Centre universitaire de santé McGill

McGill University Health Centre

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Technology Assessment Unit of the McGill University Health Centre

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MANDATE

Mission Statement

- To advise the hospital in difficult resource allocation decisions, using an approach based on sound, scientific technology assessments, and a transparent, fair decision-making process.
- To publish its research in peer-reviewed journals when appropriate, and contribute to the training of personnel in the field of health technology assessment.

Vision

Using the best available scientific evidence, TAU aims to aid in the delivery of quality health care, and the efficient utilization of medical resources.

"Doubt is not a pleasant condition, but certainty is an absurd one."
Voltaire (1694 - 1778)

TAU COMPOSITION

TAU is composed of a scientific research staff, and an inter-disciplinary policy committee representing physicians, nurses, allied health professionals, and patients.

Policy Committee

Nandini Dendukuri	**TAU Director**
James Brophy	**Chairperson**
Maurice McGregor	**Chair Emeritus**
External committee members	Discipline
André Bonnici	Pharmacy & Therapeutics
Sandra Dial	Clinical Epidemiology
Christian Janicki	Quality Management
Patricia Lefebvre	Quality Management
Brenda MacGibbon-Taylor	Patients' Committee
Gary Pekeles	Council of Physicians & Dentists
Guylaine Potvin	Multidisciplinary Council
Patricia O'Connor	Council of Nurses
Hugh Scott	Consultant (Invited Member)
Vacant	Administration

Research Staff

Nisha Almeida	Research Scientist
David Felipe Forero	Research Assistant
Lorraine Mines	Administrative Technician
Alain Lapointe	Consultant

TAU REPORTS

NOTE

Projects are researched and drafts prepared by the research staff of the MUHC TAU, referred to below as "the authors". They are assisted by expert consultants appointed for each project. Draft reports are then circulated, reviewed, amended and finally approved by the full TAU Policy Committee who thereby take ownership of the recommendations made.

DIFFUSION

- Our reports are indexed in the international database for the Center for Reviews and Dissemination, York University, UK: http://www.crd.york.ac.uk/CRDWeb/
- Our reports are diffused from our website: www.muhc.ca/tau

The following reports were completed this year, and are described in greater details in the following pages:

Cardiac Resynchronization Therapy in Heart Failure

Title

Cardiac Resynchronization Therapy (CRT) in Heart Failure

Requestor

Ann Lynch, Associate Director General, Clinical Operations, Adult Missions, McGill University Health Centre

Publication Date

February 22, 2016

Authors

Eva Suarthana, Nisha Almeida and Nandini Dendukuri

Background

Since the first review of cardiac resynchronisation therapy (CRT) by the Technology Assessment Unit (TAU) in 2004, there has been an expansion of the indications for its use and a steady increase in the number of devices implanted in the McGill University Health Centre (MUHC). Although landmark trials show that cardiac resynchronisation therapy (CRT) is beneficial in heart failure patients, it has also been reported that as many as one third of the patients who received the device did not respond and would have been subjected to the additional costs and risks of the procedure for no further benefit.

Conclusions

- There is sufficient evidence to support the use of CRT for patients with NYHA Class II/III, severely prolonged QRS interval (>150 msec); LBBB morphology, and LVEF 30%. Though some guidelines and HTAs have recommended CRT use in these subgroups, their recommendations appear to be based on the entry criteria and not the actual characteristics of patients enrolled in the RCTs. (It should be noted that unlike clinical guideline documents our report does not provide guidance on how individual patients should be treated. Rather our focus has been to distinguish between those situations where there is good evidence to support the use of CRT and where there is not. The decision to treat an individual patient is left to the discretion of the treating physician.)

- QRS duration >150 msec is the strongest predictor of CRT response. QRS morphology i.e. the presence of LBBB may also be a potential indicator of good response to CRT.
- The use and budget impact of CRT-P and CRT-D at the MUHC has been increasing over the years. Since 2015 the MUHC has adopted a new funding model under which the cost of these devices is now covered within the global Cardiology budget.
- At the MUHC, there is currently no systematic documentation of patient selection criteria or evaluation of patient outcomes following CRT.

