

TITLE: Delivery of Electroconvulsive Therapy in Non-Hospital Settings: A Review of the Safety and Guidelines

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CONTEXT AND POLICY ISSUES

Electroconvulsive therapy (ECT) is a treatment that uses a small electrical current to produce a generalized cerebral seizure under anesthesia in patients with severe depression, as well as other conditions including bipolar disorder, schizophrenia, schizoaffective disorder, delirium, and neuroleptic malignant syndrome.^{1,2} The mechanism of ECT is unknown however changes to the central nervous system resulting from this therapy have been documented and the procedure is considered to be safe and efficacious.^{1,2}

A recent Canadian survey of 172 centers identified as conducting ECT indicates that among registered healthcare institutions that conduct this procedure, there exists some variability with regard to written policies and procedures for ECT, the administration of medications, and treatment, however there is generally some consistency with regard to obtaining informed consent and the post-discharge accompaniment of patients.³ This reported variability has led to a call for the accreditation of facilities that perform ECT in Canada.^{3,4} It is unknown if this variability in performing ECT has had an impact on patient outcomes.

ECT may be performed on an inpatient or an outpatient setting in a dedicated ECT treatment suite, hospital post-anesthesia care unit, or an ambulatory surgery site.¹ An estimated 75,000 ECT treatments are delivered annually in Canada, and 90% of these treatments are delivered on an outpatient basis.⁵ While an outpatient setting may include non-hospital facilities (e.g. doctor's office, clinic), little is known regarding the safety of conducting ECT specifically in non-hospital environments, and if there are any risks associated with performing ECT in such settings. The present review was conducted to inform decisions regarding the safety and guidelines for ECT therapy delivered outside of hospital settings.

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RESEARCH QUESTIONS

- 1. What is the clinical evidence regarding the safety of the delivery of electroconvulsive therapy (ECT) in non-hospital settings?
- 2. What are the evidence-based guidelines regarding the delivery of ECT in non-hospital settings?

KEY FINDINGS

There is currently no explicit evidence or guidance for the safe administration of ECT in nonhospital settings. A limited number of guidelines that describe where ECT may be provided made reference to outpatient settings, however an outpatient setting may or may not be inclusive of a hospital environment.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 3), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2009 and April 8, 2014.

Selection Criteria and Methods

A single reviewer screened the titles and abstracts of the citations identified with the literature search strategy, according to the selection criteria described in Table 1. Citations which appeared to meet these selection criteria, or whose characteristics were unclear and could therefore not be excluded, were retrieved for closer scrutiny and final selection.

Population	Adults undergoing electroconvulsive therapy for mental health conditions.
Intervention	Electroconvulsive therapy in non-hospital settings.
Comparator	No comparator, electroconvulsive therapy in the hospital setting, or compared to other non-hospital settings.
Outcomes	Safety and adverse events, guidelines and best practice, appropriate settings, degree of medical support necessary.
Study Designs	HTAs, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, guidelines.

Table 1: Selection Criteria

Exclusion Criteria

Studies were excluded if they did not meet the selection criteria, were published prior to 2009, or if guidelines did not report their methodology or that their recommendations were evidence-



based.

Critical Appraisal of Individual Studies

The quality of guidelines was evaluated using the AGREE II tool.⁶ Numeric scores for this evaluation are not reported and a narrative and tabular description of the strengths and limitations of each included guideline is presented instead. As no systematic reviews, randomized trials or non-randomized studies relating to safety issues were identified, no other critical appraisal tools were used in this review.

SUMMARY OF EVIDENCE

Quantity of Research Available

A total of 132 articles were identified through the literature search strategy, and 9 additional articles were identified through a search of the grey literature. After an initial screening of the titles and abstracts, 34 articles were retrieved for further consideration and two guidelines⁷⁻¹⁰ were included. No randomized or non-randomized studies that examined the issue of safety in performing ECT in non-hospital settings were identified. Of the 30 articles that were excluded, four were not guidelines, seven were guidelines but did not provide specific guidance on the environment in which ECT can be performed, two guidelines were not evidence-based, the setting was not relevant in nine studies, the intervention was not ECT in one study, study outcomes were not related to safety on one study, and eight papers were not of a format that was relevant to this review (e.g. case study, book review, position paper). A PRISMA flowchart of the study selection is provided in Appendix 1.

