

Parkinsonism and Related Disorders

Per-oral image guided gastrojejunostomy insertion for levodopa-carbidopa intestinal gel in Parkinson's disease is safe and may be advantageous

--Manuscript Draft--

Manuscript Number:	PARKRELDIS-D-21-00224R1
Article Type:	Short Communication
Keywords:	Levodopa carbidopa intestinal gel; radiologically inserted gastrostomy; per-oral image guided gastrostomy; percutaneous endoscopic gastrostomy; Parkinson's disease
Corresponding Author:	Fahd Baig St George's University of London London, London UNITED KINGDOM
First Author:	Fahd Baig
Order of Authors:	Fahd Baig Mihaela Boca Lucy Mooney Lucy Cheminais Marianna Selikhova Michal Rolinski Konrad Szewczyk-Krolikowski Neil Collin Alan Whone
Abstract:	<p>Background</p> <p>Procedural aspects and complications of gastrojejunostomy insertion are important considerations in the use of levodopa-carbidopa intestinal gel therapy (LCIG) and may limit uptake. We describe our experience of using per-oral image guided gastrojejunostomy (PIG-J) which avoids the need for endoscopy and routine sedation in percutaneous endoscopic gastrojejunostomy (PEG-J) and allows more secure tube placement than radiologically inserted gastrojejunostomy techniques.</p> <p>Methods</p> <p>We describe a case series of 32 patients undergoing PIG-J insertion for LCIG therapy in a single centre. Under local anaesthetic, a fluoroscopy-guided gastric puncture allows access for the guidewire which is then used to pull through the gastrostomy tube allowing for secure fixation, followed by placement of the gastrojejunal extension.</p> <p>Results</p> <p>Between December 2015 to April 2020, 32/34 patients referred for PIG-J underwent this procedure successfully, 2 cases unsuccessful due to technical considerations. One patient developed delirium following successful implantation. Ten patients (31%) required a replacement tube due to blockage or displacement within the first 12 months of placement, including 2 patients who needed more than one replacement. Minor complications occurred in 10 other patients (31%), including infection (9 patients); a small haematoma not requiring intervention who later developed an infection (1 patient); and peri-stomal acid leakage (1 patient).</p> <p>Conclusion</p> <p>In summary, PIG-J insertion is safe with a similar complication rate to traditional PEG-J, well tolerated and effective for use in LCIG administration. This may widen access to LCIG for PD patients who may not be suitable or unable to tolerate PEG-J.</p>

Per-oral image guided gastrojejunostomy insertion for levodopa-carbidopa intestinal gel in Parkinson's disease is safe and may be advantageous

1. Per-oral image guided gastrojejunostomy insertion in Parkinson's disease is safe.
2. Per-oral image guided gastrojejunostomy insertion allows for effective long-term delivery of levodopa-carbidopa intestinal gel in Parkinson's patients.
3. While offering more secure tube placement than traditional radiological techniques, this method may have advantages over endoscopic techniques by avoiding sedation, the burden of endoscopy, have a higher technical success rate and offer a route of therapy for otherwise ineligible patients.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

Per-oral image guided gastrojejunostomy insertion for levodopa-carbidopa intestinal gel in Parkinson's disease is safe and may be advantageous

Fahd Baig*^{\$1,2,3}, Mihaela Boca^{\$1}, Lucy Mooney¹, Lucy Cheminais¹, Marianna Selikhova¹, Michal Rolinski^{1,3}, Konrad Szewczyk-Krolkowski¹, Neil Collin¹, Alan Whone^{1,3}

* Corresponding author; ^{\$} These authors contributed equally to this work.

1. North Bristol NHS Trust, Bristol, United Kingdom.
2. St. George's University London, United Kingdom.
3. University of Bristol, Bristol, United Kingdom.

