

A simple morpho-functional evaluation leads to a high transanal irrigation success rate in neurogenic bowel management

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Abstract: AIMS: In January 2010, we introduced a simple morphofunctional evaluation method to evaluate patients candidate to use transanal irrigation (TAI). We report long term follow up on the first 100 patients with high success rate. **Methods:** We analysed data from 106 spinal cord injury patients enrolled from January 2010 to October 2013. Six patients were rejected at the start of the study due to the presence of anatomical situation at risk, 100 patients all followed the study protocol. The method consists of diluting an iodinated contrast medium (hexabrix 320) in the water of the container. After rectal examination, the irrigation fluid, with the contrast medium, is subsequently introduced in increasing quantities, to wash the left part of the colon, with a fluoroscopic examination being performed every 100 mL. The same procedure was performed after 2 weeks to check results of TAI and to define a personalized program. **Conclusions:** the introduction of an easy method that promotes better-reasoned use of this approach leads to a higher percentage of positive results. The efficacy of TAI is referred in data published around 50%, a correct protocol for selection and follow up of patients is not clear and no evidences are reported on the dose of water to be used. On the other hand complications as bowel perforation are reported. This approach permits to simply resolve problems related on patients selection and to avoid complications. Actually we have more than 250 patients maintaining good results with this approach, none had complications.

Keywords: Constipation; Fecal Incontinence; Neurogenic bowel dysfunction; Spinal cord injury; Transanal irrigation

INTRODUCTION

Spinal cord injury (SCI) has a series of impacts on sensory and motor functions of multiple organ systems. Bowel and bladder dysfunction affects about 80% of all SCI patients¹; it has a major negative impact on the patient's quality of life due to voiding and bowel difficulties, and the social restrictions such dysfunctions imposes on the patient²⁻³.

The introduction of intermittent catheterisation (IC) by Lapides in 1972 improved the urologic morbidity and mortality considerable although recurrent urinary tract infections (UTI) is still the most common pathology linked to IC⁴. Therefore, routine examinations of the genitourinary system are mandatory for the SCI patient population.

The bowel dysfunctions consist of constipation, faecal impaction and incontinence⁵, but the examination and treatment of the bowel problems has not obtained any larger degree of medical attention; one of the potential treatment modalities that has been used for thousands of years is transanal irrigation (TAI)¹ which only lately was introduced for managing neurogenic bowel dysfunction⁶⁻⁹.

Several trials have shown that TAI is efficacious in terms of improving constipation, faecal incontinence and symptom related quality of life in adult SCI patients⁷⁻¹¹ but practical experience shows that the adherence to the procedure appears to be limited over time.

No studies has examined how to improve the practical approach to the irrigation procedure and, in particular, determined eligibility of patients, the optimal amount and speed of irrigation volume.

On this background we decided to use a fluoroscopic approach to perform a simple morpho-functional evaluation of the TAI procedure for individuals who were candidates to its use; the purpose was to define eligibility of patients, determine optimal speed and volume of irrigation and to have a basis for repeatable evaluation.

METHODS

Patient selection

From January 2010 to October 2013, potential participants were identified at scheduled urological control visits

at the department of neuro-urology of Niguarda Hospital in Milan, Italy. During this visit (baseline visit), patients were additionally screened for significant bowel dysfunction, irrespective of the present conservative bowel management. In case of bowel problems and if they met the inclusion and exclusion criteria's, they were invited to participate in the study, whose length is 6 months. Inclusion and exclusion criteria's were as follows:

Inclusion criteria

- History of SCI (full or partial section, myelitis, multiple sclerosis, spina bifida)
- Bowel evacuation difficulties in spite of conservative bowel programs
- History of symptomatic and frequent urinary tract infections despite a good bladder management

Exclusion criteria

- History of ano-rectal disease causing pain or bleed such as anal fissures, III or IV grade hemorrhoids, fistulae
- Previous abdominal or pelvic radiotherapy
- History of diverticulitis or diverticular abscess
- History of ano-rectal or pelvic surgery
- History of severe autonomic dysreflexia
- Long term corticosteroid treatment
- Coagulation disorders or anticoagulation therapy (excl. clopidogrel and aspirin)

Study flow

Baseline visit: a dedicated physician explained and discussed all aspects around the various procedures and, if the patient was willing to participate, retrieved informed consent. In case of minor patients (Tab. 1), informed consent was obtained by the parents. The physician retrieved patients' medical history, presence of fecal incontinence or impaction, stool frequency, usual bowel management (type and quantity of laxatives) as well as occurrence of UTIs. All patients were asked before dismissal to fill-up, over a 3-4 days period, a diary of evacuations and to bring it to the next visit.

