Better Electrocardiography Stress Testing

BEST study

Improving exercise electrocardiographic stress test (EST) utility through the development and evaluation of a culturally and linguistically appropriate patient education resource

STUDY OUTLINE

Contents

The Issue – inconclusive exercise electrocardiography stress tests can delay diagnosis of coronary heart disease or result in unnecessary additional testing

Background

Alice Springs Hospital (ASH), in the Northern Territory of Australia, services a dispersed and remote population of approximately 45 000 people spread over 1 million square kilometers of Central Australia. Indigenous Australians (predominantly Aboriginal Australians) represent 44% of this population.

Several primary traditional languages are spoken by Aboriginal people in Central Australia. Whilst English is often the primary means of communication between health care providers and consumers this often fails to recognize the fact that English language comprehension for Aboriginal people can be variable with English being one of several languages spoken. This may be poorly appreciated by health care providers who can sometimes assume a greater level of comprehension and understanding than is actually present. This issue is further compounded by variable health literacy and a difficulty in appreciating differences in culture and expectations between patients and health care providers. Together these can place significant impediments for patients in understanding health provider expectations and directions, potentially influencing optimal outcomes for patients, health care providers and the health system more generally.

We have shown difficulties in communication may have real implications for health service delivery. In our earlier study of electrocardiography stress testing (EST) in Alice Springs in Central Australia we found Aboriginal Australians were, independent of all other factors, nearly four times as likely (odd ratio 3.7, 95% CI 2.1–6.6) to have an inconclusive EST when undergoing investigation for possible coronary heart disease (CHD) compared with non-Indigenous Australian patients. This translated to over half Aboriginal patients (52.8%, 95% CI 42.9%–62.5%) having an inconclusive EST. Whilst there may be many factors that might influence this it is likely issues pertaining to intercultural and English language communication are key.

The implications of an inconclusive EST are significant. Typically such patients require further, more complicated and expensive myocardial stress testing in the form of CT coronary angiography or stress echocardiography. Whilst such procedures can place additional expense on the health system and inconvenience for patients they also typically entail a significant delay of weeks to months and a risk of patients being lost to ongoing clinical follow-up. This may be compounded by the difficulty patients residing in remote communities have in returning to regional centres such as Alice Springs. These issues relating to delay in diagnosis, being lost to follow-up and difficulty returning for further investigation all place such patients at a potentially preventable risk of cardiac events and particularly acute coronary syndrome (ACS) (a.k.a heart attack) with the potential consequences of sudden death or irreversible heart damage and eventual heart failure.

Given the high level of inconclusive EST results in Aboriginal Australians we believe a concerted effort to develop and evaluate a culturally and linguistically appropriate

information resource to inform EST conduct for Aboriginal Australians is warranted. A proposal for a research project to undertake such an initiative is outlined below with the aim of improving the utility of EST in this setting.

Aims

1. To develop a culturally and linguistically appropriate patient education tool to inform conduct of EST in Aboriginal and non-Indigenous Australians
2. To evaluate this tool to determine if it can reduce the proportion of inconclusive EST results

Hypothesis

A culturally and linguistically appropriate audio-visual resource will be associated with reduced inconclusive EST results in Aboriginal and non-Indigenous Australians undergoing investigation for possible CHD.

Research plan

This proposal will encompass the development and piloting of the evaluation of a culturally and linguistically appropriate patient education audio-visual tool to inform the conduct of EST in Aboriginal and non-Indigenous Australians.

BEST tool development

The development of the intervention tool will be based on the principles of adult education and training. Particularly it will adopt an approach of providing a graded education and training experience that moves from more to less structure. It will acknowledge that preferred learning styles vary and will utilize an advisory group incorporating consumers and expert clinicians to inform the content, style and ultimate learning aims of the resource. It is envisaged the content will particularly address the rationale for an EST and provide a stepped approach to its conduct including the importance of being able to complete the test. Issues raised by the advisory group which may influence successful EST completion (e.g. fear of harm) will be specifically addressed.

Once the project resource script is developed it will be translated from English into seven local Central Australian Aboriginal languages. A professional production company with experience in this setting and in the development of similar cross-cultural resources (Fringe Dweller Productions) will be utilized to facilitate this process via a number of workshops with paid Aboriginal language speakers, non-Indigenous Australians, expert clinicians and actors.

It is anticipated the final resource will comprise an approximately ten minute audio-visual presentation with the ability to dub the sound track in English or one of seven Aboriginal languages as well as English subtitling.

BEST tool evaluation

Once developed the BEST tool will be evaluated by undertaking a randomized controlled trial. This trial aims to evaluate the BEST tool's impact on reducing inconclusive EST results in Aboriginal and non-Indigenous Australian patients presenting to the ASH with suspected CAD.

It is anticipated this evaluation will eventually extend to other hospital sites to ensure sufficient enrolments (specifically Cairns and Royal Darwin Hospital have indicated interest). Nonetheless at this stage this proposal will only seek to evaluate the feasibility of such a study at a single site.

