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KARNATAKA RADIOLOGY EDUCATION PROGRAM

CLINICAL RESEARCH – BRIDGING IMAGING & INNOVATION

SESSION – 8 – STUDY DESIGNS IN MEDICAL RESEARCH – OBSERVATIONAL STUDY

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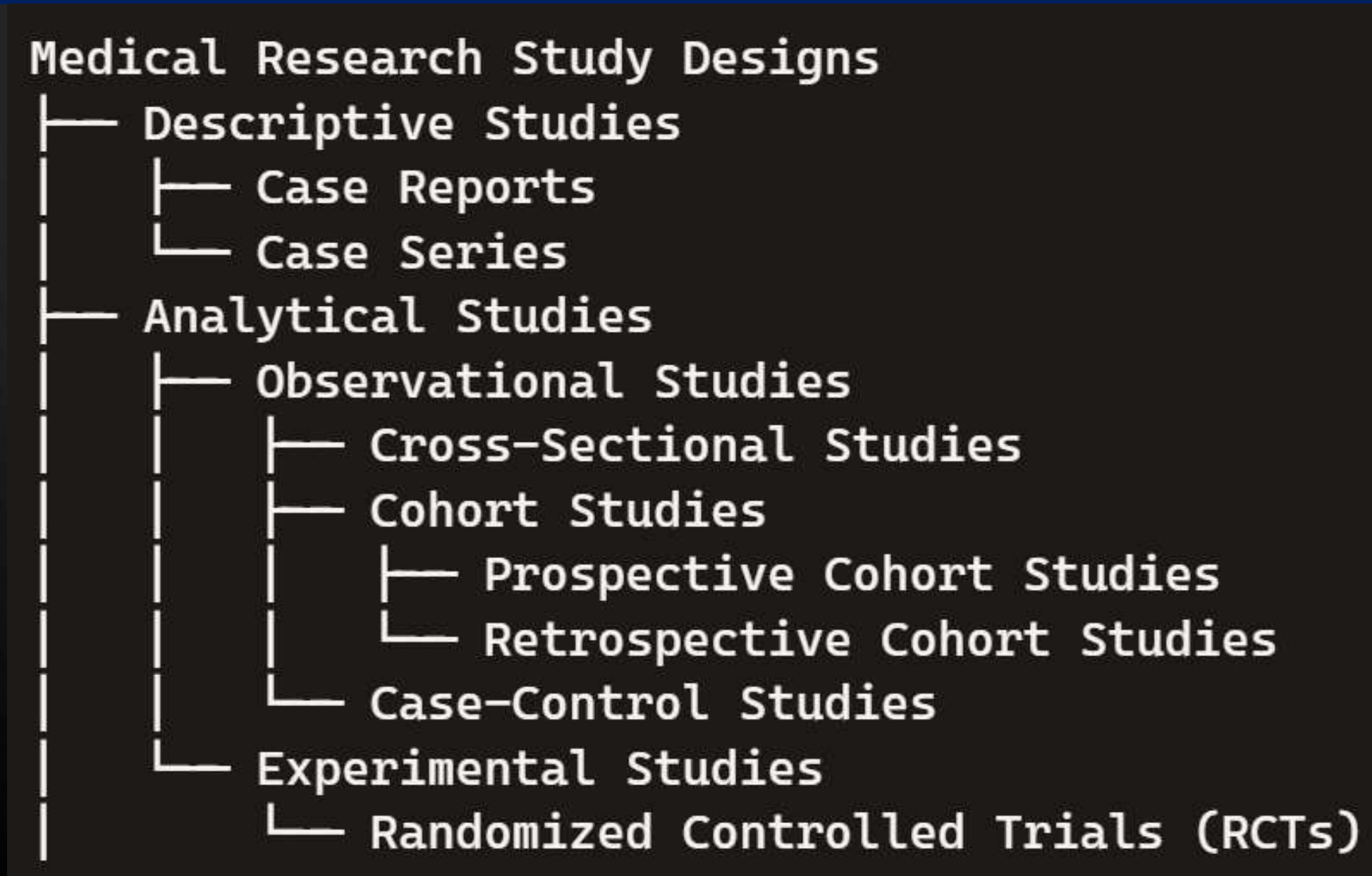
STUDY DESIGNS

- ✓ STUDY DESIGNS ARE THE FRAMEWORK THAT GUIDES
  - ✓ PLANNING
  - ✓ EXECUTION
  - ✓ ANALYSIS OF THE MEDICAL RESEARCH
- ✓ ENSURE SOUND RESEARCH METHOD
- ✓ ENSURE RELIABLE & VALID RESULTS

STUDY DESIGNS - TYPES



STUDY DESIGNS – OBSERVATIONAL STUDIES

COHORT STUDIES

- ✓ **DESCRIPTION:** THESE STUDIES FOLLOW A GROUP OF PEOPLE (COHORT) OVER A PERIOD OF TIME TO OBSERVE THE DEVELOPMENT OF OUTCOMES BASED ON EXPOSURE TO CERTAIN RISK FACTORS.
- ✓ **TYPES:** PROSPECTIVE (PARTICIPANTS ARE FOLLOWED INTO THE FUTURE) AND RETROSPECTIVE (LOOKING BACK AT PAST DATA).
- ✓ **EXAMPLE:** A STUDY TRACKING THE HEALTH OUTCOMES OF SMOKERS VS. NON-SMOKERS OVER 20 YEARS.

