KARNATAKA RADIOLOGY EDUCATION PROGRAM

CLINICAL RESEARCH – BRIDGING IMAGING & INNOVATION

SESSION – 9 – MANUSCRIPT WRITING - II

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SCIENTIFIC MANUSCRIPT – MATERIALS & METHODS

STUDY DESIGN AND SUBJECTS

✓ **APPROVAL AND CONSENT:** STATE THAT THE INSTITUTIONAL REVIEW BOARD APPROVED THE STUDY AND WHETHER SUBJECTS PROVIDED INFORMED CONSENT.

✓ **STUDY TYPE:** SPECIFY WHETHER THE STUDY IS "PROSPECTIVE" OR "RETROSPECTIVE".

✓ **SAMPLING METHOD:** INDICATE WHETHER SAMPLING WAS "CONSECUTIVE" OR "RANDOM".

✓ **INCLUSION AND EXCLUSION CRITERIA:** EXPLICITLY LIST THE CRITERIA FOR INCLUSION AND EXCLUSION.

✓ **FLOW CHART:** PROVIDE A FLOW CHART EXPLAINING SUBJECT RECRUITMENT, REASONS FOR EXCLUSION, AND FINAL OUTCOMES.

SCIENTIFIC MANUSCRIT – MATERIALS & METHODS

IMAGING TECHNIQUES

✓ **DETAILS:** PROVIDE SUFFICIENT DETAILS TO ALLOW READERS TO REPRODUCE THE STUDY.

✓ **IMAGING DEVICE:** STATE THE TYPE OF IMAGING DEVICE, MANUFACTURER, AND IMAGING PARAMETERS.

✓ **CONTRAST AGENT:** SPECIFY THE TYPE, AMOUNT, AND RATE OF ADMINISTRATION OF THE CONTRAST AGENT.

✓ **TABLE:** USE A TABLE IF NEEDED TO SUCCINCTLY COMMUNICATE DETAILS OF IMAGING ACQUISITION.

SCIENTIFIC MANUSCRIT – MATERIALS & METHODS

IMAGE ANALYSES

✓ **DATA ANALYSIS:** EXPLAIN HOW THE DATA WERE ANALYZED, INCLUDING WHO PERFORMED THE ANALYSIS AND THEIR LEVEL OF EXPERIENCE.

✓ **BLINDING:** STATE WHETHER READERS WERE BLINDED.

✓ **INDEPENDENT READERS:** INDICATE IF MORE THAN ONE READER WAS INVOLVED AND WHETHER THE ANALYSIS WAS PERFORMED IN CONSENSUS OR INDEPENDENTLY.

✓ **CRITERIA AND THRESHOLDS:** DEFINE CLEAR CRITERIA, THRESHOLDS, AND RANKING SYSTEMS FOR THE MEASUREMENT AND ANALYSIS METHODS.

✓ **QUALITY EVALUATION:** DESCRIBE HOW THE QUALITY OF THE RESULTS WAS EVALUATED, INCLUDING RELIABILITY AND VALIDITY.

✓ **REFERENCE STANDARD:** CLEARLY EXPLAIN THE STANDARD OF REFERENCE USED FOR DIAGNOSTIC PERFORMANCE TESTS.

MATERIALS & METHODS – STUDY DESIGN & SUBJECT

- ✓ **APPROVAL AND CONSENT:** THE STUDY WAS APPROVED BY THE INSTITUTIONAL REVIEW BOARD (IRB) OF XYZ HOSPITAL, AND INFORMED CONSENT WAS OBTAINED FROM ALL SUBJECTS.

- ✓ **STUDY TYPE:** THIS STUDY WAS A PROSPECTIVE COHORT STUDY.

- ✓ **SAMPLING METHOD:** SUBJECTS WERE SELECTED USING CONSECUTIVE SAMPLING.

- ✓ **INCLUSION AND EXCLUSION CRITERIA:**

  - ✓ **INCLUSION:** PATIENTS AGED 18-75 WITH SUSPECTED HEPATIC STEATOSIS REFERRED FOR MRI.

  - ✓ **EXCLUSION:** PATIENTS WITH KNOWN ALLERGIES TO CONTRAST AGENTS, PREGNANT WOMEN, AND THOSE WITH CONTRAINDICATIONS TO MRI.

- ✓ **FLOW CHART:** A FLOW CHART WAS PROVIDED TO EXPLAIN THE RECRUITMENT PROCESS, INCLUDING REASONS FOR EXCLUSION AND FINAL OUTCOMES.