Address correspondence and reprint requests to Dr Fahd Baig

Word counts: Title: 125 characters, Abstract: 244 words, Paper: 2097, References: 15, Tables / figs : 2 (max 2)

Running title: PIG for LCIG

Key words: Levodopa carbidopa intestinal gel, radiologically inserted gastrostomy, per-oral image guided gastrostomy, percutaneous endoscopic gastrostomy, Parkinson's disease

ABSTRACT

Background

Procedural aspects and complications of gastrojejunostomy insertion are important considerations in the use of levodopa-carbidopa intestinal gel therapy (LCIG) and may limit uptake. We describe our experience of using per-oral image guided gastrojejunostomy (PIG-J) which avoids the need for endoscopy and routine sedation in percutaneous endoscopic gastrojejunostomy (PEG-J) and allows more secure tube placement than radiologically inserted gastrojejunostomy techniques.

Methods

We describe a case series of 32 patients undergoing PIG-J insertion for LCIG therapy in a single centre. Under local anaesthetic, a fluoroscopy-guided gastric puncture allows access for the guidewire which is then used to pull through the gastrostomy tube allowing for secure fixation, followed by placement of the gastrojejunal extension.

Results

Between December 2015 to April 2020, 32/34 patients referred for PIG-J underwent this procedure successfully, 2 cases unsuccessful due to technical considerations. One patient developed delirium following successful implantation. Ten patients (31%) required a replacement tube due to blockage or displacement within the first 12 months of placement, including 2 patients who needed more than one replacement. Minor complications occurred in 10 other patients (31%), including infection (9 patients); a small haematoma not requiring intervention who later developed an infection (1 patient); and peri-stomal acid leakage (1 patient).

Conclusion

In summary, PIG-J insertion is safe with a similar complication rate to traditional PEG-J, well tolerated and effective for use in LCIG administration. This may widen access to LCIG for PD patients who may not be suitable or unable to tolerate PEG-J.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

Introduction

1
2
3 Levodopa-carbidopa intestinal gel (LCIG) is an effective treatment in the complex stage of
4
5 Parkinson's disease (PD), improving motor and non-motor symptoms, activities of daily
6
7 living and quality of life. A major consideration, in this often elderly and relatively frail
8
9 patient group, is the gastrojejunostomy required for insertion of the drug delivery tube.
10

11
12
13 Percutaneous endoscopic gastrojejunostomy (PEG-J) is the method most commonly used in
14
15 this setting, the trans-oral route allowing for the placement of tubes with an internal flange (a
16
17 soft disc) to secure the device. In contrast to an approach requiring endoscopy, interventional
18
19 radiologists have developed techniques for insertion of a gastrostomy or gastrojejunostomy
20
21 under fluoroscopic guidance (referred to as radiologically inserted
22
23 gastrostomies/gastrojejunostomies (RIG-J)). Developed primarily for inserting feeding tubes,
24
25 the tubes are placed directly through the gastrostomy and use either a balloon or pig-tail end
26
27 to secure their placement, and show a higher technical success rate in motor neurone disease
28
29 patients.[1]
30
31
32
33
34
35

36 However, balloon or pig-tail catheters used in RIG-J placement have a higher risk of the tube
37
38 becoming dislodged than tubes fixed more securely with a solid internal flange, as the pigtail
39
40 may unravel or the balloon lose volume or burst leading to displacement. A variation on this
41
42 technique is the per-oral image guided gastrojejunostomy (PIG-J), which allows the insertion
43
44 of the tube with the more secure solid fixation device. This is done by puncturing the stomach
45
46 under fluoroscopic guidance, passing a guidewire through the gastro-oesophageal junction
47
48 and through the mouth before pulling the tube back through into place.
49
50
51
52
53
54
55
56
57
58
59
60
61
62

1
2
3 Figure 1 – Pictures of the different tube fixation devices[2], with the upper tube has an
4 internal flange which is used in PIG-J and PEG-J insertion (Fresenius Bad Homburg,
5 Germany) and the lower picture shows the internal balloon fixation device which is used in
6 RIG-J insertion (Medical Innovations Corporation, Milpitas, California):
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