Summary of Study Characteristics

Details of the guideline characteristics are provided in Appendix 2.

Two guidelines⁷⁻¹⁰ were included in this review. The guideline published by Reti et al.⁷ in 2012 related to safety considerations for outpatient electroconvulsive therapy and was based on the 2001 American Psychiatric Association Task Force Report on ECT as well as on the authors' clinical experience with outpatient ECT. The guideline published by the Institute for Clinical Systems Improvement (ICSI) in 2013⁸ provided guidance for the assessment, diagnosis, and ongoing management of adults with initial and recurrent major depression. The guideline published by Reti et al.⁷ did not provide evidence recommendation grades. The ICSI guideline⁸ used the GRADE methodology for rating evidence quality and basing the strength of its recommendations, however this methodology was used only for certain specified recommendations, and the remaining recommendations, including those relating to where ECT may be performed, were based on work-group consensus.

Summary of Critical Appraisal

The strengths and limitations of the included guidelines are summarized in Appendix 3.

The strengths of the guideline published by Reti et al.⁷ were its clarity of presentation, its editorial independence, its description of the population to which applied and its consideration of health benefits, side-effects, and risks. The statement of overall objectives, specification of

health questions, involvement of relevant professional groups and method for formulating recommendations was not described. While the authors of this guideline partly based their recommendations on previously-published evidence-based guidelines, the method used to incorporate their clinical experience with this evidence to formulate final recommendations was not explicitly described, and they did not draw a specific link between recommendations and supporting evidence. In addition, they did not appear to have the guideline externally reviewed prior to publication, nor did they provide an updating procedure. Finally the applicability of the guideline was not addressed.

The guideline developed by ICSI⁸ scored highly on most factors within the six domains of the AGREE II tool.⁶ The authors stated that a consistent and defined process is used for the literature search and review for the development and update of ICSI guidelines, and a description of the GRADE methodology that was applied to some of its recommendations was described, however details on the review methods were not provided. Potential resource implications were not considered in this guideline.

Summary of Findings

What is the clinical evidence regarding the safety of the delivery of ECT in non-hospital settings?

No clinical evidence regarding the safety of the delivery of ECT in non-hospital settings was identified

What are the evidence-based guidelines regarding the delivery of ECT in non-hospital settings?

Reti et al.⁷ provided guidance for the provision of ECT in an outpatient setting. According to these recommendations, outpatient ECT may be safely initiated if the patient is safe for outpatient care (i.e. safe to self and others, able to maintain adequate self-care, and medically stable). In addition several other factors for consideration were recommended, including risk of delirium, the availability of a responsible adult for transport, and the availability of a support person during the recovery period following treatment. Finally, the recommendations stated that the patient must be committed to the treatment plan and their psychiatric status must be assessed on an ongoing basis.

The guideline published by ISCI⁸ included a section on the provision of ECT to patients with severe depression. The guideline stated that ECT is usually performed on an inpatient basis, but that for some individuals, it can be administered safely in an outpatient setting. No further details for this recommendation were provided and no explicit link to evidence was made in support of this statement.

Limitations

No clinical studies regarding the safety of the delivery of ECT in non-hospital settings were identified.

No guidelines that explicitly provided instruction on the provision of ECT outside a hospital setting were identified. Two guidelines that made reference to outpatient settings were

identified, however the term 'outpatient' may or may not be inclusive of non-hospital settings, and this distinction was not made clear in the reviewed guidance.

