

TOPIC INFO

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| TOPIC: | ROLE OF IR IN TREATMENT OF PROGRESSIVE PARKINSON'S DISEASE |
| SPEAKER: | SANJIV PARIKH MD |
| TITLE: | INTERVENTIONAL RADIOLOGIST |
| AFFILIATION | RADIA INC |
| TIME: | 30 minutes |

PRACTICE GAP ANALYSIS:

Describe the problems or gaps in practice this activity will address:

What are you trying to change?

describe below the current state.

Patients at late stage Parkinson's disease (PD) develop several motor and nonmotor complications, which dramatically impair their quality of life. These complications include motor fluctuations, dyskinesia, unpredictable or absent response to medications, falls, dysautonomia, dementia, hallucinations, sleep disorders, depression, and psychosis. Dopamine replacement with levodopa was first shown to reduce clinical signs and symptoms of Parkinson's disease (PD) in the 1960s [1], and since then has been the mainstay of PD treatment [2,3]. However, the majority of patients who respond to levodopa eventually experience a narrowing of the therapeutic window, resulting in motor complications, including "Off" time (when medication has worn off and parkinsonian symptoms re-emerge) and levodopa-induced dyskinesias [2]. These complications can be a major source of distress and disability for patients and are difficult to treat [4,5]. "Off" time is of particular interest, as this is arguably the biggest contributor to functional impairment in patients with advancing PD [6–9]. Hence, the ability to reduce "Off" time without an associated increase in dyskinesia is an important goal of therapy development.

What is the problem?

Describe the desired state.

Levodopa–carbidopa intestinal gel (LCIG) delivered continuously via percutaneous endoscopic gastrojejunostomy (PEG-J) tube has been reported, mainly in small open-label studies, to significantly alleviate motor complications in Parkinson's disease (PD). A prospective open-label, 54-week, international study of LCIG is ongoing in advanced PD patients experiencing motor fluctuations despite optimized pharmacologic therapy. Pre-planned interim analyses were conducted on all enrolled patients (n = 192) who had their PEG-J tube inserted at least 12 weeks before data cutoff (July 30, 2010). Outcomes include the 24-h patient diary of motor fluctuations, Unified Parkinson's Disease Rating Scale (UPDRS), Clinical Global Impression-Improvement (CGI-I), Parkinson's Disease Questionnaire (PDQ-39), and safety evaluations. Patients (average PD duration 12.4 yrs) were taking at least one PD medication at baseline. The mean (±SD) exposure to LCIG was 256.7 (±126.0) days. Baseline mean "Off" time was 6.7 h/day. "Off" time was reduced by a mean of 3.9 (±3.2) h/day and "On" time without troublesome dyskinesia was increased by 4.6 (±3.5) h/day at Week 12 compared to baseline. For the 168 patients (87.5%) reporting any adverse event (AE), the most common were abdominal pain (30.7%), complication of device insertion (21.4%), and procedural pain (17.7%). Serious AEs occurred in 60 (31.3%) patients. Twenty-four (12.5%) patients discontinued, including 14 (7.3%) due to AEs. Four (2.1%) patients died (none deemed related to LCIG). Interim results from this advanced PD cohort demonstrate that LCIG produced meaningful clinical improvements. LCIG was generally well-tolerated; however, device and procedural complications, while generally of mild severity, were common.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3661282/>

How did you assess and/or measure these issues?

How was the educational need/practice gap for this activity identified? Place an X by each source utilized to identify the need for this activity.

Attach copies of documentation for each source indicated (REQUIRED)

* please make sure when selecting your needs assessment data and references that you highlight applicable components.

| Method | Example of required document |
|--------------------------------------|--------------------------------|
| Previous participant evaluation data | Copy of tool and summary data |
| Research/literature review | Abstract(s) or articles |
| X Expert Opinion | Summary |
| Target audience survey | Copy of tool and summary data |
| Regulatory body requirements | Requirements summary |
| Data from public health sources | Abstract, articles, references |
| Other (describe) | |

Describe the needs of learners underlying the gaps in practice:

| What are the causes of the gaps in practice? Check all that apply | | |
|--|--|---|
| X | Lack of awareness of the problem, | Poor self-efficacy, |
| X | Lack of familiarity with the guideline, | Inability to overcome the inertia of previous practice, and |
| | Non-agreement with the recommendations, | Presence of external barriers to perform recommendations |
| | Other | |
| Why does the gap exist? Check all that apply | | |
| X | Lack of Knowledge competence | Lack of time to assess or counsel patients |
| | Performance-based. | Cost / Insurance/reimbursement issues |
| | Lack of consensus on professional guidelines | Patient Compliance Issues |
| | Other: | |
| What do learners need to be able to know or do to be able to address the gaps in practice? | | |
| <p>Explain your CME Objectives here</p> <p>The latest treatment for progressive Parkinson's disease can be learning Treatments of progressive Parkinson's disease.</p> <p>Understanding role of Dopa Gel pump via dedicated Gastrojejunostomy tube in treatment of Parkinson's disease</p> <p>Understanding Efficacy of Dopa Gel</p> | | |

