledge 40 Emergency management: 14 Anxiety: 88 Adult Group: difference from control after intervention Knowledge 3.94 (3.21; 4.68) vs. 1.27 (0.48; 2.06) ARR 2.67 Emergency management 7.14 (6.17; 8.11) vs. 1.13 (0.07; 2.20) ARR 6.0 Depression N/S Anxiety N/S NNT's (1/ARR) Knowledge: 37 Emerg. Mgt.: 17
2. How precise was the estimate of the treatment effect? (CI's?)	See CI's all of those that were significant had reasonably narrow CI's suggesting fairly precise results
III How can I apply the results to patient care?	
1. Were the study patients similar to my patients?	 Not at all. Inclusion criteria: 1. Confirmed diagnosis of anaphylaxis by allergist 2. Existing prescription for EpiPen 3. "sufficient" [German] language skills 4. Non-ED patient population 5. 50% lower education probably close to us 6. No racial background 7. Germans have benefit of free lifetime healthcare.

2. Were all clinically important outcomes considered?	This is difficult to say definitively as the rubric for grading the OSCE which was used to assess emergency management competence was not included. I think that time to auto- injection, correct administration of auto-injection, patient's clinical outcome, and preparedness are all clinically important factors to consider and were measured in a simulation setting only and not a "real-life" anaphylaxis situation. No calculations for potential lives saved or harms avoided.
3. Are the likely treatment benefits worth the potential harm and costs?	Surely there are benefits to the educational intervention, but I would say many clinicians would not elect to undergo a 30h training course and even fewer patients would elect to undergo a 6h training. Furthermore, I would say that most patients that are prescribed an EpiPen from the ED are unlikely to follow- up with an allergist to confirm diagnosis. We are lucky if they follow-up with primary care.

Limitations:

- Unclear randomization and concealment methods
- Unclear why assessors were not blinded to interventions this could be a source of performance bias.
- Did not reassess over the longer term for retention.
- Disproportionate female participants
- Inclusion criteria overall seems to have favored literate patients
- Unclear rubric for grading competence on OSCE
- Overall, 6h training for patients limits this applicability to patients who are quite involved and take initiative in their medical care AND have that time to spare.

Clinical Bottom Line:

I think this study demonstrated that a structured intervention in a motivated patient population can have a favorable impact on emergency management and basic knowledge. Patient education is always a positive thing in regard to patient understanding and clinical outcomes. I think that a more reasonable structured education that is deliverable to patients during patient care would be more applicable.

How might we affect better outcomes in our patient and workplace setting?