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The Twin-Stoma Gastrostomy and the LOOPPEG® 3G Tube

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1. Introduction

For tube feeding, the nasogastric tube and the percutaneous endoscopic gastrostomy (PEG) have been the main options, putting aside their minor variations, for decades. The relative relationship between these two options is illustrated in Figure 1. And the clinical evidence is undeniable: the nasogastric tube is low-comfort and low-risk whereas the PEG is high-comfort and high-risk.

For long-term use, patients and caregivers want a high-comfort and low-risk option (✓).

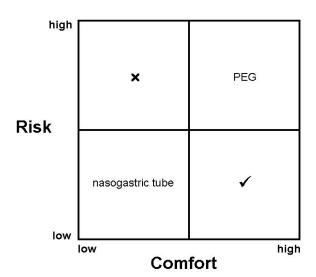


Fig. 1. The best-in-class option is high-comfort and low-risk

2. Why the nasogastric tube is low-comfort

The popular reason is the sensitive mucosal lining of the nose. Less often cited is the episodic increase in the effort of breathing caused by the tube. During upper respiratory tract infections, e.g. rhinorrhoea and rhinitis, the nasal mucosa becomes congested and

oedematous. At these times, breathing through both nostrils is exhausting even for a normal person. For the patient with one nostril plugged by the tube and the other by mucus, the sensation is akin to suffocation.

Despite the use of soft materials like silicone, the nasogastric tube remains an uncomfortable option. A thinner tube will cause less discomfort but will choke faster. Tube exchange is far more distressing than a tube *in-situ*. Thus, from the comfort perspective, a thinner tube may not be a better deal because it must be exchanged more frequently.

The fault, if a normal structure can be faulted, lies with the nose and pharynx. Sneezing and gagging are basic reflexes. In a person who is unrestrained, if these reflexes do not clear the noxious stimulus (the tube), his hands and head will move to do so.

Clearly, to be a high-comfort option, the tube must bypass the nose and pharynx.

3. Why the PEG is high-risk

After more than 3 decades of clinical use, the complications associated with the PEG are well known (Gauderer, 2001).

The following complications have occurred because the PEG moved out of position: death, peritonitis, buried bumper syndrome, hemorrhage, oesophageal dislocation, intestinal obstruction, necrotizing fasciitis, track stenosis and loss of stoma. The following complications have occurred because of difficult tube exchange: track disruption, hemorrhage, peritonitis and death.

For the PEG, good tube security and easy tube exchange appear to be incompatible bedfellows. If the tube is anchored securely, it won't be easy to exchange. If made easy to exchange, it is not secure. Clearly, to be a low-risk option, the tube must always stay in position *and* must be easy to exchange.

4. Why the LOOPPEG® 3G tube is high-comfort and low-risk

The LOOPPEG® 3G tube, being a gastrostomy tube, is high-comfort because it by-passes the sensitive nose and pharynx. It is low-risk because it is devoid of complications which plaque the PEG.

It is a hollow silicone tube with the exit opening at its midpoint. Distances from the opening are marked on the tube. Each end is fitted with a dilator for pull-through like a PEG (Figure 2). After pull-through, the ends are crossed and locked together. When locked in this configuration, the tube cannot be dislodged, inward or outward. All the complications due to tube insecurity that plagued the PEG cannot happen.

The tube can be exchanged in four simple steps (Figure 3). First, unlock the old tube. Second, attach a new tube to any end of the old tube using the connector. Third, pull the other end of the old tube, removing it and guiding the new tube into position. Fourth, detach the old tube and lock the new tube. From a caregiver's perspective, it is easier to exchange the 3G tube than the nasogastric tube. All the complications due to difficult tube exchange that plagued the PEG cannot happen.

Visit www.looppeg.com for more information about this tube, the best in class. In the subsequent paragraphs, we will refer to it simply as the 3G tube. Other suitable names would be the loop-gastrostomy tube, u-tube, sg-tube, loop-PEG, buddy-PEG, twin-PEG and U-PEG.

