



## TRANSNASAL SAVARY GILLIARD DILATATION OF THE ESOPHAGUS: INNOVATIVE TECHNIQUE FROM OUR CENTRE

### Gastroenterology

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### ABSTRACT

**Background:** Pharyngoesophageal strictures (PES) affect 3–7% of patients submitted to head and neck as well as esophageal cancer therapy making such dilatation technically challenging. Objective was to describe the safety, overall efficacy and our experience with fluoroscopically guided Transnasal Savary-Gilliard (SG) dilations of esophageal strictures. We describe our innovative technique in patients with hypopharyngeal/cervical esophageal malignancy or stricture in who endoscopically guided guidewire placement was challenging or futile due to close proximity of such lesions to the oropharynx and hence no stability or support offered to the endoscopy tip for placement of the guidewire across the lesion.

**Methods:** This study was a prospective cross-sectional study carried out at Madras Medical College, Institute of Medical Gastroenterology on all patients undergoing Transnasal Savary-Gilliard dilation from August 2018 to January 2019. Dilation was performed with Savary-Gilliard polyvinyl dilators (Wilson-Cook Medical) over a hydra guidewire (straight tip) that was advanced transnasal under fluoroscopy to the stomach. Patients were asked to answer a questionnaire determining prospectively the dilation program efficacy as dysphagia improvement, and any complication during and/or post procedure was recorded.

**Results:** Fifty eight transnasal esophageal Savary-Gilliard dilations were performed on 50 patients. The mean age of the cohort was 57 years (37-71 years). Thirty three patients were male (66%). Pharyngeal and cricopharyngeal region was the most frequent dilation site (96%). Indications included supraglottic squamous cell carcinoma (30%), hypopharyngeal carcinoma (26%), post-radiotherapy (post-RT) strictures for head and neck carcinoma (28%), stenosis of surgical anastomosis (8%), and corrosive stricture (8%). One procedure (2%) was aborted due to laryngospasm or gagging. There were no clinically significant complications. The mean predilation dysphagia Mellow-Pinkas score was 3 and the initial stenosis diameter was 6 mm, and 60% postdilation had dysphagia improvement.

**Conclusion:** Transnasal esophageal Savary-Gilliard dilation can be performed in unsedated patients with a very low complication rate and in technically challenging cases by transoral route. The procedure was well tolerated in 98% of our patients. This technique formerly done only through endoscopy guidance and under sedation, allows for dilation as an outpatient procedure.

### KEYWORDS

Esophageal stenosis; Pharyngoesophageal stenosis; Dysphagia; Transnasal dilation

### INTRODUCTION

For the patient with a narrowed pharyngoesophageal lumen caused by either a benign or malignant process, esophageal dilation is an important therapeutic modality. In 1955 Puestow described a method whereby a guide wire was inserted through the stenotic area and then a series of semi-flexible carrier system were passed over the guide wire.<sup>2</sup> Modifications have been made in both the technique for inserting the guidewire and the equipment, but the method has been the standard nonsurgical method for dilation of narrow diameter firm strictures for the past half of a century.<sup>3</sup> Head and neck cancer (HNC) is the fifth most common cancer worldwide and accounts for approximately 3% of all malignancies in the US.<sup>4</sup> Survival for patients with advanced stage disease undergoing adjuvant or primary chemoradiation (CRT) regimens has increased but is sometimes associated with late toxicities that may diminish the patient's quality of life.<sup>5</sup> Dysphagia, caused by partial or complete esophageal stenosis, is a particularly debilitating treatment consequence. The close proximity of mucous membranes in the pharyngoesophageal area makes this site especially susceptible for stenosis formation. The healing process after radiation damage, involving fibrosis and scar tissue formation, can result in a concentric stricture.<sup>6</sup> A recently published meta-analysis describes the risk for

pharyngoesophageal stenosis in HNC with conventional radiation treatment (RT) to be 5.7% and notes a more than threefold increase, to 16.7%, with intensity modulated RT in combination with chemotherapy.<sup>7</sup> Careful selection of dilation technique and establishment of the goals for luminal restoration are important as, in each case, these factors may need to be altered to suit the etiology and pathology of the stricture. The patient's dietary habits and nutritional needs must be considered when constructing an appropriate treatment plan. When treating these patients, it is important to be aware of the fact that the ultimate goal of therapy is to return patients to an oral diet while avoiding adverse events which, although rare (polled complication rate of 4% per patient), may include perforation, bleeding, and bacteremia.<sup>8</sup> Although technically challenging, the cornerstone of the management of pharyngoesophageal stricture (PES) is still dilation therapy with bougie dilators or balloons.<sup>9</sup>

