KREP

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KARNATAKA RADIOLOGY EDUCATION PROGRAM

CLINICAL RESEARCH – BRIDGING IMAGING & INNOVATION

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

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STUDY DESIGNS – EXPERIMENTAL STUDIES

RANDOMIZED CONTROLLED TRIALS (RCTS)

- ✓ **DESCRIPTION:** PARTICIPANTS ARE RANDOMLY ASSIGNED TO EITHER AN INTERVENTION GROUP OR A CONTROL GROUP TO COMPARE THE EFFECTS OF THE INTERVENTION.
- ✓ **GOLD STANDARD:** CONSIDERED THE GOLD STANDARD FOR EVALUATING THE EFFICACY OF TREATMENTS.
- ✓ **EXAMPLE:** A STUDY COMPARING THE EFFECTIVENESS OF A NEW DRUG VERSUS A PLACEBO.

STUDY DESIGNS – RANDOMIZED CONTROL TRIAL

Small hepatocellular carcinoma in cirrhosis: randomized comparison of radio-frequency thermal ablation versus percutaneous ethanol injection

Riccardo A Lencioni [1], Hans-Peter Allgaier, Dania Cioni, Manfred Olschewski, Peter Deibert, Laura Crocetti, Holger Frings, Joerg Laubenberger, Ina Zuber, Hubert E Blum, Carlo Bartolozzi

Affiliations + expand

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Abstract

Purpose: To compare the effectiveness of radio-frequency (RF) thermal ablation with that of percutaneous ethanol injection (PEI) for the treatment of small hepatocellular carcinoma (HCC) in patients with cirrhosis.

Materials and methods: A series of 102 patients with hepatic cirrhosis and either single HCC 5 cm in diameter or smaller or as many as three HCCs each 3 cm or smaller (overall number of lesions, 142) randomly received either RF ablation (n = 52) or PEI (n = 50) as the sole first-line anticancer treatment. Mean follow-up was 22.9 months +/- 9.4 (SD) in the RF group and 22.4 months +/- 8.6 in the PEI group. Prognostic value of treatment techniques was assessed with univariate and multivariate Cox proportional hazards regression models.

Results: One- and 2-year survival rates were 100% and 98% in the RF group and 96% and 88% in the PEI group, respectively (univariate relative risk [RR] = 0.20; 95% CI: 0.02, 1.69; P =.138). One- and 2-year local recurrence-free survival rates were 98% and 96% in the RF group and 83% and 62% in the PEI group, respectively (univariate RR = 0.17; 95% CI: 0.06, 0.51; P =.002). One- and 2-year event-free survival rates were 86% and 64% for the RF group and 77% and 43% for the PEI group, respectively (univariate RR = 0.48; 95% CI: 0.27, 0.85; P =.012). RF treatment was confirmed as an independent prognostic factor for local recurrence-free survival rates with multivariate analysis (adjusted RR = 0.20; 95% CI: 0.05, 0.73; P =.015).

Conclusion: RF ablation is superior to PEI with respect to local recurrence-free survival rates.

STUDY DESIGNS – EXPERIMENTAL STUDIES

QUASI-EXPERIMENTAL STUDIES

- ✓ **DESCRIPTION:** SIMILAR TO RCTS, BUT PARTICIPANTS ARE NOT RANDOMLY ASSIGNED TO GROUPS. OFTEN USED WHEN RANDOMIZATION IS NOT FEASIBLE.
- ✓ **LESS CONTROL:** THESE STUDIES MAY BE SUBJECT TO CONFOUNDING VARIABLES THAT COULD AFFECT THE OUTCOME.
- ✓ **EXAMPLE:** EVALUATING THE IMPACT OF A PUBLIC HEALTH INTERVENTION IMPLEMENTED IN ONE CITY BUT NOT IN ANOTHER.

STUDY DESIGNS – QUASI-EXPERIMENTAL STUDIES

Educational Module Intervention for Radiographers to Reduce Repetition Rate of Routine Digital Chest Radiography in Makkah Region of Saudi Arabia Tertiary Hospitals: Protocol of a Quasi-Experimental Study

Abdullah A Almalki [1], Rosliza Abdul Manaf [1,✉,#], Muhamad Hanafiah Juni [1], Hayati Kadir Shahar [1], Noramaliza Mohd Noor [2], Abdelsafi Gabbad [3]

Editor: Gunther Eysenbach

Reviewed by: Pooyan Khalighinejad, Elizabeth Krupinski

▸ Author information ▸ Article notes ▸ Copyright and License information

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Abstract

Background

Repetition of an image is a critical event in any radiology department. When the repetition rate of routine digital chest radiographs is high, radiation exposure of staff and patients is increased. In addition, repetition consumes the equipment's life span, thus affecting the annual budget of the department.

Objective

The aim of this study is to determine the impact of a printed educational module on reducing the repetition rate of routine digital chest radiography among radiographers in Makkah

STUDY DESIGNS – EXPERIMENTAL STUDIES

BEFORE-AND-AFTER STUDIES

- ✓ **DESCRIPTION:** THESE STUDIES MEASURE OUTCOMES BEFORE AND AFTER THE IMPLEMENTATION OF AN INTERVENTION WITHIN THE SAME GROUP.
- ✓ **SELF-COMPARISON:** PARTICIPANTS SERVE AS THEIR OWN CONTROL GROUP.
- ✓ **EXAMPLE:** ASSESSING THE IMPACT OF A NEW SURGICAL TECHNIQUE BY COMPARING PATIENT OUTCOMES BEFORE AND AFTER ITS IMPLEMENTATION.