The guidelines that were reviewed had some limitations, particularly with regard to the link between recommendations for outpatient ECT and evidence.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Although ECT is generally considered to be a safe procedure in hospital and out-patient settings, there is currently no explicit evidence relating to safety or guidance for the administration of ECT in non-hospital settings. This knowledge gap may be a consideration for non-hospital facilities that consider administering this treatment to patients. Also of note is that the administration of ECT is not consistent across Canadian facilities, and that this reported variability has resulted in a call for standards for accreditation of facilities in Canada.^{3,4}

Two Australian guidelines^{9,10} that were identified in the course of this review describe requirements for licensing premises to perform ECT, outline the minimum standards for resources and equipment, provide practical clinical guidance for staff involved in administering ECT, and provide criteria which should be satisfied before patients are offered ECT on an outpatient basis. However neither of these guidelines provided sufficient information to determine if their recommendations are evidence-based, nor is their guidance explicitly linked to evidence within the document. They suggest that efforts should be made to ensure that ECT is administered by qualified personnel, that methods of treatment administration follow recognized guidelines for ECT therapy, and that patients have access to appropriate facilities, monitoring, and follow-up.

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REFERENCES

- 1. Kellner C. Technique for performing electroconvulsive therapy (ECT) in adults. 2014 [cited 2014 May 2]. In: UpToDate [Internet]. Version 17.0. Waltham (MA): UpToDate; c2005 . Available from: www.uptodate.com Subscription required.
- Kellner C. Overview of electroconvulsive therapy (ECT) for adults. 2014 [cited 2014 May 2]. In: UpToDate [Internet]. Version 17.0. Waltham (MA): UpToDate; c2005 - . Available from: <u>www.uptodate.com</u> Subscription required.
- 3. Chan P, Graf P, Enns M, Delva N, Gilron I, Lawson JS, et al. The Canadian Survey of Standards of Electroconvulsive Therapy Practice: a call for accreditation. Can J Psychiatry. 2012 Oct;57(10):634-42.
- 4. Gosselin C, Graf P, Milev R, Delva N, Lawson JS, Enns M, et al. Delivery of electroconvulsive therapy in Canada: a first national survey report on devices and technique. J ect. 2013 Sep;29(3):225-30.
- Canadian Medical Association [Internet]. 3.0. Ottawa: CMA; 2014. Electroconvulsive therapy use in Canada mapped out; 2011 Oct 15 [cited 2014 May 5]. Available from: <u>http://www.cma.ca/learning/electroconvulsive-therapy-canada</u>
- Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. AGREE II: advancing guideline development, reporting and evaluation in healthcare [Internet].The AGREE Research Trust; 2009 May; updated Sept 2013. [cited 2014 May 7]. Available from: <u>http://www.agreetrust.org/wp-content/uploads/2013/10/AGREE-II-Users-Manualand-23-item-Instrument_2009_UPDATE_2013.pdf</u>
- 7. Reti IM, Walker M, Pulia K, Gallegos J, Jayaram G, Vaidya P. Safety considerations for outpatient electroconvulsive therapy. J psychiatr pract. 2012 Mar;18(2):130-6.
- Mitchell J, Trangle M, Degnan B, Gabert T, Haight B, Kessler D, et al. Adult depression in primary care [Internet]. Bloomington (MN): Institute for Clinical Systems Improvement; 2013 Sep. [cited 2014 Apr 28]. Available from: <u>https://www.icsi.org/_asset/fnhdm3/Depr.pdf</u>
- 9. South Australian guidelines for electroconvulsive therapy [Internet]. Adelaide: Department of Health, Government of South Australia; 2014 Jan 31. (Policy guideline). [cited 2014 Apr 29]. Available from: <u>http://www.sahealth.sa.gov.au/wps/wcm/connect/cad70180420c1fda85e4adf8b1e08c6d/ECT+Policy+Guidelines+FINAL+Consultation+Draft.pdf?MOD=AJPERES&CACHEID=cad70180420c1fda85e4adf8b1e08c6d</u>
- Electroconvulsive therapy manual: licensing, legal requirements and clinical guidelines [Internet]. Melbourne, Victoria: Victorian Government Department of Human Services; 2009 Jan. [cited 2014 Apr 29]. Available from: <u>http://www.health.vic.gov.au/mentalhealth/ect/ect.pdf</u>

