Centre universitaire de santé McGill

McGill University Health Centre

ANNUAL REPORT 2015-16

Technology Assessment Unit of the McGill University Health Centre

Email: Nandini.dendukuri@mcgill.ca
Website: www.muhc.ca/tau
Tel: 514-934-1934 x 36916

Centre for Outcomes Research and Evaluation
5252 boul. de Maisonneuve Bureau 3F.50
Montreal, Quebec, H4A 3S5

CONTENTS

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

The 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
Lama Saab	Research Assistant
Eva Suarthana	Research Scientist
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:

Intrabeam

Title

Single-dose Intraoperative Radiotherapy Using Intrabeam® for Early-stage Breast cancer: An Update

Requestor

Mr. Gary Stoopler, former Administrative Director of the Surgical Mission. The new report will be presented to the current Administrative Director, Neuroscience Mission, Ms. Teresa Mack.

Publication Date

June 9, 2015

Authors

Nisha Almeida and Nandini Dendukuri

Background

Intraoperative radiotherapy (IORT) is one of the modalities of accelerated partial breast irradiation (APBI), which was introduced based on the rationale that the vast majority of local breast cancers recur within the primary tumour site. Unlike external beam radiation therapy (EBRT), which irradiates the entire affected breast in daily doses of 1.8-2.0 Gy, resulting in a cumulative dose of 45-50 Gy over 5-7 weeks, intraoperative therapy is delivered directly to the tumour bed during breast conserving surgery, and is given in a single higher dose. Intraoperative therapy thus avoids the unnecessary irradiation of vital organs such as the heart and lungs, and reduces the burden on the patient of frequent hospital visits. In IORT with Intrabeam®, low-energy x-rays are directly delivered to the tumour bed in a procedure lasting 25-30 minutes, attaining a maximum dose of 20 Gy at the surface of the tumour bed.

Efficacy of Intrabeam® has only been evaluated in a single non-inferiority trial, the TARGIT-A trial. Based on TARGIT-A's 4-year follow-up results which were suggestive of the non-inferiority of Intrabeam® to EBRT in terms of local breast cancer recurrences, TAU did not recommended use of this technology in 2012,

except in the context of a research study. In 2014, 5-year results of the TARGIT-A trial were published, necessitating an update of our earlier report.

Conclusions

- The TARGIT-A trial remains the sole trial comparing intraoperative radiation therapy using Intrabeam® to conventional external beam radiation therapy. Given the serious concerns with the results, the current evidence fails to conclusively establish the non-inferiority of Intrabeam® to external beam radiation.
- The short median follow-up time of 2.4 years in the TARGIT-A trial is particularly problematic if hormone receptor-positive women, who constituted the majority of trial participants, are more likely to have recurrences later in follow-up.
- A longer follow-up may indeed establish non-inferiority of Intrabeam®, but until such convincing evidence is available, Intrabeam® should only be considered an experimental procedure to be delivered under strict research protocols. Guidelines established by the radiation oncology societies as well as the selection criteria used in TARGIT A may serve in selecting appropriate low-risk patients in such research settings.

Recommendations

- The current evidence does not warrant a change in the recommendation previously accorded this technology which was a temporary approval, conditional on participation in research studies. Presently, Intrabeam® should not be approved for use in the MUHC except in the context of the ongoing MUHC-funded research study with:
    - continued adherence to a strict protocol and stringent collection of follow-up data on clinical outcomes, patient satisfaction and quality of life;
    - informed consent obtained from all patients agreeing to receive Intrabeam®, who would be informed in a clear and accessible way, of the lack of conclusive evidence regarding the efficacy of Intrabeam® in preventing recurrences.
    - In light of the numerous trials of Intrabeam® currently underway, the evidence should be reviewed in 5 years or when sufficient evidence has accrued about the 5-year recurrence rate.

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.

Teaching Activities

- Dr. Nandini Dendukuri and Dr. James Brophy developed a 2-credit course EPIB 670: Introduction to Health Technology Assessment, that was taught at, Department of Epidemiology, Biostatistics and Occupational Health, McGill University.

Presentations

Oral

Dr. Nandini Dendukuri presented “Technology Assessment Unit (TAU) of the MUHC” at the MUHC Medical Grand Rounds in March 2015.

Awards

Appointments

Dr. James Brophy selected to join the board of governors of Institut national d'excellence en santé et en services sociaux (INESSS) 2010-

Grants

Principal Investigator: Dr Nandini Dendukuri

Funding agency: INESSSS (Institut national d'excellence en santé et en services sociaux)

Competition: (PSI-ETMI) Programme de soutien aux initiatives en évaluation des technologies et des modes d'intervention

Title: Thérapie de resynchronisation cardiovasculaire en cas d'insuffisance ou de bloc cardiaque au Québec/Cardiovascular resynchronization therapy for patients with heart failure or heart block in Quebec

Funding period: 2014-2016

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