STUDY DESIGNS – BEFORE-AFTER STUDIES

Medical student knowledge regarding radiology before and after a radiological anatomy module: implications for vertical integration and self-directed learning

Kevin P. Murphy · Lee Crush · Eoin O'Malley · Fergus E. Daly · Colm M. P. O'Tuathaigh · Owen J. O'Connor · John F. Cryan · Michael M. Maher

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Abstract

Objectives To examine the impact that anatomy-focused radiology teaching has on non-examined knowledge regarding radiation safety and radiology as a specialty.

Methods First-year undergraduate medical students completed surveys prior to and after undertaking the first-year anatomy programme that incorporates radiological anatomy. Students were asked opinions on preferred learning methodology and tested on understanding of radiology as a specialty and radiation safety.

Results Pre-module and post-module response rates were 93 % (157/168) and 85 % (136/160), respectively. Pre-module and post-module, self-directed learning (SDL) ranked eighth (of 11) for preferred gross-anatomy teaching formats. Correct responses regarding radiologist/radiographer roles varied from 28-94 % on 16 questions with 4/16 significantly improving post-module. Identification of modalities that utilised knowledge regarding ionising radiation use, but there was no improvement in knowledge regarding radiation exposure relative per modality. A possible explanation is that students recall knowledge imparted in didactic lectures but do little reading around the subject when the content is not examined.

Teaching Points

- *Self-directed learning is not favoured as a gross anatomy teaching format amongst medical students.*
- *An imaging anatomy-focused module improved basic knowledge regarding ionising radiation use.*
- *Detailed knowledge of modality-specific radiation exposure remained suboptimal post-module.*
- *Knowledge of roles within a clinical radiology department showed little change post-module.*

Keywords Radiology · Medical student · Radiologist ·

STUDY DESIGNS – EXPERIMENTAL STUDIES

NON-RANDOMIZED CONTROLLED TRIALS

- ✓ **DESCRIPTION:** PARTICIPANTS ARE ASSIGNED TO INTERVENTION OR CONTROL GROUPS WITHOUT RANDOMIZATION.
- ✓ **POTENTIAL BIAS:** THERE IS A HIGHER RISK OF BIAS COMPARED TO RCTS DUE TO THE LACK OF RANDOMIZATION.
- ✓ **EXAMPLE:** COMPARING OUTCOMES IN HOSPITALS THAT ADOPT A NEW TREATMENT PROTOCOL WITH THOSE THAT DO NOT

STUDY DESIGNS – NON-RANDOMIZED CONTROLLED TRIAL

Research

Feasibility and effectiveness of a low cost campaign on antibiotic prescribing in Italy: community level, controlled, non-randomised trial

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Cite this as: *BMJ* 2013;347:f5391

Article | Related content | Metrics | Responses | Peer review

Giulio Formoso, epidemiologist,Barbara Paltrinieri, scientific journalist,Anna Maria Marata, clinical pharmacologist, Carlo Gagliotti, epidemiologist,Angelo Pan, infectivologist,Maria Luisa Moro, head of infective risk area,Oreste Capelli, pneumologist, Nicola Magrini, head of drug evaluation areafor the LOCAAL Study Group

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Accepted 16 August 2013

Abstract

Objectives To test the hypothesis that a multifaceted, local public campaign could be feasible and influence antibiotic prescribing for outpatients.

Design Community level, controlled, non-randomised trial.

Setting Provinces of Modena and Parma in Emilia-Romagna, northern Italy, November 2011 to February 2012.

Population 1 150 000 residents of Modena and Parma (intervention group) and 3 250 000 residents in provinces in the same region but where no campaign had been implemented (control group).

Interventions Campaign materials (mainly posters, brochures, and advertisements on local media, plus a newsletter on local antibiotic resistance targeted at doctors and pharmacists). General practitioners and paediatricians in the intervention area participated in designing the campaign messages.

Main outcomes measures Primary outcome was the average change in prescribing rates of antibiotics for outpatient in five months, measured as defined daily doses per 1000 inhabitants/day, using health districts as the unit of analysis.

QUIZ – READ THE BELOW ARTICLE; ANSWER THE FOLLOWING:
1. STUDY DESIGN
2. EVIDENCE PYRAMID POSITION

PostScript
Letter

Percutaneous cooled-probe microwave versus radiofrequency ablation in early-stage hepatocellular carcinoma: a phase III randomised controlled trial

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ANSWER

- ✓ STUDY DESIGN – RANDOMIZED CONTROLLED TRIAL
- ✓ EVIDENCE PYRAMID STATUS – UNFILTERED RESOURCES OF RANDOMIZED CONTROL TRIAL. NOT TO CONFUSE WITH EXPERT OPINION, WHICH IS THE COMMON SCENARIO IN LETTER TO EDITOR SECTION.
- ✓ WHAT MAY BE THE REASON FOR RCT PUBLISHED AS LETTER TO EDITOR ? NOTE THAT BMJ GUT – IMPACT FACTOR IS 24; AUTHORS HERE TARGETED THE HIGH IMPACT JOURNAL TO PUBLISH THEIR WORK.

THANK YOU