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CADTH RAPID RESPONSE REPORT: REFERENCE LIST

Fidaxomicin Pulse Therapy for Clostridium Difficile Infection: Clinical Effectiveness

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Research Question

What is the clinical effectiveness of fidaxomicin pulse therapy for the treatment of *Clostridium difficile* infections?

Key Findings

One randomized controlled trial and one non-randomized study were identified regarding fidaxomicin pulse therapy for C*lostridium difficile* infection.

Methods

This report makes use of a literature search strategy developed for a previous CADTH report. For the current report, a limited literature search was conducted on key resources including Medline and Embase via OVID, the Cochrane Library, 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 retrieval by study type. Where possible, retrieval was limited to the human population. The search was limited to English-language documents published between January 1, 2009 and April 1, 2019. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Adult patients, in all settings, with a *Clostridium difficile* infection
Intervention	Fidaxomicin pulse therapy
Comparator	Fidaxomcin twice daily dosing Vancomycin Metronidazole Fecal microbiota transplantation Other usual treatments Placebo No treatment
Outcomes	Clinical effectiveness (e.g., infection resolution, prevention of recurrence); safety (e.g., side effects, adverse events, mortality)
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, and non-randomized studies.

One randomized controlled trial and one non-randomized study (both from the same clinical trial) were identified regarding fidaxomicin pulse therapy for clostridium difficile infection. No relevant health technology assessments, systematic reviews or meta-analyses were identified.

Additional references of potential interest are provided in the appendix.

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials

1. Guery B, Menichetti F, Anttila VJ, et al. Extended-pulsed fidaxomicin versus vancomycin for Clostridium difficile infection in patients 60 years and older (EXTEND): a randomised, controlled, open-label, phase 3b/4 trial. *Lancet Infect Dis*. 2018;18(3):296-307.
PubMed: PM29273269

Non-Randomized Studies

2. Cornely OA, Vehreschild M, Adomakoh N, et al. Extended-pulsed fidaxomicin versus vancomycin for Clostridium difficile infection: EXTEND study subgroup analyses. *Eur J Clin Microbiol Infect Dis*. 2019;Mar 25 [epub ahead of print].
PubMed: PM30911926

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Appendix — Further Information

Previous CADTH Reports

3. Fidaxomicin pulse therapy for clostridium difficile infection: clinical effectiveness. *(CADTH Rapid response report: reference list)*. Ottawa (ON):CADTH; 2019: https://www.cadth.ca/fidaxomicin-pulse-therapy-clostridium-difficile-infection-clinical-effectiveness-0. Accessed 2019 Apr 4.

4. CADTH Canadian Drug Expert Committee (CDEC) final recommendation: fidaxomicin (Dificid – Optimer Pharmaceuticals Canada Inc.). Ottawa (ON): CADTH; 2012 Dec 19; https://www.cadth.ca/fidaxomicin-6. Accessed 2019 Apr 4.

Non-Randomized Studies

Alternative Dosing Regimen

5. Louie TJ, Miller MA, Mullane KM, et al. Fidaxomicin versus vancomycin for Clostridium difficile infection. *N Engl J Med*. 2011;364(5):422-431. PubMed: PM21288078

In Vitro Model

6. Chilton CH, Crowther GS, Todhunter SL, et al. Efficacy of alternative fidaxomicin dosing regimens for treatment of simulated Clostridium difficile infection in an in vitro human gut model. *J Antimicrob Chemother*. 2015;70(9):2598-2607. PubMed: PM26078392

Economic Evaluations

7. Cornely OA, Watt M, McCrea C, Goldenberg SD, De Nigris E. Extended-pulsed fidaxomicin versus vancomycin for Clostridium difficile infection in patients aged >=60 years (EXTEND): analysis of cost-effectiveness. *J Antimicrob Chemother*. 2018;73(9):2529-2539. PubMed: PM29800295

8. Baro E, Galperine T, Denies F, et al. Cost-effectiveness analysis of five competing strategies for the management of multiple recurrent community-onset Clostridium difficile infection in France. *PLoS ONE*. 2017;12(1):e0170258. PubMed: PM28103289

Case Studies

9. Yan WR. Fecal microbiota transplantation (FMT) bridging with fidaxomicin and vancomycin for severe refractory Clostridium difficile infection (CDI). *Am J Gastroenterol*. 2017;112:S783.

10. Soriano MM, Danziger LH, Gerding DN, Johnson S. Novel fidaxomicin treatment regimens for patients with multiple Clostridium difficile infection recurrences that are refractory to standard therapies. *Open Forum Infect Dis*. 2014;1(2):ofu069. PubMed: PM25734139

Review Articles

11. Clayton JA, Toltzis P. Recent issues in pediatric Clostridium difficile infection. *Curr Infect Dis Rep*. 2017;19(12):49.
PubMed: PM29110105

12. Taylor KN, McHale MT, Saenz CC, Plaxe SC. Diagnosis and treatment of Clostridium difficile (C. diff) colitis: review of the literature and a perspective in gynecologic oncology. *Gynecol Oncol*. 2017;144(2):428-437.
PubMed: PM27876339