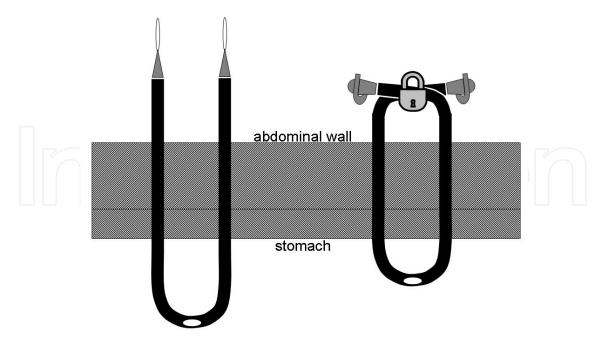


Fig. 2. LOOPPEG® 3G Tube

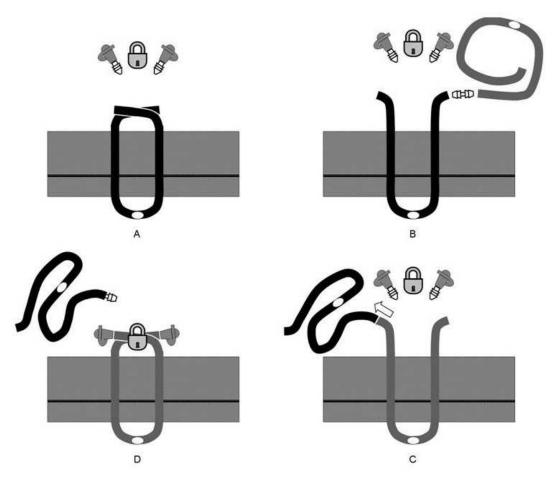


Fig. 3. LOOPPEG® 3G tube exchange is simple and easy

5. Portal versus Tube

We "blame" the sensitive mucosal lining for making the nasogastric tube low-comfort. Likewise, we blame the single stoma for the PEG being high-risk. Conversely, we credit the twin-stoma gastrostomy for making the 3G tube a high-comfort low-risk option.

It is easy to prove that portal is more important than tube. Take the 3G tube and use it with the other two portals. It will become low-comfort with one, and high-risk with the other. Then take other tubes and modify them for use with the twin-stoma gastrostomy; all will become high-comfort and low-risk. The inevitable conclusion is that the high-comfort low-risk profile is organic to the twin-stoma portal, not the tube.

To paraphrase Mark Twain, portal maketh the tube.

6. Why the twin-stoma gastrostomy is more effective

The term "twin-stoma gastrostomy" may be new but the concept, twinning for a better outcome, is not. Table 1 lists diverse examples where the concept has been successfully employed for a quantum improvement in performance.

The twin-stoma allows the use of a simple tube in a loop configuration, obviating the need for a balloon- or mushroom-shaped internal retaining structure. The single lock which keeps the tube in a loop configuration rests on normal skin, unlike the flange or bolster of the PEG. One end can be reserved for liquid food, and the other, liquid medicines.

The twin-stoma gastrostomy is akin to the dual PEG, used to treat gastric volvulus for the past 25 years (Altenwerth, 1994; Eckhauser & Ferron, 1985). Thus, it is a tried and tested procedure.

Singleton	Twins
Unicycle	Bicycle
Monohull boat	Catamaran
Single-engine aircraft	Twin-engine aircraft
Single-bolt lock	Double-bolt lock
One-key encryption	Two-key encryption
Single-point anchor	Two-point anchor
One-layer intestinal anastomosis	Two-layer intestinal anastomosis
Author	Co-authors

Table 1. Twinning is an established concept

7. Why the twin-stoma gastrostomy is safer

Suppose a large tube is split into halves, and the halves are converted into two smaller tubes. Since the total circumference of the two smaller tubes equals that of the large tube, the wounds are equal. Therefore, the twin-stoma is as large (safe) as the single-stoma, at worst. There are two reasons why the twin-stoma may have a lower infection rate than the single stoma of equivalent size. First, a smaller sized tube has been shown to have a lower infection

stoma of equivalent size. First, a smaller sized tube has been shown to have a lower infection rate (Zopf *et al.*, 2008). Since the twin-stoma uses a small sized tube, the infection rate can be lower.