Visit 1: the first TAI under fluoroscopic control was performed. For a two weeks period, until visit 2, patients were

TABLE 1. Minor patients involved in the study.

Age	Pathology
17	Spina bifida
12	Spina bifida
17	Lipomyelomeningocele
16	Spina bifida
12	Spina bifida

TABLE 2. Patient flow chart.

Screened for study: 106 patients
Rectal prolapses = 1
No accept of irrigation procedure = 5
Informed consent: 100 patients
Hemorrhoids = 1
Access to visit 1: 99 patients
Bowel occlusion = 1
Pain = 1
Bowel over-distension = 1
Access to visit 2: 96 patients
Autonomic dysreflexia = 2
Fistula = 1
No compliance or loss of caregiver = 5
Access to visit 3: Long term follow up - Finalized study: 88 patients

asked to perform TAI daily with an individualized program of laxatives (Macrogol®), and to continue their usual lifestyle. The patient was instructed to use the irrigation volume which corresponded to the volume required to opacify the left colic flexure (see below)

Visit 2: (2 weeks after visit 1), a similar TAI procedure was performed. Hereafter the patients were asked to perform irrigation three times a week, using Macrogol® if appropriate, until the next scheduled visit. The patient was instructed to use the irrigation volume which corresponded to the volume required to opacify the left colic flexure (see below).

Visit 3: (long term follow up at 6 months). During this visit, that is part of our scheduled urological follow up, a dedicated physician evaluates the patient and his bowel management using a bowel diary.

Further visits were not part of this study. Not part were scheduled as any other outpatient in our clinic every half year over (earlier controls could be obtained on patient request in case of onset of new problems (bowel linked or non)).

Transanal irrigation and Fluoroscopic procedure

TAI: performed with the Peristeen® device (Coloplast; Humlebaek, Denmark), which has been marketed since 2004. It consists of a rectal catheter with a balloon, connected to a control unit, which further is connected to a water bag containing 1L. A pump attached to the control unit allows both balloon inflation and water instillation. Once the water has been installed in the bowel, the rectal catheter is removed enabling faeces evacuation. For the purpose of this study, iodinated contrast medium (Hexabrix®, 100 ml) was added to the 1L irrigation water enabling visualization of colon through fluoroscopy (BV Pulsera, Philips Medical Systems, Sweden,).

Fluoroscopy: lying on the examination bed a digital rectal examination was performed to exclude anal-rectal pathologies. Hereafter the rectal catheter was inserted and the balloon inflated. The irrigation fluid is subsequently introduced in increasing quantities, with a fluoroscopic examination being performed before and after every 100 ml of water installed. The volume of irrigation were reported at opacification of the left colic flexure.

TABLE 3. Patient demographics-

Patients who signed informed consent	100
Men	54
Women	46
Patients undergoing full protocol	88
Age (mean) - range 12-77 year	40
Acquired Lesion	78
Congenital Lesion	22
Time since Injury (years) 1<t<5	36
Time since Injury (years) 6<t<16	23
Time since Injury (years) t>16	41
Upper Motor Neuron lesion	60
Lower Motor Neuron lesion	45
Peripheral lesion	41
Laxatives	87
Macrogol®	60
Other laxatives	72
Faecal incontinence	30
Incomplete evacuation	71
Pain for evacuation	16
Blood in the stool	3
Mucus in the stool	3
Frequency of evacuations (n° for week) 0	41
Frequency of evacuations (n° for week) 1	34
Frequency of evacuations (n° for week) 2-3	8
Frequency of evacuations (n° for week) 7	17
Solid Stool	22
Faecal impaction (faecoliths)	76
≥ 1 UTI requiring antibiotics in previous year	85
history of symptomatic and frequent urinary tract infections despite a good bladder management	100
Self-reliant patients	93
Patients with nerve stimulator	19

When the filling phase was completed, study participants were transferred to the toilet (in a sitting position) to evacuate. After evacuation the patient was replaced on examination bed to fluoroscopically determine the amount of faecal residues.