Despite lack of evidence supporting the use of one over the other,[3] the PIG-J technique has potential advantages over the PEG-J method: (i) Sedation is not routinely required, reducing the risk of hyper-acute complications especially as many advanced PD patients are frail with significant co-morbid conditions; (ii) The higher technical success rate reported in RIG-J would also be expected due to the benefits of image guidance, in addition to a reduction in risk of bowel perforation, or injury to solid viscera (iii) Endoscopy is burdensome and not required by PIG-J (iv) The jejunal extension can be accurately placed under direct imaging, avoiding the issues with kinking or displacement observed with endoscopic placement.

In light of these potential advantages, we started to use the PIG-J for implantation of the gastrostomy tube for the administration of LCIG in our patients with PD. In this paper, we present the results of our centre's experience with this technique for the administration of LCIG.

Methods

Setting, patient selection and data collection

The movement disorder department in North Bristol NHS trust serves as a tertiary referral centre for a large geographical area including but not limited to the South-West of the UK, offering device-aided therapies for PD patients with significant motor fluctuations despite optimal medical therapy. LCIG is offered in selected cases when apomorphine and deep brain stimulation are either unsuitable or ineffective, with strict eligibility criteria as outlined by the NHS commissioning criteria employed in the UK.

In selected cases where the potential benefits are borderline, patients are admitted for a trial of LCIG administered through a nasojejun tube to demonstrate a beneficial response to treatment before gastrojejunostomy insertion. In addition to regular clinic appointments, all patients at our centre are given a direct line number for the Specialist nursing team for any urgent issues. All patient encounters are recorded in the clinical notes and radiological procedures are recorded on the picture archiving and communication system, which were reviewed for this case series.

Per-oral image guided gastrostomy technique

The procedure is explained to the patient prior to obtaining informed consent. The patient is starved for 6 hours before the procedure, no other bowel preparation is required and sips of water with oral medications are allowed. Routine sedation and antibiotics are not required, although a venous cannula is inserted in case a bolus of light sedation is needed (midazolam). An abdominal ultrasound is performed in the radiology suite to ensure the liver is not overlying the stomach. The patient is placed supine and the pharynx is numbed with a local anaesthetic spray. An 8Fr nasogastric tube is placed and the stomach inflated with 100ml air. Under fluoroscopic guidance, local anaesthetic is injected and the stomach punctured with an

1 access needle and intraluminal position is confirmed with contrast, followed by insertion of a
2 4Fr sheath over guidewire. Under fluoroscopic guidance, a catheter and hydrophilic
3
4 guidewire are passed retrogradely through the gastro-oesophageal junction, and out through
5
6 the mouth. The hydrophilic wire is replaced with a 260cm stiff guidewire. The Catheter and
7
8 4Fr sheath are removed, and replaced with a 90cm 6Fr sheath, which passes through
9
10 abdominal wall, stomach and oesophagus and exits the mouth. The “pull string” of the Freka
11
12 gastrostomy is passed through the sheath and attached to the gastrostomy tube. The
13
14 gastrostomy tube is then pulled through the mouth into its final position, removing the string
15
16 and sheath with the same manoeuvre. The gastrostomy is now fixed within gastric lumen
17
18 with the internal flange, and externally with a “bumper” clip that fits around the outside of
19
20 the tube. Under fluoroscopic guidance, a catheter and hydrophilic guidewire (reused from the
21
22 first part of the procedure) are passed in through the gastrostomy tube and manipulated
23
24 through pylorus and duodenum to the duodenojejunal (DJ) flexure. The hydrophilic
25
26 guidewire is exchanged for the stiff guidewire (again reused) and a 9Fr coaxial Freka
27
28 gastrojejunal extension tube placed over guidewire through the gastrostomy tube to the
29
30 proximal jejunum. The guidewire is removed and the tube cut to length externally, then
31
32 connectors attached, giving a separate gastric and jejunal port. The procedure usually takes
33
34 30-45 minutes with 10-15 minutes screening time and radiation dose in the region of 20mGy
35
36 (0.5 mSv, equivalent to around 3 months of the average natural background radiation in the
37
38 UK).