Second, a dirty tube predisposes to wound infection. We know that the PEG is so difficult to exchange that it is hardly exchanged at all, unless forced to by tube dysfunction (Sartori *et al.*, 2003). Thus, the PEG is prone to infection. In contrast, the 3G tube is very easy to exchange, and the caregiver can exchange it monthly or even fortnightly. Therefore, with more frequent tube exchanges, and better tube hygiene, the twin-stoma can have a lower infection rate.

Many medical examples of twinning to improve safety exist. A two-layer intestinal anastomosis has twice as many punctures as the single-layer anastomosis, each puncture created by the same needle. Yet it is accepted as safer by many surgeons. Another example is *double*-ligature of a major artery to keep hemorrhage at bay, practised by almost all surgeons. Most medical journals have a *two*-peer review process.

Thus, whether by way of analysis or medical example, the twin-stoma is safer than the single stoma.

8. How to add a gastropexy

Gastrostomy and gastropexy are related but separate moieties. By excluding the peritoneal cavity, the latter enhances the safety of the former.

For the twin-stoma gastrostomy, the gastropexy may be effected with T-fasteners or suturing. An alternative method is the loop-lock technique. A secondary loop is created at the midportion of the 3G tube with absorbable ligatures. Two ligatures, each comprising two square knots, are required (Figure 4). This is done before pull-through.

After pull-through, the secondary loop and lock are used to appose the stomach wall to the abdominal wall (Figure 5B). When the LOOPPEG® is used in this fashion, we refer to it as the LOOPPEGGTM (the additional G to represent the gastropexy).

A polyglactin 3/0 ligature will undergo gastric acid hydrolysis and release the secondary loop about 30 days later (Chu, 1982). This duration is sufficient for adhesions to develop. If a longer duration is desired, polydioxanone may be selected (Hoile, 1983). Release is easily detected; the lock is lifted off the skin (Figure 5D).

Our current practice is to always insert the 3G tube with a secondary loop. Besides providing traction, the secondary loop keeps the central opening of the tube within the stomach and away from the gastric puncture sites.

Tube exchange using the percutaneous method (Figure 3) cannot be done unless the secondary loop is released. Thus, do not select a ligature material which takes a long time to biodegrade. Ideally, the material should biodegrade after adhesions have formed but before tube exchange is due. If tube exchange (or removal) is required before release, it must be done endoscopically.

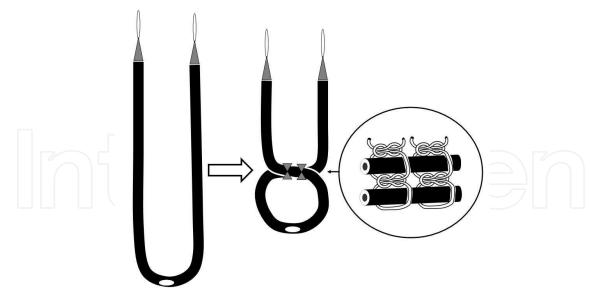


Fig. 4. The secondary loop is created with absorbable ligatures

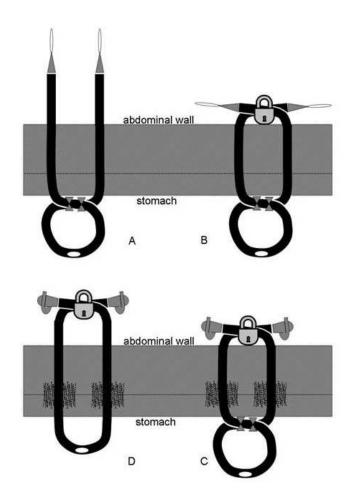


Fig. 5. The secondary loop is created before pull-through (A). The secondary loop and lock keep stomach apposed to abdominal wall (B). Adhesions develop with time (C). The lock is lifted off the skin when the ligatures undergo biodegradation, and release the secondary loop (D)

9. How to convert the single-stoma PEG to twin-stoma gastrostomy

Where feasible, the stoma occupied by the PEG should be used as one of the twin stomas. In this way, a matured track is not wasted; only one extra gastric puncture is needed.