During the whole procedure, the patient were asked to report any abnormal sensation to allow for early identification of autonomic dysreflexia.

During the fluoroscopy, the X-ray exposition is less or equivalent than the one during a routine videourodynamic evaluation.

The ability to directly assist in the procedure and display the bowel situation during the sessions of TAI with fluoroscopic control, seeing the positive effects of the control

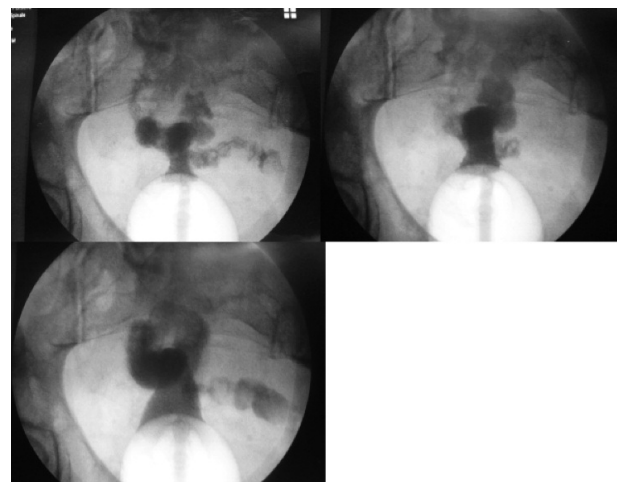


Figure 1. – Fistula.

TABLE 4. Volume of water at the first visit – 99 patients.
* 3 cases of dilation of the ampulla during the filling phase.

	Sigma	Transverse (Slit left colic)	Slit right colic	Ciecum
Volume H ₂ O average (ml)	200	300	520	620
N° of patients that reach the mentioned irrigation level	99*	80	28	22

TABLE 5. Long Term Follow up (after undergoing visit 3 on 88 patients).

Average volume of H ₂ O irrigation (ml)	430
Number of patients using laxatives (%)	54 (61,4%)
Number of evacuations (programmed with TAI)	3
Number of patients symptomatic UTI requiring antibiotics	4 (4,5%)
Number of faecal incontinent patients (%)	2 (2,3%)

TABLE 6. Comparison of pre- and post-protocol patients.

	Before TAI	After TAI
UTI's	85 %	4,5 %
Use of Laxatives	87%	61,4 %
Referred Incontinence	30%	2,3 %
Mean Time for evacuation (min/day)	>60	<30
Faecal impaction (faecoliths)	76%	22 %

procedure was one of the characteristics of this method. The direct involvement of the patient allowed a high adherence to the program.

Bowel fluoroscopic evaluations and bowel diary

With the fluoroscopy we can evaluate: the presence of faecoliths, the dilation of the ampulla, the presence of bowel peristalsis.

All patients involved in the study are followed in our centre, for this reason the population of this study was submitted to scheduled neuro-urological follow up, which include even bowel evaluations, performed by a dedicated physician using a bowel diary.

RESULTS

Patient flow through study

The patient flow is described in detail in Table 2. Of the 106 patients screened, 100 agreed to participate and signed informed consent. In 1 patient haemorrhoids (grade III-IV) were detected before starting the first irrigation and another 3 and 8 patients were excluded respectively during the first or second irrigation procedure, leaving 88 to fulfil the protocol (per protocol population).

Demographic data

The demographic data of the 100 patients who gave informed consent are presented in detail in Table 3. In short, 54 were men and 46 women with a mean age of 40 (12-77) years; of these 5 were minor (12-17 years), the specific data of this group of patients are presented in Table 1. Seventy-eight patients had acquired lesions whereas the remaining 22 were congenital. Time since injury varied between 1 to 15 years.

Regarding the bowel management, 87 used laxatives, mainly Macrogol®. The weekly stool frequency was < 2 in

75 patients and ≥ 2 in the remaining 25 patients. Ninety-three patients were self-reliant with respect to their bowel management. Faecal incontinence and impaction was reported by 30 and 76 patients, respectively.

In terms of bladder emptying, all patients used intermittent catheterization. Eighty-five of patients reported at least one episode of antibiotic requiring UTI in the year prior to study inclusion.

A subpopulation consisted of 19 patients with an implanted sacral or pudendal neurostimulator (urological indication) in whom bowel function was not altered after implantation.

