



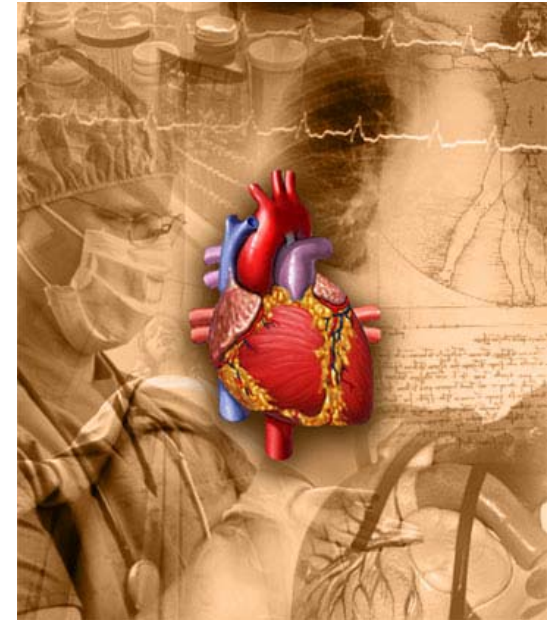
The
University
Of
Sheffield.

Can we trust patient-reported outcomes in health technology assessments?

A systematic review of the efficacy and safety of transmyocardial and percutaneous laser revascularisation for refractory angina pectoris

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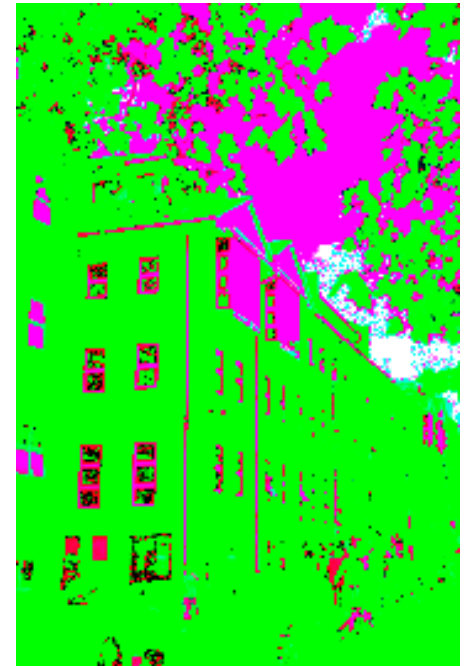
Presentation Outline

- Role of the research centre
- Interventions and evidence
- Methods
- Results
- Patient-reported outcomes
- Conclusion



Role of Research Centre

- ReBIP (the Review Body for Interventional Procedures)
 - Joint venture between University of Sheffield and Aberdeen University
 - Collaboration with the National Institute for Health and Clinical Excellence's (NICE) Interventional Procedures Programme (IPP)
- IPP Advisory Committee Requires:
 - Systematic reviews or additional data
 - Evidence for safety and efficacy





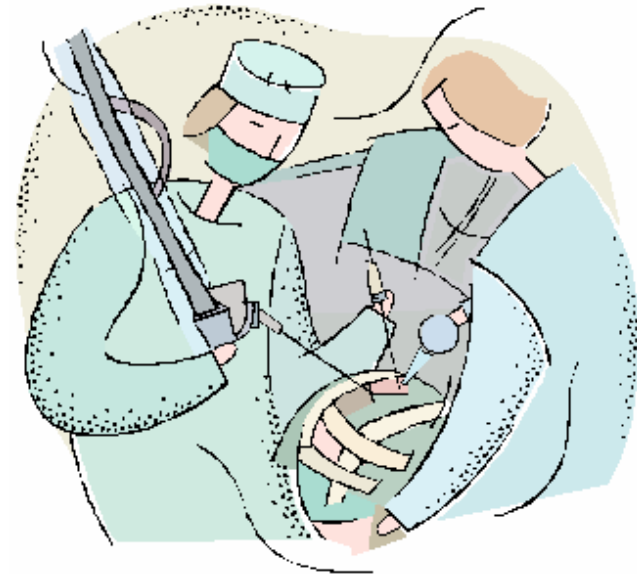
Interventions and Evidence

- Two Interventions:
 - Percutaneous laser revascularization (PMR)
 - Transmyocardial laser revascularization (TMLR)
 - Create shallow channels in the myocardium
 - Encourage revascularisation
 - Practised worldwide
 - Debated and poorly understood effects