STUDY DESIGNS – COHORT STUDY

Adverse events with radiographic contrast agents: results of the SCVIR Contrast Agent Registry

M A Bettmann [1], T Heeren, A Greenfield, C Goudey

Affiliations + expand

PMID: 9169677 DOI: 10.1148/radiology.203.3.9169677

Abstract

Purpose: To determine prospectively the incidence of adverse events in angiography related to contrast agents, and the relative incidence of events with use of high-osmolality contrast agents (HOCAs) and low-osmolality contrast agents (LOCAs) and to ascertain if risk factors can help identify increased risk of an adverse event and patients likely to benefit from use of LOCAs.

Materials and methods: From 26 high-volume institutions, data were collected on every patient who underwent angiography from July 1, 1990, to June 30, 1992. Information included demographic and risk factors, general medical status, previous administration of contrast media, procedural information, occurrence and characteristics of all adverse events up to 12 hours after procedures, and relation to contrast agents, treatment, and outcome.

Results: In 60,891 patients, there were 75,616 studies, 56% with nonionic LOCAs, 8% with the ionic LOCA, and 36% with HOCAs. Most major risk factors correlated with an increased incidence of adverse events related to contrast media. Incidence of these adverse events varied with type of procedure, with a higher incidence associated with cardiac and interventional procedures. Overall adverse events related to contrast media and those for which treatment was necessary were significantly increased ($P < .001$) with use of HOCAs for all but arterial interventional procedures. Serious adverse events were not different between the two classes of agents except for cardiac procedures. Previous reaction to contrast medium was the most important risk factor in prediction of an adverse event.

Conclusion: The safety benefit of use of LOCAs is limited. Patients most likely to benefit are those with a previous reaction or more than one other major risk factor. Selective use of LOCAs is an appropriate strategy.

STUDY DESIGNS – OBSERVATIONAL STUDIES

CASE-CONTROL STUDIES

- ✓ **DESCRIPTION:** THESE STUDIES COMPARE INDIVIDUALS WITH A SPECIFIC CONDITION (CASES) TO THOSE WITHOUT THE CONDITION (CONTROLS) TO IDENTIFY POTENTIAL RISK FACTORS.
- ✓ **RETROSPECTIVE NATURE:** TYPICALLY, THESE STUDIES ARE RETROSPECTIVE, LOOKING BACK AT DATA FROM BOTH GROUPS.
- ✓ **EXAMPLE:** INVESTIGATING THE DIETARY HABITS OF PATIENTS WITH A RARE CANCER COMPARED TO A SIMILAR GROUP WITHOUT THE CANCER.

STUDY DESIGNS – CASE-CONTROL STDUY

Cervical spine imaging in patients with trauma: determination of fracture risk to optimize use

C C Blackmore [1], S S Emerson, F A Mann, T D Koepsell

Affiliations + expand

PMID: 10352603 DOI: 10.1148/radiology.211.3.r99jn22759

Abstract

Purpose: To develop a method to use clinically apparent factors to determine cervical spine fracture risk to guide selection of optimal imaging strategies.

Materials and methods: Records from 472 patients with trauma (168 with fractures, 304 control patients) who visited the emergency department in 1994 and 1995 were reviewed for 20 potential predictors of cervical spine fracture in this retrospective case-control study. Simple logistic regression was used to determine predictors of cervical spine fracture. Prediction rules were formulated by using multiple logistic regression and recursive partitioning with bootstrap validation. Posttest fracture probabilities were calculated from base prevalence and likelihood ratios derived for predictors by using Bayes theorem.

Results: Predictors of cervical spine fracture included severe head injury (adjusted odds ratio [OR] = 8.5, 95% CI: 4.0, 17.0), high-energy cause (OR = 11.6, 95% CI: 5.4, 25.0), and focal neurologic deficit (OR = 58, 95% CI: 12, 283). The prediction rule was used to stratify patients into groups with fracture probabilities of 0.04%-19.70%. After adjusting for overfitting, the area under the receiver operating characteristic curve was 0.87.

Conclusion: Clinically apparent factors, including cause of injury, associated injuries, and age, can be used to determine the probability of cervical spine fracture. Development of evidence-based imaging guidelines should incorporate knowledge of fracture probability.

STUDY DESIGNS – OBSERVATIONAL STUDIES

CROSS-SECTIONAL STUDIES

- ✓ **DESCRIPTION:** THESE STUDIES ANALYZE DATA FROM A POPULATION AT A SPECIFIC POINT IN TIME. THEY ASSESS THE PREVALENCE AND RELATIONSHIP OF VARIABLES.
- ✓ **SNAPSHOT IN TIME:** PROVIDES A SNAPSHOT OF THE HEALTH AND RISK FACTORS WITHIN A POPULATION.
- ✓ **EXAMPLE:** A SURVEY MEASURING THE PREVALENCE OF DIABETES IN A COMMUNITY AT ONE PARTICULAR TIME.