49 **Results**

50 All participants undergoing a PIG-J insertion between December 2015 to April 2020 were
51
52 included in this study - see table 1 for demographics and procedure related complications.
53
54

55 Thirteen had efficacy data such as diary recordings available at 12 months. Thirty-two out of
56
57 34 patients referred underwent this procedure successfully. One procedure was abandoned
58
59
60

1 due to technical considerations; no safe puncture site was possible past the large bowel
2 overlying the gastric antrum; and the other was converted to gastrostomy due to suspected
3 injury to the transverse colon when attempting the gastric puncture. The patient recovered
4 well without systemic sequelae or further complications, and responded well to LCIG therapy
5 which is ongoing. Repeat clinical assessments at 1 year follow-up were available in 13
6 patients at the time of writing.
7

8
9
10
11
12
13
14
15 As expected, the most common complications were stoma-site infections and displaced tubes.
16
17 During the follow-up period, 13 patients were suspected of having a stoma-site infection of
18 which 9 were confirmed and treated with antibiotics. Of the 9 patients who required a tube
19 replacement, one required 2 replacements and another had 3 replaced. Shortly after the
20 procedure, one patient had a small haematoma which did not require intervention and one
21 patient developed inflamed skin around the stoma site caused by acid leaking around the
22 tube. A short course of a high dose proton pump inhibitor resolved this issue and the patient
23 has had no further problems in the subsequent 2 years.
24
25
26
27
28
29
30
31
32
33
34

35 During the follow-up period, 1 patient died of unrelated co-morbidities and 4 patients ceased
36 LCIG therapy: one patient with known cognitive impairment pulled out their tube during a
37 confusional episode despite good motor symptom control; one developed a peripheral
38 neuropathy due to B12 deficiency; one patient found the pump an annoyance; and one patient
39 experienced abdominal discomfort with no identifiable gastro-intestinal complication.
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

Discussion

1
2
3 Per-oral image guided gastrojejunostomy insertion for levodopa-carbidopa intestinal gel is
4
5 safe and well tolerated in this small cohort of patients with advanced Parkinson's. The rate of
6
7 complications is comparable to reported rates for similar procedures in this patient group.[4,
8
9 5] The size of this cohort, and length of follow-up, precludes any firm conclusions being
10
11 drawn as to the potential advantages of this technique. However, based on this preliminary
12
13 data, we propose that this implantation technique warrants further investigation as it has the
14
15 potential to reduce procedure failures and may also widen access to LCIG therapy for patients
16
17 in which PEG-J is unsuitable or not tolerated. We suggest that the potential advantages
18
19 inferred from radiologically guided tube insertions in other patient groups may benefit the PD
20
21 population and are worth further exploration. While offering secure tube placement, this
22
23 technique avoids sedation, may have a higher technical success rate and offer a route of
24
25 therapy for otherwise ineligible patients.
26
27
28
29
30
31

32
33 Innovations within the field of interventional radiology continue to offer alternative solutions
34
35 to an increasing number of surgical procedures, in many cases replacing them and becoming
36
37 the standard of care. PEG has largely replaced surgical gastrostomy since its publication in
38
39 1980, with RIG techniques starting to be pioneered shortly thereafter.[6] Most centres use
40
41 PEG as the first choice option, the most common indication being enteral feeding, with RIG
42
43 reserved for those who are not suitable for the endoscopic route. In older patients, there is
44
45 good evidence available for safety of these procedures in the context of patients with motor
46
47 neurone disease (MND), stroke and dementia.[4, 7] RIG procedures are now often preferred
48
49 in patients with MND who require enteral feeding, as it has similar safety profile,[1] a higher
50
51 technical success rate and an advantage of avoiding the risks of ventilatory failure associated
52
53 with the sedation needed for PEG.
54
55
56
57
58
59
60
61
62
63
64
65