Recommendations

- The use of CRT is recommended for the treatment of heart failure patients only after careful consideration of clinical criteria known to influence the outcomes (i.e. severely prolonged QRS interval and LBBB morphology).
- Given the paucity of evidence in the literature and lack of consensus in published guidelines regarding other criteria (including NYHA Class IV-ambulatory, moderate QRS interval (120-150 msec), non-LBBB morphology, and LVEF >30%), it is necessary to systematically document patient selection criteria for CRT and to evaluate whether patient outcomes improve following CRT. Furthermore, as clinical decision-making requires taking into consideration multiple factors such as patient preference, referring doctor preference, and comorbidities, among other variables, it is necessary that these reasons also be systematically documented.
- The increasing use, high costs and residual uncertainty of the benefits of CRT in certain patients underscore the need for the development of a database to systematically document patient selection criteria and outcomes. The availability of local data is important for hospital decision-making and patient welfare. Furthermore, in light of reduced government funding and an impending provincial evaluation of CRT, unavailability of local data may further hamper funding of a technology with proven benefits in a significant proportion of heart failure patients. Therefore, it is recommended that continued use of CRT at the MUHC be made conditional on a systematic recording of patient data. The TAU recommends the systematic collection of a few key variables

(Appendix E), either in the patient chart or electronically, to evaluate patient selection and outcomes.

- These recommendations should be reviewed in 6 months to assess progress or barriers to progress in implementing a data documentation system.

Use of Biventricular Pacing in Atrioventricular Heart Block

Title

Use of Biventricular Pacing in Atrioventricular Heart Block

Requestor

Ann Lynch, Associate Director General, Clinical Operations, Adult Missions, McGill University Health Centre

Publication Date

March 8, 2016

Authors

Lama Saab, Eva Suarthana, Nisha Almeida and Nandini Dendukuri

Background

Heart block or atrioventricular (AV) block is a conduction disorder. It can range from asymptomatic first degree heart block to severe third degree block associated with a high risk of sudden cardiac arrest and death. Third degree block is an indication for right ventricular pacing (RVP).

RVP may induce left ventricular (LV) dysfunction and ventricular dyssynchrony which may contribute to heart failure (HF) over time. Therefore, there has been an interest in comparing biventricular pacing (BVP) (also known as cardiac resynchronization therapy (CRT)), an accepted therapy for moderate/severe HF, to RVP as a primary pacing choice for AV block patients.

Conclusions

- The available evidence regarding the use of BVP in AV block patients is weak in terms of the number of studies identified, the relatively small sample sizes, and the lack of meaningful clinical outcome data and short duration of follow-up within each study. Based on the GRADE guidelines the quality of the evidence was rated as Low to Very Low on all outcomes.
- In patients with normal LVEF, the use of BVP as an initial mode of pacing in AV block patients remains unsupported as the evidence shows no significant difference in clinical endpoints compared to RVP.
- In patients with low LVEF undergoing de novo pacing and in those with HF undergoing an upgrade from RVP, there is fairly consistent evidence of modest

improvement of ventricular function (increased LVEF, reduced end systolic volume), and modest symptomatic improvement (NYHA score, walk test and QoL). It should be noted that these studies included a substantial number of patients with characteristics that are indications for BVP in heart failure at baseline, and therefore do not provide evidence regarding the independent risk of AV block in contributing to heart failure.

