ARTICLE:

- Citation: An Observational Study of 2,248 Patients Presenting With Headache, Suggestive of Subarachnoid Hemorrhage, Who Received Lumbar Punctures Following Normal Computed Tomography of the Head David Sayer, MRCS*, Ben Bloom, FRCEM, Katalin Fernando, MD, Stuart Jones, FRCPath, Sally Benton, FRCPath, Shumontha Dev, FRCEM, Sathish Deverapalli, MBBS, and Tim Harris, FRCEM. Academic Emergency Medicine. November 2015, Vol. 22, No. 11. 1267-1273
- Country: UK
- Funding Sources: Authors report no relevant financial information or conflicts to disclosed

PURPOSE:

- Research Question(s): What is / are the primary questions being addressed by this study? Usually found just before the methods.
  - What is the incidence of subarachnoid bleed due to vascular anomaly among patients with SAH type headache but an initial negative head CT

- Hypothesis: What is the anticipated outcome or alternatively, the null hypothesis (there will be no difference between groups).
  - Head CT will not be 100% sensitive for aneurismal SAH

DESIGN:

- Study Design:
  - Major types of quantitative designs: Descriptive (case / series) Correlational (prospective / restrospective cohort), Quasi-Experimental, and Experimental (Randomized Controlled).
    - Retrospective chart review

- Dependent / outcome Variable(s): What is the variable of interest / outcome being studied.
  - Positive LP, vascular abnormality on imaging

- Independent / research Variable: What is the variable that is modified among groups?
  - LP performed, patients with LP performed were the only ones included in the study.
SETTING / SUBJECTS:

- **Research Setting**: Inpatient / outpatient, rural / urban, academic / community, EM / non-em, etc.
  - Multiple hospitals in London, tertiart care centers staffed by attending ED physicians, one referral hospital for neurosurgery.

- **Subjects**:
  - **Study population**: Who was studied (eg: all adults presenting with chest pain, all children with wheezing, etc).
    - All patients who had an LP performed after a negative CT scan in whom SAH was the main diagnostic concern
  - **Inclusion / Exclusion criteria**: Are there any important inclusion or exclusion criteria, especially those that may affect generalizability.
    - Patient’s under 17 were excluded
    - Patients who had LP as part of workup for meningitis were excluded
    - Patients who did not have a LP performed were excluded (the number of patients meeting this criteria is never reported)

- **Number (control / intervention groups)**: Number of subjects in each group.
  - There is only one group. Patients who got LP after negative CT in the wu for SAH. There were 2248

- **Demographics**: Age, sex, race, etc.
  - Demographics were not collected on the majority of patients

- **Attrition**: Did patients exit the study or were patients lost to follow up.
  - There was no follow up for clinical outcomes. Of the patients with uninterpretable LP, more than half had no follow up imaging.

METHODS:

- **Interventions**: What, if any, interventions were performed among the study groups.
  - There was only one group, LP was the intervention

- **Study Groups**: What were the various study groups (eg: control / placebo, intervention 1, intervention 2, etc)

- **Instruments**: What devices, special equipment, surveys, rating scales, etc. were utilized.
  - LPs were analyzed using spectrophotometry to find bilirubin and oxyhemoglobin

- **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.
  - Data was collected through chart review by searching all LP results and then seeing if patient met inclusion and did not meet exclusion criteria.
Data on demographics of the patients was not consistent across the sites included in the study.

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)
  - categorical
- **Statistics Used:** What type of statistical tests were utilized (eg: T-test, ANOVA, regression analysis).
  - Mean, median, standard deviation
- **What, if any, variables were controlled for?:** Do the results adjust for confounding variables?
  - none

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?
  - In patients who received an LP in the diagnostic workup for SAH following negative non contrast head CT, 92 (4.8%) had positive LP for SAH, among these there were 9 (0.45%) who had a vascular anomaly.
  - 299 (15.0%) LPs were inconclusive. None of these patients had a vascular anomaly found but likely only 50% (number not reported) had follow up imaging.
  - 350 (15.6%) had uninterpretable results. Among these two aneurisms were found. The handling of uninterpretable results was analyzed only at two sites, less than half of these patients ended up getting imaging.

- **Additional findings:** An any additional findings other than the primary research questions discussed? Were these expected or unexpected based on the study design?
  - Among the 9 patients who had a positive LP and then an aneurism found on imaging, one had the initial CT scan within 6 hours of headache onset. Because the number of patient presenting with headache and getting CT originally is not reported in this study, a sensitivity for CT within 6 h of headache onset cannot be calculated, but it cannot be 100%.

- **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.
• **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 The diagnostic tool used in this study is not the same that we use. Spectrophotometry for diagnosis of SAH is more sensitive and less specific than visible xanthochromia and red cell counts.
  
  o We do not know how many patients there were that originally presented with headache concerning for SAH. We don’t know how many never had an LP performed. The population studied would have represented a higher risk group unless every patient in these hospitals who had a headache had an LP. We are not given this information.
  
  o The outcomes measured are lab values and imaging findings and not clinical outcomes. There is no clinical follow up on patients who did not receive LP, patients who had positive LP but no vascular anomaly, etc.

**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 I am not sure what the study population is, but this does apply to my clinical practice in that I know CT for SAH within 6 H is not 100% sensitive from this study.

• **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 While LPs are analyzed differently in the US, the procedure is feasible and is the standard of care at this time.

• **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 My current practice is to perform LP on patients with concerning headache and negative CT when they present outside of 6 h window and to offer LP for patients who present within the 6 h window, knowing that CT is very sensitive but not 100%. I have a discussion with the patient regarding the chance of missed diagnosis and the potential fatal result and then help with shared decision making. This study does not suggest a change to that practice pattern.
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
- 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