While balloon/bougie dilators have been used for decades in sedated endoscopy, the transnasal technique is novel and offers some important advantages over the traditional techniques. The aim of this study is to assess success rates and safety of transnasal esophageal dilation in HNC, esophageal carcinoma patients and those who have

undergone chemoradiation (CRT) or radiotherapy developing stenosis close to the oropharynx in which endoscopically placement of guidewire is challenging. Most patients in our study was referred to our department of gastroenterology for Ryle's tube insertion prior to radiotherapy for head and neck malignancy, and patients with post radiotherapy strictures involving the pharyngoesophageal region for feeding purpose and hence a dilation to achieve sufficient diameter to pass the Ryle's tube was the primary aim in these patients and also dysphagia improvement was assessed. The Savary Gilliard system is more logical in its technical design, easier to use, possibly safer and efficacious.

**METHODS**

This was a prospective cross sectional study conducted on patients undergoing transnasal dilation of the esophagus at Rajiv Gandhi Government General Hospital, Madras Medical College, from August 2018 to January 2019. This study was approved by the institutional review board. The study population consisted of consecutive patients with primary tumors of the hypopharynx, supraglottic region, cervical esophagus and post radiotherapy patients for Head and Neck Cancer (HNC) presenting with dysphagia. The medical chart of all persons undergoing transnasal dilation of the esophagus was analyzed. Information regarding patient demographics, indications, procedure efficacy and complications was assessed. Patients with hypopharyngeal malignancy / pharyngoesophageal (PES) strictures presenting as complete stenosis prior to dilation, as assessed by barium swallow and/or endoscopy were excluded from this study. All information was coded using SPSS software (version 22.0).

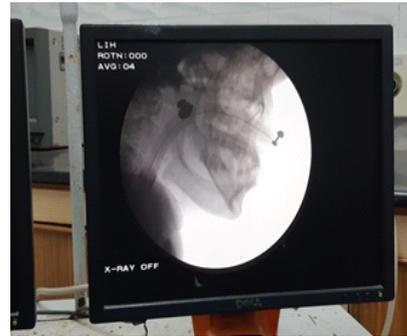
Transnasal dilation of the esophagus was performed with topical anesthesia or with the patient under conscious sedation, at the preference of the patient. The patient's more patent nasal cavity was topically anesthetized and decongested with a combination of oxymetazoline hydrochloride 0.05%, and lidocaine spray 10%. Fluoroscopy was used to monitor the position of the guidewire, which should be targeted at least 30 cm below the lowest point of the stricture.<sup>10</sup> mostly; the distal tip was positioned in the gastric antrum along the greater curvature of the stomach. Wire-guided dilators offer the potential effects of both radial and longitudinal dilation, depending on whether additional to-and-fro movement was performed after the initial static radial dilation. Wire-Guided Polyvinyl Dilators (Savary-Gilliard, Cook Medical) offer a safer approach than bougie dilators by ensuring that the dilator remains in the axis of the lumen and does not buckle or bend laterally into the wall of the stricture and create an increased risk of perforation. This technique was conducted under fluoroscopy, to allow visualization of the dilator passing through the stricture and is preferred for complex strictures.



**Figure 1: Savary Gilliard dilator being placed via the transnasal route**



**Figure 2: Guidewire placed across the stricture with the dilator positioned above the stenotic area under fluoroscopic guidance**