- The 2013 guidelines for use of BVP published by the Canadian Cardiovascular Society (CCS) also reached a similar conclusion to our report in terms of the quality of evidence. Based on the BLOCK-HF trial alone, the CCS noted that the quality of evidence was "moderate". None the less, they issued a "Conditional Recommendation" that BVP "might be considered for patients with new-onset high-degree AV block requiring chronic RV pacing, signs and/or symptoms of HF, and LVEF≤ 45%". The CCS guideline points out that the BLOCK-HF trial enrolled only those with de novo implants and its results may not apply to those who are already chronically paced. Further it notes that most patients in the BLOCK-HF trial had symptomatic HF. This is similar to our own observation above regarding RCTs of de novo BVP implantation in AV Block patients with low LVEF.
- It should be noted that unlike clinical guideline documents our report does not provide guidance on how individual patients should be treated. Rather our focus has been to distinguish between those situations where there is good evidence to support the use of BVP and where there is not.

Recommendations

- In AV block patients with normal LVEF, the use of BVP as an initial mode of pacing in AV block patients is not recommended.
- In AV block patients with low LVEF, there is insufficient evidence to justify the routine use of BVP either for de novo implantation or for an upgrade from RVP.
- Given the paucity of evidence available so far, any usage of BVP in AV block patients with heart failure should be conditional on documentation of patient selection criteria and patient outcomes (see Report on Cardiac Resynchronization Therapy in Heart Failure for details).

Barrett's Esophagus

Title

Radiofrequency ablation for the treatment of Barrett's esophagus with high-grade and low grade dysplasia: An update

Requestor

Dr. Vicky Baffis, Interim Chief of Division of Gastroenterology at the MUHC

Publication Date

May 16, 2016

Authors

Nisha Almeida and Nandini Dendukuri

Background

Barrett's esophagus (BE) is a pre-malignant condition that may progress from a nondysplastic phase (metaplasia) to low-grade (LGD) or high-grade dysplasia (HGD), before progressing to esophageal cancer. Due to the higher progression rates of HGD to cancer, HGD has previously been treated with esophagectomy. More recently, endoscopic eradication therapies such as radiofrequency ablation (RFA) have replaced esophagectomy, which is associated with severe morbidity. Since our previous report in 2009, which evaluated a single randomized controlled trial of RFA treatment for HGD and recommended its use at the MUHC, several observational studies have established the safety, durability and effectiveness of RFA. However, the use of RFA to treat low-grade dysplasia remains controversial because of uncertainty both in the diagnostic accuracy and in the progression rates of LGD to cancer. Thus, the current report evaluates the most recent evidence for the use of RFA in the treatment of low-grade and high-grade dysplasia.

Conclusions

- Radiofrequency ablation is now the standard of care for the treatment of Barrett's patients with high grade dysplasia because there is good evidence for its effectiveness and safety in eliminating dysplastic tissue, and because the alternative treatment with esophagectomy is associated with higher morbidity

- Ablation therapy for LGD remains controversial because of the lack of data on diagnostic accuracy, and uncertainty surrounding the progression rates from LGD to cancer. Although recent evidence from two randomized controlled trials suggest RFA is effective in treating LGD, uncertainties in diagnostic accuracy and progression rates to cancer, and the spontaneous reversion of LGD in some patients do not warrant routine treatment of LGD patients with endoscopic ablation therapies.
- Currently, the MUHC only treats patients with confirmed HGD with radiofrequency ablation, and 38 HGD patients have been treated since 2010. Of these, one patient required esophagectomy 5 years after diagnosis.

Recommendations

- The current evidence reinforces the previous TAU recommendation that RFA be used and funded at the MUHC for the treatment of Barrett's esophagus with high grade dysplasia.
- The TAU does not recommend the routine use of RFA for the treatment of low grade dysplasia given the lack of consistent evidence at this time for progression rates of LGD to cancer, and the reversible nature of LGD. However, in LGD patients with risk factors suggestive of higher risk of progression to HGD/cancer, such as multifocal, long segment or persistent BE, RFA may be considered after comprehensive discussion of potential risks and benefits with the patient. This recommendation should be reviewed if new evidence becomes available on biomarkers or other risk factors that better predict progression of LGD to cancer.