STUDY DESIGNS – CROSS-SECTIONAL STUDY

Cross-sectional analysis of whole-brain microstructural changes in adult patients with bipolar and unipolar depression by diffusion kurtosis imaging

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PMCID: PMC10034704 PMID: 35817080

Abstract

Rationale and Objectives

More than half of the bipolar depression (BD) subjects are misdiagnosed as unipolar depression (UD) due to lack of objective diagnostic criteria. We aimed to identify microstructural neuronal changes differentiating BD from UD groups using diffusion kurtosis imaging (DKI). The objective of the study is to identify an objective neuro-imaging marker to differentiate BD from UD.

Materials and Methods

A prospective, cross-sectional study included total of 62 subjects with diagnosis of bipolar depression (n = 21), unipolar depression (n = 21), and healthy controls (n = 20). All subjects underwent diffusion-weighted imaging (b = 0,1000,2000) of the whole brain on 3-Tesla MR scanner. DKI data was analyzed using 189 region whole-brain atlas. Eight diffusion and

STUDY DESIGNS – OBSERVATIONAL STUDIES

CASE SERIES AND CASE REPORTS

- ✓ **DESCRIPTION:** THESE STUDIES DESCRIBE THE CHARACTERISTICS AND OUTCOMES OF A SMALL NUMBER OF PATIENTS WITH A SPECIFIC CONDITION (CASE SERIES) OR A SINGLE PATIENT (CASE REPORT).
- ✓ **DESCRIPTIVE NATURE:** THESE STUDIES ARE PURELY DESCRIPTIVE AND DO NOT INVOLVE A CONTROL GROUP.
- ✓ **EXAMPLE:** DETAILED REPORT OF AN UNUSUAL SIDE EFFECT OBSERVED IN ONE PATIENT.

STUDY DESIGNS – CASE REPORT

Case Report

The Fatty Dilemma: A Rare Instance of Extra- and Intravascular Lipoma of the Brachiocephalic Vein

Roja Hiregouja Eranna , Suhasini Devi Pokanati , B. Rajkumar

› Author Affiliations

› Further Information

› Also available at eRef MedOne

Abstract | Full Text | References

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Abstract

Oftentimes, incidental findings are made on routine diagnostic imaging. An intra- and extravascular lipoma is one example of an important incidental finding. Intravascular lipomas are rare benign vascular tumors that are typically asymptomatic. They are most commonly found in the inferior vena cava but have also been recorded in the superior vena cava, brachiocephalic vein, subclavian vein, internal jugular vein, external jugular vein, and common femoral vein. Here, we presented the case of a 64-year-old female patient with an incidentally discovered intra- and extravascular lipoma affecting the right subclavian and brachiocephalic veins. While benign, intravascular lipoma on imaging can resemble a malignant tumor such as leiomyosarcoma or thrombus. As a result, appropriate identification and classification of this imaging finding is crucial for avoiding an exorbitant and futile workup.

Keywords

lipoma - intravenous lipoma - intra- and extravascular lipoma - brachiocephalic vein - intravascular tumor

Patient Consent

QUIZ

WHAT IS THE MAIN CHARACTERISTIC THAT DISTINGUISHES AN OBSERVATIONAL STUDY FROM AN EXPERIMENTAL STUDY, AND WHY IS IT IMPORTANT TO ACCOUNT FOR POTENTIAL CONFOUNDING VARIABLES IN AN OBSERVATIONAL STUDY?

A) OBSERVATIONAL STUDIES INVOLVE RANDOM ASSIGNMENT OF SUBJECTS TO DIFFERENT GROUPS.
B) OBSERVATIONAL STUDIES DO NOT INVOLVE INTERVENTION OR MANIPULATION BY THE RESEARCHER.
C) OBSERVATIONAL STUDIES ALWAYS HAVE HIGHER STATISTICAL POWER THAN EXPERIMENTAL STUDIES.
D) OBSERVATIONAL STUDIES ARE ALWAYS LESS RELIABLE THAN EXPERIMENTAL STUDIES.

ANSWER

B) OBSERVATIONAL STUDIES DO NOT INVOLVE INTERVENTION OR MANIPULATION BY THE RESEARCHER.

EXPLANATION: THE MAIN CHARACTERISTIC THAT DISTINGUISHES AN OBSERVATIONAL STUDY IS THAT IT DOES NOT INVOLVE INTERVENTION OR MANIPULATION BY THE RESEARCHER; INSTEAD, THE RESEARCHER OBSERVES AND COLLECTS DATA ON NATURALLY OCCURRING VARIABLES. ACCOUNTING FOR POTENTIAL CONFOUNDING VARIABLES IS IMPORTANT BECAUSE THESE VARIABLES CAN AFFECT THE OBSERVED OUTCOMES AND LEAD TO INCORRECT CONCLUSIONS ABOUT THE RELATIONSHIPS BETWEEN VARIABLES.

THANK YOU