1 In our centre, interest in this alternative technique was based on a failed PEG-J insertion and
2 subsequent successful PIG-J insertion. The interventional radiologist (NC) had experience
3 and expertise in this technique in similar elderly and frail patient groups with good results
4 and offered to take on this service. In part due to patient feedback, and also the potential
5 advantages of this technique, it has now become the standard of care in our centre for LCIG
6 administration.
7
8
9
10
11
12
13
14

15 Our technique is similar to that published by Montgomery et al.,[8] this hybrid technique
16 potentially offering the benefits of an image guided procedure with the more robust tube
17 device.
18
19
20
21
22

23 There are multiple studies which have demonstrated the long-term safety of PEG-J for LCIG,
24 but the rate of gastrointestinal complications both minor and major remains frequent.[9-13]
25
26
27

28 The largest published study of LCIG administration in Parkinson's included 324 cases
29 undergoing PEG-J insertion within the comparable 12 month follow-up, reporting procedure
30 or device related adverse events in 68.5% of patients, primarily complications of device
31 insertion (33.6%), abdominal pain (26.5%), procedural pain (20.4%), and most seriously
32 pneumoperitoneum (5.9%).[14] More recently, the Greenfield study of a 145 cases of LCIG
33 administered via PEG-J with a mean follow-up of 2.8 years, which reported a device related
34 complaints in 37.2% of the cohort.[13] In each of these cohorts, as is our experience, the
35 complications are rarely serious and the benefits of the therapy outweigh the risks.
36
37
38
39
40
41
42
43
44
45
46
47

48 The major limiting factor in the use of RIG-J in the administration of LCIG is the potential
49 for high occlusion rates due to the smaller tubes required and the less reliable internal
50 fixation. Intuitively, as the tube device is the same for the PEG-J and the PIG-J techniques
51 (and indeed the similar pull-through method), one would expect a similar rate of tube related
52 complications. To our knowledge, there is a single published paper comparing the outcomes
53
54
55
56
57
58
59
60
61
62
63
64
65

1 of RIG-J and PEG-J for the use of LCIG, with the authors describing the placement of pigtail
2 retaining 14Fr tube.[5] Despite a lack of significant difference, potentially due to the small
3 numbers, there was a trend to a higher rate of tube replacements in the RIG-J group. They
4 described 42 replacement tubes in 30 patients (1.4 tube replacements per patient) in the PEG-
5 J group compared to 29 replacements in 12 patients (2.4 tube replacements per patient) in the
6 RIG-J group. With a similar follow-up period (15.6 months vs 16.8 months), the frequency of
7 tube replacements using the PIG-J method in this 32-patient series was less than required
8 using the RIG-J procedure (13 vs 29, chi-squared $p < 0.001$).
9

10
11
12 An alternative to the above described techniques is direct percutaneous endoscopic
13 jejunostomy (DPEJ). With the stoma inserted directly into the jejunum, this is thought to
14 provide more stable access and thus require fewer repeat interventions than PEG-J or PIG-J.
15 However, this has a relatively low placement success rate (around 85%), is more technically
16 challenging and requires at least moderate sedation.[15]
17
18

19
20 In summary, our case series shows that PIG-J insertion is safe, well tolerated and an effective
21 method for use in LCIG administration. Further studies are required to investigate its
22 superiority over the endoscopic technique and to establish long-term safety and efficacy.
23
24
25
26
27
28
29
30
31
32

1
2
3
4
5
6
Ethics

Formal ethical approval was not required.

7
8
9
10
11
12
13
Acknowledgements

We would like to acknowledge the efforts of all the staff who contribute to the advanced treatment service at North Bristol NHS Trust, and our patients who are at the centre of all this work.

14
15
16
17
18
19
20
Funding

This work had no external funding.

21
22
23
24
25
26
27
Author Roles

Data collection, manuscript editing – LM, LC, MS, MR, KSK

Study design, data collection and manuscript editing – AW, NC

Study design, data analysis and manuscript writing and editing – FB, MB

28
29
30
31
32
33
34
35
Conflicts of interest

No conflicts of interest declared by any of the authors.

