Journal Club / Research Article Summary - (Adapted from Schultz Table)

Date: ___2/11/16________
Presenter: ______Calvn Simmons__________

ARTICLE:

- Country: USA
- Funding Sources:

PURPOSE:
- Research Question(s): What is / are the primary questions being addressed by this study? Usually found just before the methods.
  - Is Floseal more effective than nasal packing in the management of anterior epistaxis in the ED.

- Hypothesis: What is the anticipated outcome or alternatively, the null hypothesis (there will be no difference between groups).
  - Floseal is more effective than nasal packing for management of anterior epistaxis in the ED.

DESIGN:
- Study Design:
  - Major types of quantitative designs: Descriptive (case / series) Correlational (prospective / restrospective cohort), Quasi-Experimental, and Experimental (Randomized Controlled).
    - Randomized controlled trial
  - ? prospective vs. restrospective.
    - prospective
  - ? blinding
    - Not blinded, not possible

- Dependent / outcome Variable(s): What is the variable of interest / outcome being studied.
  - Need for HNS consult
  - Rebleed within 7 days of the procedure
  - Rebleeding at follow up (removal of nasal pack)
  - Percent crossover
  - MS assessments: effectiveness, ease of use, satisfaction
  - Patient assessments: comfort at time of placement, comfort at time of follow up, satisfaction
• **Independent / research Variable:** What is the variable that is modified among groups?
  o Use of anterior nasal pack vs floseal, nasal pack chosen by the treating physician, merocel, rhino rocket, surgicel

**SETTING / SUBJECTS:**
• **Research Setting:** Inpatient / outpatient, rural / urban, academic / community, EM / non-em, etc.
  o ED at Kaiser Permanente in Oakland, EPs were the treating doctors, HNS the follow up doctors

• **Subjects:**
  o **Study population:** Who was studied (eg: all adults presenting with chest pain, all children with wheezing, etc).
    - Adults presenting with acute anterior epistaxis
  o **Inclusion / Exclusion criteria:** Are there any important inclusion or exclusion criteria, especially those that may affect generalizability.
    - INR over 4
    - Posterior epistaxis
    - Patients with hypersensitivity to bovine products
  o **Number (control / intervention groups):** Number of subjects in each group.
    - 35 in each group
  o **Demographics:** Age, sex race, etc.
    - No SS differences between the two groups, there was a trend towards more anticoagulated patients/higher average INR in the Floseal group
  o **Attrition:** Did patients exit the study or were patients lost to follow up.
    - No loss to follow up

**METHODS:**
• **Interventions:** What, if any, interventions were performed among the study groups.
  o Blood pressure control at the discretion of the ED doctor, anterior rhinoscopy, suctioning of blood and clot, topical oxymetazoline in all patients
  o Then anterior pack was placed by EP discretion or Floseal was placed, followed by bacitracin soaked gauze pack
  o Patients were crossed over to the other group if packing did not stop bleeding or if 2 attempts at Floseal were unsuccessful

• **Study Groups:** What were the various study groups (eg: control / placebo, intervention 1, intervention 2, etc)
  o Nasal pack, Floseal
• **Instruments:** What devices, special equipment, surveys, rating scales, etc. were utilized.
  o Rating scale for bleeding: 1= spotting on tissue, 2= soaked tissue, 3= bowl needed
  o Scales of 1-10 for subjective measurements.

• **Data Collection:** Who collected data? What was their training? Was there consistency among data collectors? Were there changes to data collection / study protocol during the period of the study.
  o ED attendings, HNS residents with attending supervision, consistent collection

**DATA ANALYSIS:**
• **Level of Data:** Categorical (two or more categories without order, (ie: male / female) Ordinal (hierarchical categories without set spacing, (ie: education level, death / discharge) Interval (continuous data with set spacing, (ie: age, weight, hemoglobin)
• **Statistics Used:** What type of statistical tests were utilized (eg: T-test, ANOVA, regression analysis).
  o Data were entered into a computerized spreadsheet program and analyzed using a two-tailed Student’s t test for means and Fisher’s exact test for percentages.
• **What, if any, variables were controlled for?:** Do the results adjust for confounding variables?
  o Nothing controlled for, no condounding variables identified by the author.

**RESULTS:**
• **Brief answers to research questions:** What were the conclusions made by the authors? Do they answer the original research questions? Do you think their conclusions are valid based on the data reported?
  o Floseal is more effective than anterior nasal packing (fewer HNS consults, fewer rebleeds, no bleeds at follow up, fewer crossovers)
  o Floseal is higher rated (EP liked it more, patients liked it more, it was less painful at insertion)

• **Additional findings:** Any any additional findings other than the primary research questions discussed? Were these expected or unexpected based on the study design?
  o No scarring or adhesions were seen but the authors comment that this is a potential side effect of floseal use.

• **Other possible explanation for findings:** Are their other possible / probable explanations for the results other than those presented by the authors? Do the results correspond with the purpose of the study? Consider: sample size issues, measurement issues (did they measure the right outcomes?), attrition, treatment integrity
(was the intervention always delivered exactly the same way?), and other issues you identify.
  o Subjective measurements in a non blinded study

• **Limitations:** Are their important limitations identified by the authors? Do you see any other important limitations? Do these limitations significantly alter the conclusion or the applicability of the study?
  o Sample size was small, too small to assess for complications such as scarring,

**IMPLICATIONS FOR PRACTICE:**
• **Applicable to this clinical practice:** Is the study population generalizable to the population likely to be affected by this intervention / outcome in your clinical practice? If not, what setting may this be applicable to?
  o Yes, if we have floseal in our ED

• **Feasible (cost, resources, etc):** Is this an intervention that would be reasonable to institute in clinical practice? Are instruments / medications available? Does the study adequately assess risks and unforeseen outcomes? Is the intervention cost / resource effective? Does the study account for cost / benefit? Are there more effective treatments available?
  o Yes

• **Clinically Relevant:** Is this intervention likely to make a clinically significant impact on your patients if instituted? That is, some interventions may show statistically significant changes without making an impact that is clinically important.
  o Yes

**LEVEL OF EVIDENCE / DECISION FOR USE:**
• Background x Consider Replication  Ready for use

• **Level of Evidence:**
  Ia  Evidence obtained from meta-analysis of randomized controlled trials
  x  Ib  Evidence obtained from at least one RCT
  IIa Evidence obtained from at least one well-designed controlled study without randomization
  IIb Evidence obtained from at least one other type of well-designed quasi-experimental study
  III  Well-designed non-experimental studies
  IV  Expert committee reports, opinions of experts