If there is a size discrepancy, the PEG stoma is likely to be too loose for the 15 Fr 3G tube. Parenteral feeding may be used while the track stenose spontaneously to provide a snug fit.

For removal of the PEG, we recommend the technique described by Turner *et al.* (2010). The technique involves transfixion-ligature of the PEG. It is helpful to keep the end of the transfixion-ligature long for easy retrieval by a tripod snare. Removal is done after initial gastroscopy and the extra gastric puncture. If this sequence is not followed, air leak from the PEG stoma may cause loss of gastric distension, and interfere with the conduct of the conversion.

10. The road ahead

The twin-stoma gastrostomy and the 3G tube refer to the same thing, the best-in-class option (Figure 1). They are suitable for extended-term use; for patients who tend to pull on their tubes (e.g. mental retardation and dementia); for situations demanding stringent hygiene and frequent tube exchange (e.g. diabetes mellitus); and for places where access to medical facilities is limited (e.g. physically vast country).

22% of physically restrained residents in nursing homes in Singapore were "abused" to protect their nasogastric tubes from being pulled out (Mamun & Lim, 2005). In the Netherlands, a developed country, 22% of patients with nasogastric tubes were physically restrained for the same reason (Baeten & Hoefnagels, 1992). We hope the twin-stoma gastrostomy will encourage caregivers to convert their patients, reduce misuse of the nasogastric tube, and nip needless immobilisation by physical restraints.

A few doctors disagree with the use of the PEG in the demented elderly (Akner, 2005). What tipped the balance might have been its high-risk relative to the few months of remaining life. If so, the availability of the low-risk 3G tube should invite a re-think. The lack of improved survival with a feeding tube should not be a reason to reject it. After all, Medicine is not just about cure. More often, it is about caring and compassion, making the journey "less inhumane" for a loved one who will depart soon. The feeding tube can provide palliative decompression too (Pang, 2011).

Others believe that the gastrostomy tube should be established early, not late (Figueiredo *et al.*, 2007). For them, the twin-stoma gastrostomy (or 3G tube) should help their cause.

11. Misconceptions

At the roadshows of the 3G tube for doctors, a frequent question posed to us was whether it had been "proven to be safe and effective with a randomized controlled trial (RCT)." This misconception immediately tells two things about the questioner. First, he is not a general surgeon. The practicing general surgeon, or one capable of anything more complex than a gastrectomy, from operative experience, knows intuitively that the 3G tube is safe and effective.

Second, the questioner is not conversant with the limitations of a RCT. Randomization is just a means to control bias in a study, in this case an experiment in human beings. After

randomization, if the test group is given the 3G tube, the control group would not be given it. In other words, the control group will get a sham tube. Two issues become apparent. Isn't the study, particularly the control (sham tube) arm, unethical? Isn't the conclusion, specifically the finding in the test group, predicable? Of course, the answer is yes for both. Thus, the bona fide general surgeon will not conduct a RCT on the 3G tube, for no reason other than he is ethical and does not perform sham operations. (This is not to say that he cannot collect a case series, and report it in a medical journal. My own cases have been reported elsewhere.)

Another misconception is that the 3G tube should not be allowed into mainstream practice unless it has been shown to prolong patient survival. But a feeding tube cannot cure the dysphagic patient of his primary condition, be it stroke, dementia, Parkinsonism, cancer, motor neurone disease, etc. Many of these patients will die soon after they become dependent on the feeding tube. It is unreasonable to expect the 3G tube to be a miracle drug.