APPENDIX 1: Selection of Included Studies



all



APPENDIX 2: Characteristics of Included Guidelines

Objectives		Methodology				
Intended users/target population	Intervention and Practice considered	Major outcomes considered	Evidence collection, selection and synthesis	Evidence quality and strength	Recommendations development and evaluation	Guideline validation
Reti et al.' (20	012)					
Intended users not clearly defined / patients undergoing ECT	ECT for outpatients	Safety issues	Previous guidelines and authors' opinion	Unclear	Based on 2001 APA ECT Guideline and updated with authors' clinical experience	Unclear
ICSI ⁸ (2013)						
Primary care delivery of care for adult patients with depression	Diagnosis, treatment, and management	Not explicitly stated	Systematic review; GRADE method.	Low to High	GRADE methodology	Unclear

APA: American Psychiatric Association; ECT: electroconvulsive therapy

APPENDIX 3: Quality Appraisal of Included Guidelines (AGREE II Instrument6)

Domain	Strengths	Limitations
Reti et al. ⁷ (2012)	Olioligino	Linitatione
SCOPE AND PURPOSE	Applicable population described.	Overall objectives and health questions not completely described.
STAKEHOLDER INVOLVEMENT	No major strengths	Unclear if guideline development group includes individuals from all relevant professional groups;
		Not indicated that views and preferences of the target population (patients, public, etc.) have been sought;
		Target users not clearly defined.
RIGOUR OF DEVELOPMENT	Health benefits, side effects and risks have been considered in the recommendations.	Systematic methods not used; Strengths and limitations of evidence not
		described;
		Method for formulating recommendations unclear;
		No explicit link between recommendations and supporting evidence;
		No external review prior to publications;
		Procedure for updating guideline not provided.
CLARITY OF PRESENTATION	Recommendations specific and unambiguous;	No major limitations
	Different option for management of health condition presented;	
	Key recommendations easily identifiable.	
APPLICABILITY	No major strengths	Facilitators and barriers to guideline application not provided;
		Advice or tools for putting guidelines into practice not provided;
		Potential resource implications not considered;
		No monitoring or auditing criteria provided.
EDITORIAL INDEPENDENCE	Views of funding body do not appear to have influenced guideline content;	No major limitations
	Competing interests recorded and addressed.	

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Domain	Strengths	Limitations
ICSI ⁸ (2013)		
SCOPE AND PURPOSE	Applicable population described. Overall objectives specifically	No major limitations
	described; Health questions specifically described.	
STAKEHOLDER INVOLVEMENT	Guideline development group includes individuals from all relevant professional groups;	Unclear if views and preferences of the target population (patients, public, etc.) have been sought;
	Target users clearly defined.	
RIGOUR OF DEVELOPMENT	Systematic methods used;	Selection criteria not clearly described;
	Method for formulating recommendations described;	Strengths and limitations of evidence not described;
	Health benefits, side effects and risks have been considered in the recommendations;	
	Links made between recommendations and supporting evidence;	
	External review prior to publications;	
	Procedure for updating guideline provided.	
CLARITY OF PRESENTATION	Recommendations specific and unambiguous;	No major limitations
	Different option for management of health condition presented;	
	Key recommendations easily identifiable.	
APPLICABILITY	Facilitators and barriers to guideline application described;	Potential resource implications not considered;
	Advice or tools for putting guidelines into practice provided;	
	Monitoring and/or auditing criteria provided.	
EDITORIAL INDEPENDENCE	Views of funding body do not appear to have influenced guideline content;	No major limitations
	Competing interests recorded and addressed.	