CME OBJECTIVES

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| <p>State at least three or more things that participants should be able to do after they participate in this CME activity. Please note these objectives should be measurable, specific, actionable and timely.</p> <p>Upon completion of this activity, attendees should be able to:</p> | |
| 1 | Describe treatment of Progressive Parkinson's Disease. |
| 2 | Describe Dopa Gel pump via dedicated Gastrojejunostomy tube |
| 3 | Discuss Efficacy of Dopa Gel |
| <p>The ACCME does not want you to use the words - think, understand, know, appreciate, learn, comprehend, be aware of, be familiar with, etc. as they are not measurable.</p> <p>You can use words such as Analyze, Categorize, Classify, Compare, Conclude, Construct, Critique, Define, Demonstrate, Describe, Discuss, Evaluate, Identify, List, Name, Outline, Show</p> | |

COMPETENCIES:

What ACGME or IOM related competency is associated with this activity? (check all that apply)

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|---|----------------------|---|----------------------------|
| X | Patient Care | Practice-Based Learning and Improvement | Medical/Clinical Knowledge |
| | Procedural Skills | Interdisciplinary Teams | Teams and Teamwork |
| | Communication Skills | Professionalism | Systems-based Practice |
| | Quality Improvement | Utilization of Informatics | Evidence-based Practice |

What is the activity designed to change

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| X | <p>Competence - (knowing how to do something) Selecting this option requires the CME activity being planned provide participants with an opportunity to:</p> <ul style="list-style-type: none"> hear information related to advances or best practice hear examples of application in practice of information presented |
| | <p>Performance- (actually doing something) Selecting this option requires the CME activity being planned provide participants with an opportunity to:</p> <ul style="list-style-type: none"> practice what they have learned during the CME activity receive feedback about doing what they have learned during the CME activity |
| | <p>Patient Outcomes- (actually measure change in patients) Selecting this option requires the CME activity track change in patient outcomes:</p> <ul style="list-style-type: none"> provide tangible improvements and data to support overall change to patient outcomes |

What potential barriers do you anticipate attendees may encounter when incorporating new objectives into their practice?

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|---|--|-------------------|
| X | Lack of time to assess or counsel patients | Other – describe: |
| | Cost | |
| | No perceived barriers | |
| | Lack of administrative support/resources | |
| | reimbursement issues | |
| | Insurance/ | |

Describe how will this educational activity address these potential barriers and the strategies used?

RESULTS:

please describe the results expected (outcomes) for this activity in terms of specific improvements in patient care and/or other work related to the practice of medicine.

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| | Your Description |
| X | Improvements in patient care based on evidence-based treatment |
| | Reduce Health care costs |
| | Streamline care of patients |

MEASURING YOUR SUCCESS:

Will use pre-and post CME activity questionnaire to measure success.
Please provide 3 questions and answers that will asked to the audience before and after your talk. The answer to these questions should be in your presentation. Please highlight the correct answer and limit your possible answers to a maximum of 4 with only one correct answer. The others can be partially correct or wrong

Question 1. L-Dopa |Carbidopa is the best treatment of Parkinson’s Disease

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| | Answers |
| 1 | True |
| 2 | False |
| | <p>Feedback:</p> <ol style="list-style-type: none"> True False: Correct Answer. |

Oral L-Dopa |Carbidopa is not good enough for sustaining levels of Dopamine during wakeful cycle

Question 2: Where is the optimal absorption of L-Dopa | Carbidopa in the intestine

Answers

- 1 Stomach
- 2 Duodenum
- 3 Jejunum

Feedback:

- 1. Stomach
- 2. Duodenum
- 3. Jejunum: Correct Answer.

Question 3: What are the complications of Gastrostomy tube placement.

Answers

- 1 Peritonitis
- 2 Gastric Bleeding
- 3 Tube Occlusion
- 4 All of the above

Feedback:

- 1. Peritonitis: Partially Correct.
- 2. Gastric Bleeding: Partially Correct.
- 3. Tube Occlusion: Partially Correct.
- 4. All of the above: Correct Answer.