Transanal irrigation

Table 4 shows data about the volume of water and the bowel level reached with the irrigation, detected at the first visit (99 patients).

After the first evaluation, we recommend the patients to use the volume of water necessary to reach the left flexure in order to reproduce a physiological bowel avoiding. The data about the volume of water don't change a lot between visit 2 and 3.

At visit 3 (long term follow up at 6 months), the mean irrigation volume for reaching the left flexure was 430 ml, range 200 – 500 YY.

Table 5 shows the results at long term follow up (visit 3, performed at 6 months).

Results before and after use of TAI

The results after use of the TAI procedure:

- 61,4% continued to take oral laxatives the previous day
- Significant decrease of faecal incontinence
- Significant decrease of number of symptomatic UTI's
- Significant reduction of faecal impaction

DISCUSSION

Correct bowel rehabilitation following SCI requires a programme to promote faecal movement and permit complete evacuation.

Proper hydration and the introduction of dietary fibre, together with a planned evacuation programme, is the basis of the rehabilitation programme. This should be associated with the evaluation of correct evacuation times in relation to bowel activity linked to the gastrocolic reflex. Various methods can be used to encourage evacuation: from me-

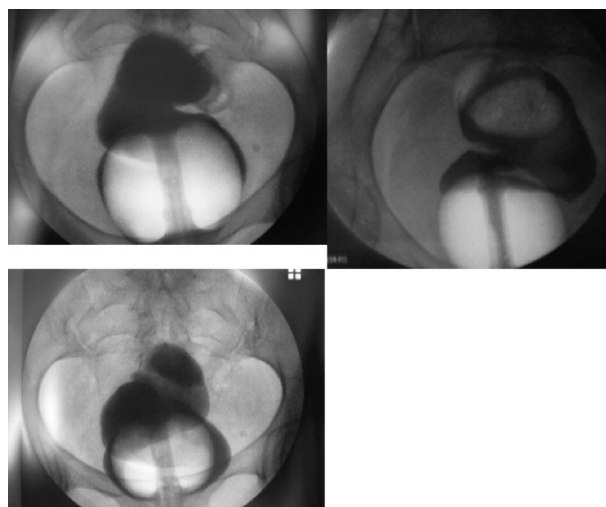


Figure 2. – The presence of fecaloma causes intestinal blockage and does not allow the liquid to go up again.

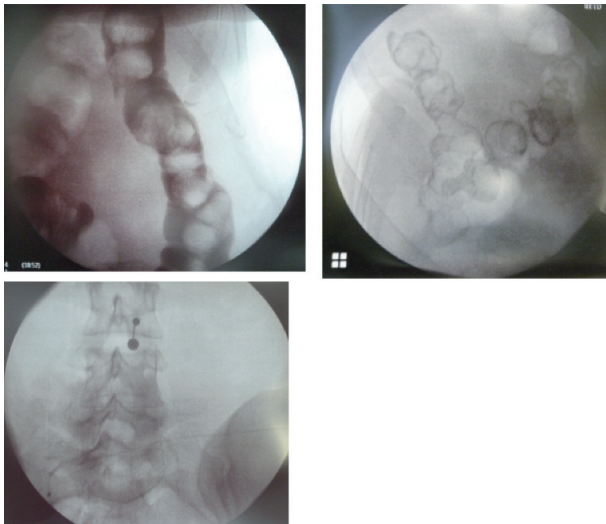


Figure 3. – Bowel before and after TAI.

chanical stimulation to rectal exploration, and the use of laxative or glycerine suppositories.

Numerous methods have been proposed to encourage normal stool consistency and promote complete evacuation. Abdominal massage, the use of the Valsalva manoeuvre, the combination of laxatives and drugs that reduce stool consistency, and prokinetic drugs are all suggested aids.

The introduction of TAI has been found to be a possible effective alternative, although the level of evidence is not high yet. In our experience, the introduction of an easy method that promotes better-reasoned use of this approach leads to a higher percentage of positive results. There is no data in the literature regarding the reasons for abandoning the procedure or on side effects associated with TAI (about 50%).

Following this, it is possible to describe the TAI procedure as an excellent alternative capable of aiding intestinal evacuation allowing complete evacuation of the left colic flexure.

Observation of this case study lets us make the following considerations:

the method of transanal irrigation is safe for the patient once anatomical changes such as fistulas, stenoses or diverticula are excluded while introducing liquids. This situation is possible after a long story of incomplete intestinal evacuation which is frequent in these patients.