**Figure 3: SG dilator placed across the stenotic lesion by wire guided technique**

**Technique of Dilation**

The “rule of three,” as it applies to bougie dilators, has become the standard guide to the number of dilators passed per session. This rule suggests that in a single session, no more than three dilators of sequential size should be passed once moderate or greater resistance is evident.<sup>11</sup> Savary dilators may or may not offer the same tactile resistance. In these cases, the starting size of the lumen at the stricture should be estimated, and the optimal target for luminal patency should be determined by the underlying etiology, initial stricture lumen diameter and the patient's dietary needs and preferences.<sup>12</sup> After imaging studies were reviewed, esophagoscopy was performed to further delineate the anatomy of the stricture – including the lumen diameter – in order to assist in selecting the appropriate initial dilator size. Stenotic area was assessed using an open biopsy forceps in the narrowest lumen of the stricture (standard open biopsy jaws = 7 mm). The initial dilator to start with was 1–2 mm larger than the estimated luminal diameter; mostly we started with a 7 mm sized dilator. The maximum dilator size used through the transnasal route was 11 mm. Then fluoroscopy was used for positioning of the Savary Gilliard dilator just above the stenotic area and to guide placement of the guidewire across the stenotic segment into to the stomach. The patient's head position should be chin-neutral or down, and never extended with the head back. This flexed position reduces the natural cervical spine lordosis and helps to open the hypopharynx. The shaft of the dilator should be gripped firmly for pushing with the thumb and first three fingertips of the right hand and not by a full, closed, tight hand grasp. This technique allows for better tactile sensation with which to judge stricture or other structural resistance during dilator passage. During passage of over-the-wire dilators, either the operator or an assistant should provide slight wire retraction and avoid antegrade or retrograde wire displacement.<sup>13</sup> Repeat dilation sessions was needed if severe resistance was met with, without achieving a diameter of at least 11mm or failure to pass Ryle's tube following a single session. It was done 3 days after the 1<sup>st</sup> attempted dilation of the esophagus. Post procedure patients were kept under observation for about 24 hours to monitor for any complications.

Prior to dilation, barium swallow was undertaken in most patients. Stricture location was categorized as: pharyngeal, cricopharyngeal, or esophageal. Stricture severity was endoscopically gauged by the size of the stenotic segment: partial stenosis ≤ 7mm; and partial stenosis > 7mm.

Dysphagia assessment pre and post dilation was done by Mellow and Pinkas dysphagia score as a measurement for success of dilation; 0= able to eat normal diet / no dysphagia, 1= able to swallow some solid food, 2= able to swallow only semi solid foods, 3= able to swallow liquids only, 4= unable to swallow anything / total dysphagia.

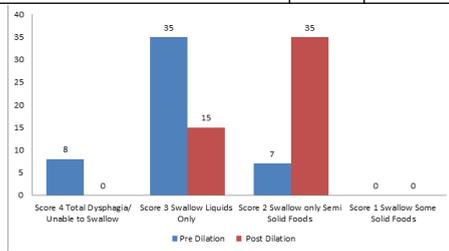
Two types of success dimensions were addressed in our study: technical success and clinical success. The first definition concerns the ability of the endoscopist to traverse the stricture with the chosen dilator and subsequent completion of dilation effectively increasing the luminal diameter usually by 3 mm and seldom by ≤5 mm.<sup>14</sup> The definition of clinical success is less consistent. We in our study defined clinical success as dysphagia improvement (or tolerance of soft diet / liquid diet) measured by the Mellow Pinkas dysphagia scores and requiring a variable dilation-free period. Dilation was done in our study to meet the requirements of patient as in placement of Ryle's tube prior to radiotherapy for HNC and for feeding purpose in patients with post radiotherapy strictures.

**RESULTS**

Fifty patients underwent transnasal dilation of the esophagus. A total of fifty eight dilations were performed i.e. about eight patients required a second session of dilation to achieve the technical success as defined in this study. Patient, etiology and stricture characteristics are shown in Table 1. The mean age of the cohort was 57 years (37-71years). Thirty three patients were male (66%). Pharyngeal, cricopharyngeal region malignancy and pharyngo-esophageal strictures were the most frequent dilation site (96%), followed by upper esophagus (4%). Indications included supraglottic squamous cell carcinoma (30%), hypopharyngeal carcinoma (26%), post-radiotherapy (post-RT) strictures for head and neck carcinoma (28%), stenosis of surgical anastomosis (8%), and corrosive stricture (8%). Predilation dysphagia Mellow- Pinkas score and luminal diameter were 3 ± 0.5 and 6 ± 1.8 mm, respectively. 60% had dysphagia improvement and the median final dysphagia score was 2 (Figure 4). One procedure (2%) was aborted due to laryngospasm or gagging, with an overall efficacy of 98% in achieving the required luminal diameter for successful insertion of a Ryle's tube. Pain over the dilated region was very common being reported in 74% of the patients. Four (8%) patients had minor complications like infection and bleeding requiring i.v. antibiotics and observation. There were no clinically significant complications Table 2.