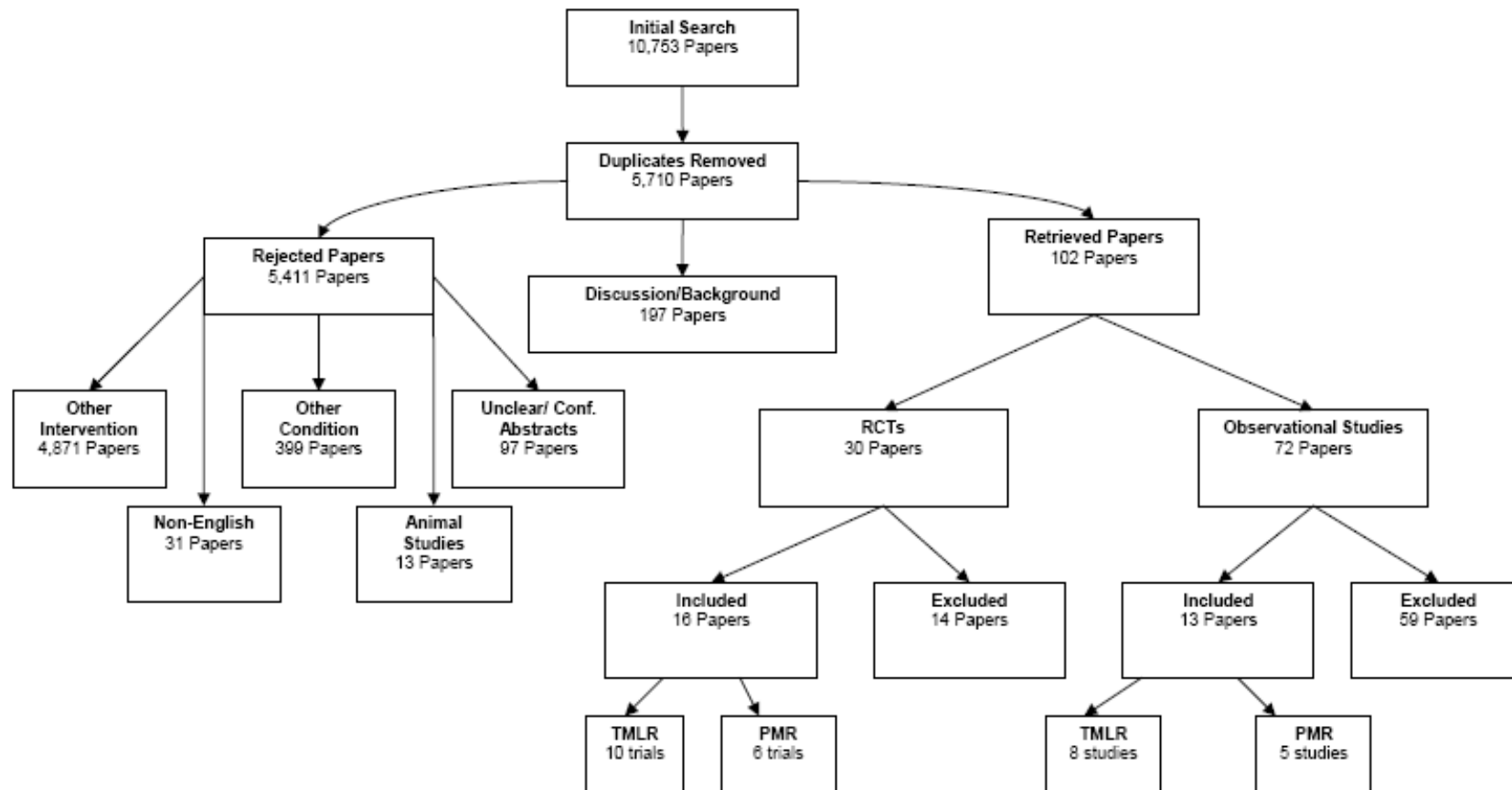
Methods Investigating Interventions

- Systematic review:
 - Electronic database searches and bibliographic searching
 - Exclusion and inclusion criteria
 - Types of interventions
- Outcomes of interest:
 - Mortality rate
 - Exercise tolerance test
 - Angina score
 - Quality of life
 - Left ventricular ejection fraction
 - Adverse events