Participants

Inclusion criteria:

1. >=18 years of age
2. patient (Aboriginal or non-Indigenous Australian) undergoing maximal EST at the Alice Springs Hospital
3. inpatient/outpatient
4. able to provide informed consent

Exclusion criteria

1. < 18 years of age
2. clinician assessment deems physically incapable of undergoing an EST
3. maximal EST deemed inappropriate by supervising clinician (e.g. uninterpretable electrocardiogram (ECG) such as left bundle branch block)
4. maximal EST deemed to be contraindicated by supervising clinician (e.g. recent ACS)
5. unable/unwilling to provide informed consent

Intervention

Participants will be randomly allocated to the active intervention or control intervention using a system of concealed allocation. All study participants will also receive usual care including briefing and instruction prior to and during the EST from technicians and supervising clinicians.

Active intervention

The BEST tool will be played to the study participants using a hand-held tablet computer (iPad) in English or one of seven local Central Australian Indigenous languages. The preference for language will be determined by subject self-selection.

Control intervention

The control intervention will be a placebo version of the BEST tool. This will be a ten-minute Heart Foundation educational video 'Warning signs of a heart attack'. This resource will only be available in English.

Informed consent

Potential participants will be assessed against inclusion and exclusion criteria. Those that are suitable will be provided with a brief description of the study. If they agree they will be provided with a written information sheet and will be asked to sign a consent form.

Randomization and allocation

Once informed consent is obtained eligibility will be reassessed and if the patient is suitable they will be allocated a sequential unique study identification number. Only once this code is allocated will a double sealed envelop be opened which matches this identification number to active or control intervention. The order of allocation will be pre-determined using a random list generated by the Stata statistical package ‘runiform’ command.

Data collection

Data collection will relate to patient demographics, potential confounders associated with successful completion of EST, potential factors associated with health and English literacy and the outcome of the EST.

Primary endpoint

This will be the proportion of participants with an EST outcome defined as conclusive (positive or negative) or inconclusive.

A conclusive test will be defined as an EST that was terminated due to a factor apart from patient fatigue, shortness of breath, wheezing, leg cramps, or claudication. Whilst the indications for terminating an EST will be based on existing clinical practice these typically relate to defined absolute and relative indications that reflect the American Heart Association’s Exercise Standards for Testing and Training. In this case the only relative indication for test termination that WILL NOT be sufficient rationale for determining a conclusive EST result will be ‘Fatigue, shortness of breath, wheezing, leg cramps, or claudication’.

An **inconclusive test** will be defined as a failure to reach 85% of the age-predicted maximal heart rate unless the test is terminated for an absolute or relative indication (except fatigue, shortness of breath, wheezing, leg cramps, or claudication).

Demographic and additional data

Additional data collected will include participant demographics (age, gender, ethnicity, usual place of residency), the language selected for the BEST tool (if allocated to this) and factors

that may influence comprehension (language spoken at home, highest level of formal education).

Sample size and statistical analysis

This study will comprise a piloting of this methodology prior to anticipated extension to other sites. Whilst it would require the enrolment of 206 Aboriginal people to detect a reduction in the proportion of inconclusive tests from 50% to 30% (compared with 20% for non-Indigenous Australians) (assumed alpha 0.05, beta 0.2, power 0.8) this study will commence with the aim of enrolling 100 patients undergoing an EST, 50 randomized to the active intervention and 50 to the control intervention, with equal numbers of Aboriginal and non-Indigenous Australian participants. Currently Alice Springs Hospital conducts approximately 270 ESTs per year.

Statistical analysis will be undertaken using Stata 13 (StataCorp, Texas, USA). Analysis of the primary endpoint will be undertaken using the χ^2 statistic. Factors associated with a conclusive as compared with inconclusive test will be investigated using standard bivariate techniques and multivariable logistic regression. A p value less than 0.05 will be taken to indicate statistical significance and all tests will be two-sided.

Ethical considerations

The risks for participants associated with participating in this study will be minimal. Selection and conduct of the EST will be as per usual clinical care and will not in itself form a component of this study. It is not anticipated watching either the active or control intervention video will pose any significant risk to participants. The main issue will be that of informed consent and confidentiality. A patient information sheet will be provided and the study explained (where necessary using hospital local language translator and Indigenous liaison officers) in line with usual clinical care at Alice Springs Hospital prior to signing a consent form. Standard techniques for confidentiality and data security will be applied including the use of locked filing cabinets, password protected databases and de-identified final analysis. No individual participants will be identified in final dissemination and translation of the project findings. At all times Good Clinical Practice for the conduct of human clinical trails will be adhered to (www.tga.gov.au/word/clinical-trials-handbook.docx).

Ethics approval will be sought from the Central Australian and Deakin University Human Research Ethics Committees (where Ricky Mentha – a research Masters student involved in this study is enrolled).

Trial registration

Following ethics approval the trial will be registered with the Australian New Zealand Clinical Trials Registry (www.anzctr.org.au).

Advisory groups

Two advisory groups will be formed; one community advisory committee consisting of five local Indigenous community members to discuss the study and identify if there are cultural sensitivities researchers should consider.