References

- [1] T.-w. Yuan, Y. He, S.-b. Wang, P. Kong, J. Cao, Technical success rate and safety of radiologically inserted gastrostomy *versus* percutaneous endoscopic gastrostomy in motor neuron disease patients undergoing: A systematic review and meta-analysis, *Journal of the Neurological Sciences* 410 (2020).
- [2] P. Godbole, G. Margabanthu, D.C. Crabbe, A. Thomas, J.W. Puntis, G. Abel, R.J. Arthur, M.D. Stringer, Limitations and uses of gastrojejunal feeding tubes, *Arch Dis Child* 86(2) (2002) 134-7.
- [3] Y. Yuan, Y. Zhao, T. Xie, Y. Hu, Percutaneous endoscopic gastrostomy versus percutaneous radiological gastrostomy for swallowing disturbances, *Cochrane Database Syst Rev* 2 (2016) Cd009198.
- [4] V. Hermush, Y. Berner, Y. Katz, Y. Kunin, I. Krasniansky, Y. Schwartz, D. Mimran Nahon, A. Elizariev, G. Mendelson, Gastrostomy Tube Placement by Radiological Methods for Older Patients Requiring Enteral Nutrition: Not to be Forgotten, *Frontiers in medicine* 5 (2018) 274-274.
- [5] M.V. Saddi, M. Sarchioto, G. Serra, D. Murgia, V. Ricchi, M. Melis, R. Arca, P. Carreras, L. Sitzia, S. Zedda, G. Dui, R. Rossi, A. Ticca, M. Melis, G. Cossu, Percutaneous Endoscopic Transgastric Jejunostomy (PEG-J) Tube Placement for Levodopa-Carbidopa Intrajejunal Gel Therapy in the Interventional Radiology Suite: A Long-term Follow-up, *Mov Disord Clin Pract* 5(2) (2018) 191-194.
- [6] J. Sutcliffe, A. Wigham, N. McEniff, P. Dvorak, L. Crocetti, R. Uberoi, CIRSE Standards of Practice Guidelines on Gastrostomy, *Cardiovasc Intervent Radiol* 39(7) (2016) 973-87.
- [7] G. ProGas Study, Gastrostomy in patients with amyotrophic lateral sclerosis (ProGas): a prospective cohort study, *The Lancet. Neurology* 14(7) (2015) 702-709.
- [8] M.L. Montgomery, N.K. Miner, M.J. Soileau, D.K. McDonald, Placement of the AbbVie PEG-J tube for the treatment of Parkinson's disease in the interventional radiology suite, *Proceedings (Baylor University. Medical Center)* 29(4) (2016) 420-422.
- [9] A. Antonini, A. Yegin, C. Preda, L. Bergmann, W. Poewe, Global long-term study on motor and non-motor symptoms and safety of levodopa-carbidopa intestinal gel in routine care of advanced Parkinson's disease patients; 12-month interim outcomes, *Parkinsonism & Related Disorders* 21(3) (2015) 231-235.
- [10] H.H. Fernandez, J.T. Boyd, V.S.C. Fung, M.F. Lew, R.L. Rodriguez, J.T. Slevin, D.G. Standaert, C. Zadikoff, A.D. Vanagunas, K. Chatamra, S. Eaton, M.F. Facheris, C. Hall, W.Z. Robieson, J. Benesh, A.J. Espay, Long-term safety and efficacy of levodopa-carbidopa intestinal gel in advanced Parkinson's disease, *Mov Disord* 33(6) (2018) 928-936.
- [11] J. Cheron, J. Deviere, F. Supiot, A. Ballarin, P. Eisendrath, E. Toussaint, V. Huberty, C. Musala, D. Blero, A. Lemmers, A. Van Gossum, M. Arvanitakis, The use of enteral access for continuous delivery of levodopa-carbidopa in patients with advanced Parkinson's disease, *United European gastroenterology journal* 5(1) (2017) 60-68.
- [12] J.T. Slevin, H.H. Fernandez, C. Zadikoff, C. Hall, S. Eaton, J. Dubow, K. Chatamra, J. Benesh, Long-term safety and maintenance of efficacy of levodopa-carbidopa intestinal gel: an open-label extension of the double-blind pivotal study in advanced Parkinson's disease patients, *J Parkinsons Dis* 5(1) (2015) 165-74.
- [13] L. Lopiano, N. Modugno, P. Marano, M. Sensi, G. Meco, P. Solla, G. Gusmaroli, F. Tamma, F. Mancini, R. Quatrala, R. Zangaglia, A. Bentivoglio, R. Eleopra, G. Gualberti, G. Melzi, A. Antonini, Motor and non-motor outcomes in patients with advanced Parkinson's disease treated with levodopa/carbidopa intestinal gel: final results of the GREENFIELD observational study, *J Neurol* 266(9) (2019) 2164-2176.
- [14] H.H. Fernandez, D.G. Standaert, R.A. Hauser, A.E. Lang, V.S. Fung, F. Klostermann, M.F. Lew, P. Odin, M. Steiger, E.Z. Yakupov, S. Chouinard, O. Suchowersky, J. Dubow, C.M. Hall, K. Chatamra, W.Z. Robieson, J.A. Benesh, A.J. Espay, Levodopa-carbidopa intestinal gel in advanced Parkinson's disease: final 12-month, open-label results, *Mov Disord* 30(4) (2015) 500-9.

