Journal Club Eastern Virginia Medical School

Resident: Bota

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CITATION: Flinn RB, Merrill JP, Welzan WR: **Treatment of the oliguric patient with a new sodium ion- exchange resin and sorbitol: A preliminary re-port.** *N Engl J Med* 264: 111–115, 1961

GUIDE	Comments
A. **Are the results of the study valid?**	
1. Were patients randomized?	No, selection/sampling bias largely present, undermines external validity. There is also significant potential for unequal prognostic characteristics.
2. Was randomization concealed (Blinded)	Not randomized. Patients/family/clinical assessors all privy to group allocation.
3. Were patients analyzed in the groups to which they were randomized?	No, intention to treat analysis cannot be applied. Furthermore, results not analyzed independently but as an average.
4. Were patients in the treatment and control groups similar with respect to known prognostic factors?	This is unclear but for our purposes no. There are no demographics provided, compromising prognostic equivalence and external validity. Controls are poorly defined and few in number - no controls for age, sex, race, etiology of oliguria, dialysis requirement/administration, Cr clearance, other medications, other comorbidities.
5. Were patients aware of group allocation?	Makes no mention, but presumably yes.
6. Were clinicians aware of group allocation?	Were clinicians and outcome assessors aware of group allocation? - Presumably yes

7. Were outcome assessors aware of group allocation?	Yes.
8. Was follow-up complete?	No mention of ANY follow-up
B. What were the results?	
1. How large was the treatment effect? (difference between treatment and control group).	Mean reduction of 1.7/1.4/2.5 mEq for groups 1/2/3 respectively. PO sorb + kayex increased serum Na by a mean of 9. PO sorb alone decreased bicarb by 1.2 on avg. Stool losses of K unreported. These are averaged results.
2. How precise was the estimated treatment effect at a 95% confidence interval?	No CI's reported, very low precision and likely wide range given the low power of the study.
C. How can I apply the results to patient care	
IV. Were the study patients similar to my patients?	Maybe? Probable similar comorbidities, however, study takes place in the inpatient setting over long-term treatment.
1. Were all clinically important outcomes considered?	No patient-oriented outcomes such as fatalities, symptomatic improvement, side effects. Also, no mention of reasons for patient attrition.
2. Are the likely treatment benefits worth the potential harms and costs?	Cannot make conclusions based on too many significant limitations.

Clinical Bottom Line:
This is a non-randomized, poorly controlled, heavily biased, and poorly implemented study, which claims that PO kayexalate is "effective and practical" at lowerling K in the acutely hyperkalemic oliguria patient with sorbitol as a "good adjunct" that corrects for overhydration. In order to draw any meaningful conclusions, the study requires larger

trials/higher power, controls that are clearly delineated and appropriate, randomization with blinding, follow up, and clearly defined outcomes that are patient centered.