**Table 1: Patient Characteristics**

Factors	N	%
<b>Gender</b>		
Male	33	66%
Female	17	34%
<b>Age</b>		
Median, range	57, 37-71	
<b>Primary Tumor Site / Etiology</b>		
Oropharynx/Supraglottic	15	30%
Hypopharyngeal	13	26%
Post-Radiotherapy Stricture	14	28%
a) Hypopharyngeal	12	
b) Cervical esophagus	2	
Corrosive Stricture	4	8%
Stenosis of Surgical Anastomosis	4	8%
<b>Stenosis Location</b>		
Pharyngeal	33	66%
Cricopharyngeal	15	30%
Esophageal	2	4%
<b>Diameter of Stenosis</b>		
≤ 7mm	36	72%
> 7mm	14	28%



**Figure 4. Mellow Pinkas Dysphagia Score Pre and Post Dilatation**

**Table 2: Complications**

Complication	No dilations (%)	Management
All complications in 50 patients	5/50 (10%)	
Increased length of hospital	8/50 (16%)	Patients who required a second session of dilation
All Perforations	NIL	
• Microperforations with no intervention		
• Perforation requiring intervention		
Minor post procedure infections, bleeding	4/50 (8%)	i.v. Antibiotics, observation, serial CXR
Local Site pain (post dilation)	37/50 (74%)	Observation and follow up
Laryngospasm or Gagging	1/50 (2%)	Procedure deferred

**DISCUSSION**

Endoscopic dilations with both bougie and balloon dilators are not a novel concept. Gastroenterologists have performed bougie esophageal dilation for more than a century since Chevalier Jackson developed the rigid esophagoscope.<sup>15</sup> Bougie dilation using Savary dilators in the unsedated patient has also been described, although the dilators have to be passed through the mouth. With our innovative technique since the procedure is transnasal, not transoral, gagging is less of an issue, and it is not necessary for the patient to be completely unconscious during the procedure. Most of our patients tolerated the procedure well with topical anesthesia only. Over 50% of complications associated with sedated endoscopy are cardiopulmonary events, and dilation in the unsedated patient obviates these risks.<sup>16</sup> Even when conscious sedation is preferred by the patient, very light sedation can be used because all of the instruments go through the topically anesthetized nose rather than the oropharynx. Transnasal technique is particularly advantageous in patients with altered airway anatomy secondary to surgery and/or head and neck radiation. For example; a patient who has undergone radiation therapy and who has severe trismus, airway edema, and a concomitant upper esophageal stricture would not be a candidate for transoral dilation of the esophagus.<sup>17</sup> Another advantage in case of a tight stricture (as demonstrated in our study as most patients that underwent this procedure had a diameter less than 7mm, 72%) that cannot be traversed with the routine oral endoscope, the guide wire can be safely passed beyond the stricture by placing the Savary-Gilliard of 7mm diameter just above the stenotic region under fluoroscopic guidance. The area can be dilated enough to allow the scope to pass and further assess the distal esophagus.

This procedure had a technical success of 98% as in our study. Our overall complication rate was low at 10% demonstrating that dilations via transnasal route are relatively safe and efficacious. In conclusion, this is the first reported series (to our knowledge) using a transnasal technique for esophageal dilation. This technique formerly available only through larger caliber oral gastroscopes and under sedation, allows for esophageal dilation as an outpatient procedure. In this small series, there were no major complications and no esophageal perforations. This study highlighted that endoscopy was not a prerequisite prior to dilation and that transnasal approach for a stenotic region close to the oropharynx was a novel technique for placement of the guidewire with the help of Savary-Gilliard polyvinyl dilators.

Transnasal Savary-Gilliard dilation can be done with only local topical anesthesia under fluoroscopic guidance with a very low complication rate. Long-term follow-up and larger studies are needed to more fully understand the role of this procedure in our practice.

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**Conflict of interest: None declared**

**Ethical approval: The study was approved by the Institutional ethics committee**

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