The second advisory group will consist of clinical experts such as a cardiac nurse coordinator, cardiology registrar, cardiology technician and a Northern Territory visiting cardiologist, to identify key content for the BEST tool and health system factors the researchers may need to consider in developing the resource and implementing this study.

Resource implications and in kind support

The time of the student research (Ricky Mentha) will be provided as part of existing study leave (currently 0.2 FTE) provided by his employer (Baker IDI). Research project supervision will also be provided by Graeme Maguire (physician at Alice Springs Hospital, Professor of Medicine (Monash University) and Associate Director and researcher, Baker IDI Aboriginal Health program) and Wendy Anders (Lecturer Institute of Koorie Education, Deakin University).

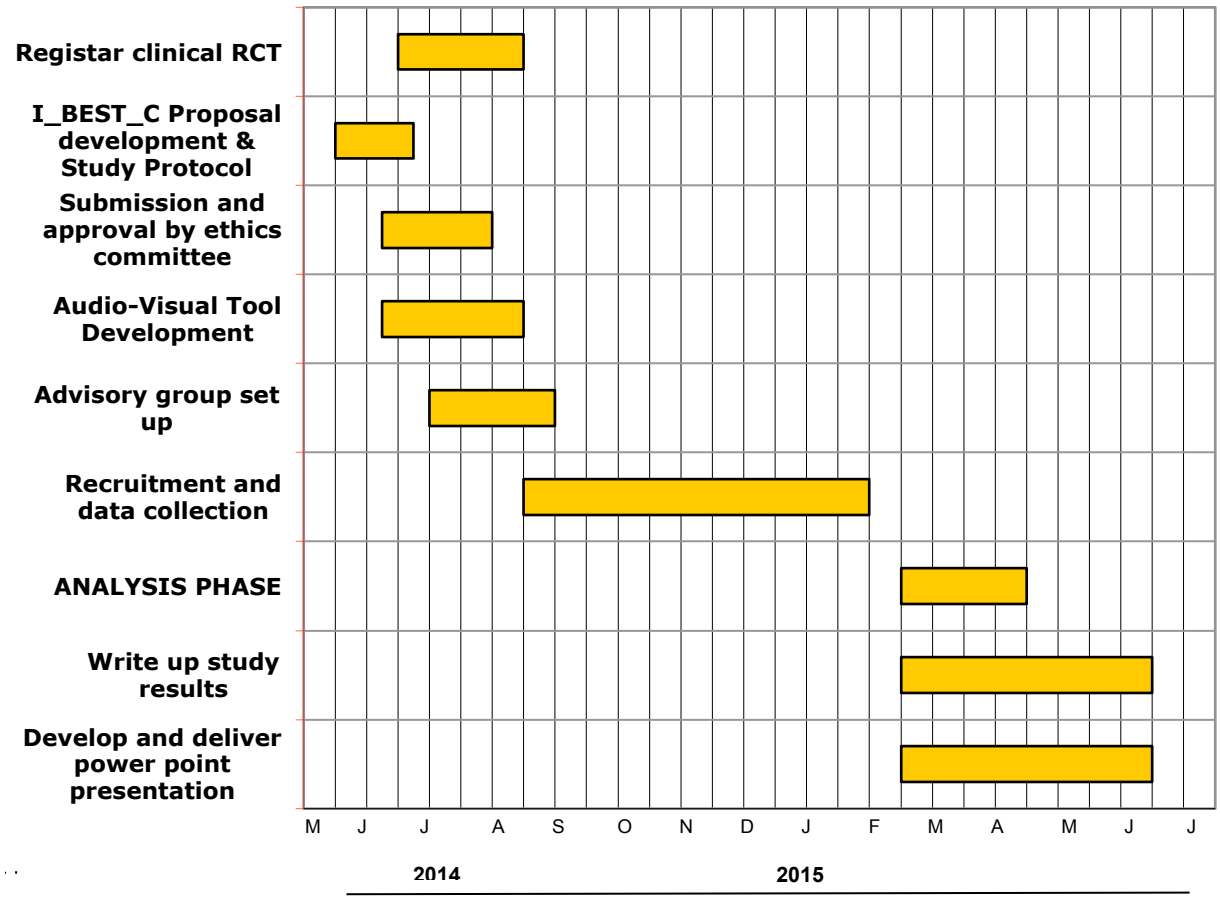
In consultation with the cardiac technicians the ability of these Alice Springs Hospital employees to facilitate consent will be explored. It is anticipated this would take at most five minutes for each participant. Funding has been identified to support the development of the audio-visual resource production and the time of the Indigenous advisory group members and translators.

Implications for patients and health care

If shown to be effective this resource will expedite the diagnosis of CHD and reduce the need, cost and inconvenience associated with further investigation for patients with suspected CHD. As such it has the potential to improve patient outcomes and facilitate time and cost savings for Alice Springs Hospital and cardiology services more generally.

Time Line

An overview of the proposed study time line is outlined in the Gantt below. If this piloting study is shown to be feasible then opportunities to adapt the resource and expand its evaluation to other Australian sites with significant Aboriginal and Torres Strait Islander populations (e.g. Darwin, the Kimberley in Western Australia and Cairns and Townsville in far north Queensland) will be explored.



Study summary