This procedure must be chosen with caution in situations where medical treatment has had no effect on the presence of elevated intestinal blockage by fecaloma which do not allow the liquid to go up again. The presence of fecal matter with a blockage of the sigmoid colon and with dilation of the rectal ampulla at the beginning of the procedure must include as precaution a daily program of washing with low doses of macrogol.

After a new morphological check, it is possible to proceed with an increase in the washing dose and to alternate days.

The presence of peristalsis during irrigation can cause painful symptoms and delay the following evacuation for a possible activation of retrograde peristalsis. These visual observations are in contrast with the theory that the efficacy of TAI is related on an activation of peristalsis due to water effect. In these patients however the presence of peristalsis favours an efficient evacuation afterwards. Analysing the mechanisms which are lost under the neurophysiologic pro-

file following medullary lesions, it is possible to assume that the situation of lack of peristalsis in the patient with inveterate medullary lesions can be attributed to a situation of persistent intestinal overflow with anatomical changes from the wall and the myenteric plexus.

The use of sacral and pudendal neuromodulation falls within the recommended methodologies in terms of research into the treatment of constipation in neurogenic situations (ICI 2009).

CONCLUSIONS

These data describe the first group of individuals who followed the protocol. 72 individuals are currently enrolled and a long-term analysis of the entire population is underway. The current finding is that this approach makes it possible to offer a genuine, measured and effective response to neurogenic bowel dysfunction.

With this approach we are able to perform an objective evaluation during the use of TAI. This approach allows to clarify a lot of aspects and questions about the use of TAI.

We would like to underline the following topics in the study:

1. Consensus review open questions:

- Diagnostic approach before TAI to avoid side effects: with our method we don't have adverse events because we can exclude cases at risk

- Amount of water: with our method we find the specific volume of water for every person to promote a physiological evacuation, emptying the bowel until the left flexure. The media amount of water is less than recommended one.

- In the consensus review is suggested a pyramidal approach, but the study shows the need of a multimodal approach that can involve TAI, neurostimulation and laxatives.

- Repeatability of the approach to simplify follow up.

For all these reasons, our success rate with TAI is high, even in patients that started to use TAI in other centers without showing results.

2. This method bring us to have many information about TAI and its use. A lot of these findings, for example the amount of water and the combined use of TAI and laxatives, can be useful even with the standard use of TAI.

3. Morphological control of TAI effects allows a really better understanding of bowel dysfunction after spinal cord injury.

1 The procedure is known under a number of synonyms like colonic irrigation, rectal irrigation, enema clyster.

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Comment

The study aims to investigate different aspects related to the action and the improved effectiveness of TAI, performed with modern “positive and constant air pressure” devices such as Coloplast Peristeen®. This is an important issue because the reasons leading to the patients’ progressive drop-out are not clearly defined yet: leaving aside the causes due to bureaucratic and organizational problems (the absence of these devices in the National Health Care Range of Fees and the resulting reimbursement difficulty in some Local Health Authorities, etc.), the most frequent reasons are associated to changes over time of the feasibility of TAI and/or of its effectiveness in producing a satisfactory and complete evacuation.

Moreover, a proper patient selection is certainly an important factor in determining the continuity of adherence to treatment, so the fluoroscopic procedure, that allows to evaluate the characteristics of the rise of irrigation water in the colon, is extremely useful to collect any patient's peculiarities that, if not properly corrected or removed, could undermine the effectiveness of TAI.

The method, proposed by Michele Spinelli’s group of Niguarda and described in the article, proves to be a convincing approach to allow a more rational patient selection to start the procedure, to identify the main causes of its low effectiveness and to define which parameters will ensure the best use: the amount of irrigation water and its ways of spreading in the large intestine.

The physiopathological interpretation of these phenomena is certainly “affected” by the neuourological background of the authors (as a proof of that please note that the presence of the enteric nervous system in the colon wall, while it is absent in the bladder, makes the response mechanisms to the endoluminal increase in volume or pressure on its basal tone even more complicated. To this end, please see many studies with the barostat by Camilleri and Aspiroz), but the phenomena described undoubtedly convey the “operational” aspects of the bowel which are necessary to differentiate all circumstances produced by TAI with a device such as Peristeen®.

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