Linear and Radial Endobronchial Ultrasound (EBUS) and Electromagnetic Navigation Bronchoscopy (ENB)

Title

A Mini-Health Technology Assessment of Linear and Radial Endobronchial Ultrasound (EBUS) and Electromagnetic Navigation Bronchoscopy (ENB) in the Diagnosis and Staging of Lung Cancer in Adults

Requestor

Antoinette Di Re, Director, Therapeutic and Allied Health Services

Publication Date

May 2016

Authors

David Felipe Forero and Nandini Dendukuri

Background

Linear EBUS (L-EBUS), radial EBUS (R-EBUS) and ENB were first carried out in early 2000s and were acquired at the MUHC in 2009 and 2014 to enable biopsy of intrathoracic pathologies with use of less invasive procedures. An extensive literature1 5-19 has now accrued evaluating these devices in terms of diagnostic yield, accuracy, safety and other relevant outcomes; as well as comparisons with more invasive alternatives.

Conclusions

L-EBUS is the first choice for mediastinal staging of non-small cell lung cancer. When L-EBUS is negative, mediastinoscopy is recommended. R-EBUS and ENB are recommended for indications related to diagnosis of peripheral lung lesions. ENB seems to improve the navigation across the bronchial tree but no guideline mentioned the combination of both. In general, all guidelines note that the particular technology selected should be determined in accordance with the indication, nodule size, location and proximity to a patent airway; patient's risk assessment (surgical and procedure risks), clinical probability of cancer and the availability of expertise for using the technology.

Recommendations

There is sufficient evidence supporting the use of linear EBUS as a first-line approach for lung cancer staging.

For investigation of peripheral nodules suspected of lung cancer, radial EBUS should be available for use at the clinician's discretion.

There is very limited evidence supporting the usage of ENB together with R-EBUS. Therefore, this technology should be judiciously used only when the yield of radial EBUS is felt to be lower than usual and TTNA is best avoided.

Given the residual uncertainty in patient selection and the low quality of evidence on efficacy, particularly for R-EBUS and ENB technologies, it is recommended that a prospective database be maintained that will allow the study of patient characteristics and patient outcomes that can aid decision making. Such a database has been commenced for ENB at the MUHC and should be extended to include R-EBUS and L-EBUS.

KNOWLEDGE TRANSLATION ACTIVITIES

Collaborations

- TAU staff members represented TAU at quarterly meetings of hospital-based technology assessment units in Quebec that are organized at INESSS.
- TAU collaborated with INESSS on a field evaluation on the use of defibrillators across Quebec hospitals.

Teaching Activities

- Dr. Nandini Dendukuri taught a workshop entitled “Accessible Bayesian Methods to Support Evidence-Based Medicine” at the 2016 CADTH Symposium.
- Dr. Nandini Dendukuri and Dr. James Brophy taught a 2-credit course, EPIB 670: Introduction to Health Technology Assessment, during the summer at the Department of Epidemiology, Biostatistics and Occupational Health, McGill University.

Conferences

Oral

Dr. Nisha Almeida presented “A framework for translating evidence to recommendations within a hospital-based HTA” at the 2016 CADTH symposium in Ottawa.

Poster

Dr. Nandini Dendukuri presented “Cardiac Resynchronization Therapy in Heart Failure: Evidence-based guidelines do not always agree with the evidence” the 2016 CADTH symposium in Ottawa.

POSTSCRIPT

"The TAU attempts to adjust the services we offer to conform to the resources available in a transparent, logical, fair, and consistent fashion. While some of our recommendations have not supported the acquisition of a technology, and have thus "saved money", others have supported new developments because they have identified the benefits, and found them to be sufficient to justify the increased expenditure. Our sincere thanks are due to the many members of the MUHC who have assisted with data collection, to those who have served as Consultants, and to the members of the Committee who have dedicated many hours to the consideration of these problems."

Maurice McGregor