[15] P.K. Simoes, K.M. Woo, M. Shike, R.B. Mendelsohn, H. Gerdes, A.J. Markowitz, E. Ludwig, P.M. Shah, M.A. Schattner, Direct Percutaneous Endoscopic Jejunostomy: Procedural and Nutrition Outcomes in a Large Patient Cohort, JPEN J Parenter Enteral Nutr 42(5) (2018) 898-906.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

Table 1 – Demographics and complications of all patients in case series

Demographics and clinical assessments	
Total number of patients (n)	32
Age at PIG-J insertion in years (mean (SD))	66.9 (8.4)
Female gender (n (%))	14 (43.8)
Disease duration from diagnosis in years (mean (SD))	16.0 (5.7)
‘Off’ UPDRS III score at baseline (mean (SD))	45.8 (8.8)
‘On’ UPDRS III score at baseline (mean (SD))	24.2 (8.6)
Mean off time in hours at baseline (mean (SD))	7.2 (3.3)
Follow-up duration in years (mean (SD), range)	1.3 (0.9), 0.2 to 3.3
Mean off time reduction (in hours) from baseline to 12 month follow-up (mean (SD))	5.5 (3.8) ^d
Cognitive score at onset ^a	9.0 (3.3)
Depression score at onset ^b	14.5 (6.6)
Minor procedure related complications (no tube replacement required):	
- Stoma site infections (n (%))	9 (28%)
- Peri-stomal leakage (n (%))	1 (3%)
Major procedure related complications:	
- Number of patients requiring tube replacements (n (%))	10 (31%)
- Time to first tube replacement in months (median (range))	12.0 (5 to 40)
Any other complications*	1 small abdominal haematoma, 1 peripheral neuropathy, 1 tube removed by patient with cognitive impairment, 1 non-specific abdominal pain

Only patients with successful PIG-J are included.

^aMattis Dementia Rating Scale-2 age and education corrected score (higher scores represent better cognitive function). ^bBeck’s Depression Inventory II (higher scores represent greater levels of depression). ^cIncluding dislodged and blocked tubes. ^dData available from 13 patients.

* 2 procedures abandoned: 1 converted to gastrostomy due to suspected injury to the transverse colon when attempting the gastric puncture, 1 abandoned due to anatomical unsuitability for percutaneous gastrostomy (transverse colon overlying the front of the stomach)