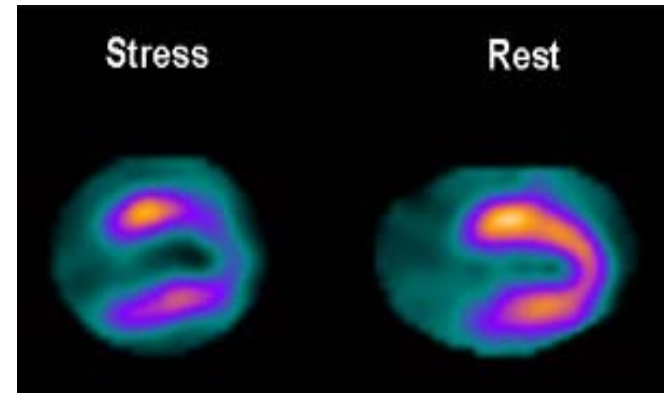


Paper Selection Process for Laser Angina Systematic Review



Results- TMLR Objective Outcomes

- Objectively assessed outcomes showed no difference between intervention and control:
 - Mortality at 12 months (OR 0.83 CI 0.49 to 1.41)
 - Myocardial perfusion tests (narrative analysis)
 - Left ventricular ejection fraction (LVEF) (narrative analysis)
- Statistically significant increased odds of perioperative death (OR 0.35 95% CI 0.13 to 0.93)
- Adverse events- range harmful events more likely to affect the intervention group



Results- TMLR Patient Reported Outcomes

- Patient reported outcomes showed a pattern of effect:
 - Exercise tolerance increase by 81.9 seconds (95% CI 26.7 to 137.3)
 - Angina score data reduced by -1 CCSA class (95% CI -1.7 to -0.3)
 - Quality of life scores data ???
- The effect of blinding
 - Exercise tests effects lost in sensitivity analysis
 - Angina scores and blinding
 - No blinding for quality of life



Results- PMR Objective Outcomes

- Objectively assessed outcomes showed no difference between intervention and control:
 - Mortality at 12 months (OR 0.74 95% CI 0.32 to 1.7)
 - Myocardial perfusion tests (1 trial, no significant difference between groups)
 - Left ventricular ejection fraction (LVEF) (2 trials, no significant difference between groups)
- Perioperative death- no difference between treatment and intervention group (odds ratio 1.35 95% CI 0.37 to 4.92)
- Adverse events- risks of experiencing a range of cardiovascular and vascular adverse events with treatment



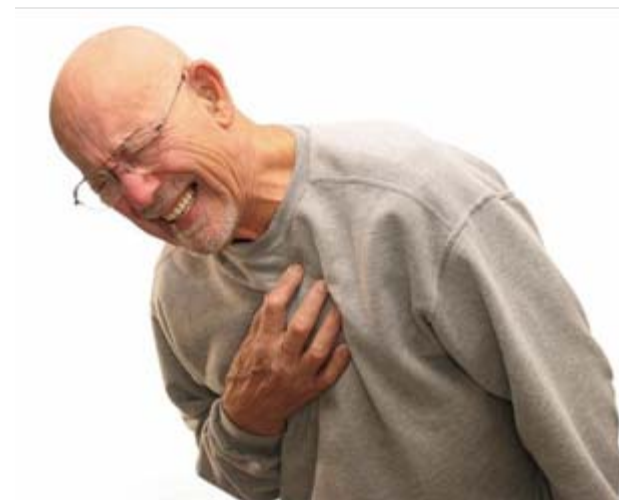
Results- PMR Patient Reported Outcomes

- Patient reported outcomes showed a pattern of effect:
 - Exercise tolerance increase by 17.7 seconds (95% CI 4.4 to 31.0).
 - Angina score data reduced by -1 CCSA class (95% CI -1.7 to -0.3)
 - Quality of life scores data- Only one trial found statistically significant difference between intervention and control
- The effect of blinding
 - Exercise tests and angina scores effects lost in sensitivity analysis
 - Quality of life



Trusting Patient-Reported Outcomes

- Patients with severe angina
- Exhausted all forms of conventional therapy
- Patients motivated to novel therapies for relief
- Patient-reported outcomes effects are lost when blinded





Conclusions

- Objective outcomes measures may be more reliable
- Patient-reported outcomes can be more reliable if blinding is considered
- Wider applicability of these findings

Sources of Information:

- NICE Report: [Systematic review of the efficacy and safety of transmyocardial and percutaneous laser revascularisation for refractory angina pectoris. A](#)
- Available online:
http://www.nice.org.uk/nicemedia/pdf/374_and_390_Angina_review_for_web_120509.pdf
- Google Keywords: [Laser Angina NICE](#)
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