MATERIALS & METHODS – IMAGING TECHNIQUES

- ✓ **DETAILS:** IMAGING DATA WERE ACQUIRED USING A 3.0 TESLA MRI SCANNER (GE HEALTHCARE). IMAGING PARAMETERS INCLUDED T1-WEIGHTED AND T2-WEIGHTED SEQUENCES.

- ✓ **IMAGING DEVICE:** MRI SCANNER: 3.0 TESLA (GE HEALTHCARE).

- ✓ **CONTRAST AGENT:** GADOLINIUM-BASED CONTRAST AGENT (GADOVIST) WAS ADMINISTERED AT A DOSE OF 0.1 MMOL/KG BODY WEIGHT AT A RATE OF 1.0 ML/S.

- ✓ **TABLE:** A TABLE WAS USED TO SUCCINCTLY COMMUNICATE IMAGING ACQUISITION DETAILS.

MATERIALS & METHODS – IMAGE ANALYSIS

✓ **DATA ANALYSIS:** TWO RADIOLOGISTS WITH 10 YEARS OF EXPERIENCE EACH INDEPENDENTLY ANALYZED THE MRI IMAGES.

✓ **BLINDING:** RADIOLOGISTS WERE BLINDED TO THE CLINICAL DATA OF THE SUBJECTS.

✓ **INDEPENDENT READERS:** TWO INDEPENDENT READERS ANALYZED THE IMAGES, AND CONSENSUS WAS ACHIEVED THROUGH DISCUSSION.

✓ **CRITERIA AND THRESHOLDS:** THE SEVERITY OF HEPATIC STEATOSIS WAS GRADED AS 0, 1-5, 6-10, AND >10 LESIONS.

✓ **QUALITY EVALUATION:** INTRA- AND INTEROBSERVER VARIABILITY WERE ASSESSED TO DETERMINE RELIABILITY. DIAGNOSTIC PERFORMANCE WAS EVALUATED USING HISTOPATHOLOGY AS THE REFERENCE STANDARD.

MATERIALS & METHODS – STATISTICAL ANALYSIS

✓ **STATISTICAL TESTS:** DESCRIPTIVE STATISTICS, T-TESTS, AND CHI-SQUARE TESTS WERE APPLIED TO ANALYZE THE DATA. RECEIVER OPERATING CHARACTERISTIC (ROC) ANALYSIS WAS CONDUCTED TO ASSESS DIAGNOSTIC ACCURACY.

✓ **SIGNIFICANCE LEVEL:** THE LEVEL OF SIGNIFICANCE FOR P-VALUES WAS SET AT 0.05, WITH CORRECTIONS FOR MULTIPLE COMPARISONS WHERE NECESSARY.

✓ **SOFTWARE:** STATISTICAL ANALYSES WERE PERFORMED USING SPSS VERSION 25.0 (IBM).

QUIZ

WHAT ARE THE ESSENTIAL COMPONENTS TO INCLUDE IN THE MATERIALS AND METHODS SECTION TO ENSURE THAT OTHER EXPERTS CAN REPRODUCE THE EXPERIMENTS, AND WHY IS IT IMPORTANT TO EXPLICITLY LIST THE INCLUSION AND EXCLUSION CRITERIA OF THE STUDY?

A) STUDY TYPE, IMAGING DEVICE, DATA INTERPRETATION
B) STUDY DESIGN, IMAGING TECHNIQUES, INCLUSION AND EXCLUSION CRITERIA, STATISTICAL ANALYSES
C) INTRODUCTION, HYPOTHESIS, RESULTS
D) APPROVAL AND CONSENT, HYPOTHESES, CONCLUSION

ANSWER

B) STUDY DESIGN, IMAGING TECHNIQUES, INCLUSION AND EXCLUSION CRITERIA, STATISTICAL ANALYSES

EXPLANATION: THE MATERIALS AND METHODS SECTION SHOULD INCLUDE STUDY DESIGN AND SUBJECTS, IMAGING TECHNIQUES, IMAGE ANALYSES, AND STATISTICAL ANALYSES TO PROVIDE DETAILED AND UNAMBIGUOUS PROCEDURES. EXPLICITLY LISTING THE INCLUSION AND EXCLUSION CRITERIA IS IMPORTANT BECAUSE IT DEFINES THE SUBJECT POPULATION, ENSURING THE RESULTS ARE APPLICABLE AND PREVENTING SELECTION BIAS.