The 3G tube is a device, not a drug. Its effects are "local and predictable" in the words of the Food and Drug Administration of the United States of America. It is silly to obstruct its introduction into clinical practice, or deny the patient his rights to have a secure and easy to exchange gastrostomy tube, using oppressive and irrelevant requirements like "Phase I – IV clinical trials".

Yet another common misconception is that two stomas will cause more pain to the patient. While this is true if we use a 3G tube which is as large as the PEG, it need not be so. A fine bore tube can always be used as the 3G tube because we are not bothered by tube blockage. If blockage happens, we can simply and easily exchange the tube. In contrast, we always need to use the largest PEG tolerable by the patient. With the PEG, we dread blockage; we want to avoid having to exchange a blocked PEG and all the attendant dangers.

Critics of the 3G tube tend to harp: "The insertion of the loop PEG requires more steps than the PEG. Why should I do the more difficult operation?" These critics have forgotten the Hippocratic Oath. PEG tube dislodgements are extremely traumatic events: physically, psychologically and financially, for the victim, not the doctor (Pang & Low). Doing a simpler PEG operation may result in a lifetime of worry about tube accidents for the patient and his family. On the other hand, the 3G tube, more "difficult" for the doctor – by virtue of one more gastric puncture with a 14G needle - will lessen the burden of care for the patient. To turn away from the 3G tube is to turn a blind eye to the plight of dysphagic patients (Pang & Maetani, 2011).

Early adopters of the 3G tube should be aware of a bizarre hazard. Until the rationale of the twin-stoma becomes widely known, it will appear that these adopters have violated their patients with an unnecessary extra wound. They may find themselves hauled by their rivals to appear before the regulatory authority to answer a charge of professional misconduct. Strange as it may seem here, it did happen to me.

12. Conclusion

The twin-stoma gastrostomy, high-comfort and low-risk, is the option for all seasons. One complete approach is provided by the LOOPPEG® 3G tube. For the cost of a strand of absorbable material, a gastropexy can be added.

13. Acknowledgements

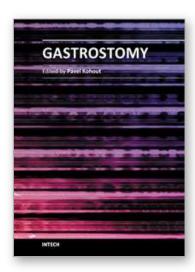
The Franciscan Missionaries of the Divine Motherhood in Singapore provided the author with opportunity, space and inspiration, without which the 3G tube would not have been invented. For the record, the FMDM nuns did not agree to be acknowledged. But their selflessness was all the more worthy of acknowledging. SGN Pte Ltd (www.looppeg.com) funded the Article Processing Charge. To Dr Chia Siew Cheng, this article is dedicated.

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Edited by Dr. Pavel Kohout

ISBN 978-953-307-365-1
Hard cover, 152 pages
Publisher InTech
Published online 02, December, 2011
Published in print edition December, 2011

The gastrostomy placement is a method of providing nutrition to the patients who are unable to eat. In this book you can find chapters focused on the use of gastrostomy in children, patients with neurological impairment and patients with head and neck tumours. Home enteral nutrition is suitable for all of these groups of patients and is far easier with gastrostomy. The new indications (especially in very young children) required new techniques such as: laparoscopic gastrostomy, laparoscopy assisted endoscopic gastrostomy with/without fundoplication, ultrasonography assisted gastronomy. All information about these techniques can be found in this book. This book does not serve as a basic textbook, but as an interesting reading material and as an aid for physicians who are already familiar with the indication for gastrostomy and want to know more.

How to reference

In order to correctly reference this scholarly work, feel free to copy and paste the following:

Ah San, Pang (2011). The Twin-Stoma Gastrostomy and the LOOPPEG® 3G Tube, Gastrostomy, Dr. Pavel Kohout (Ed.), ISBN: 978-953-307-365-1, InTech, Available from: http://www.intechopen.com/books/gastrostomy/the-twin-stoma-gastrostomy-and-the-looppeg-3g-tube

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