# THE TRIALS IN THE CYTOLOGICAL DIAGNOSIS OF GASTRIC CANCER

# PART I NEW BALLOON TECHNIQUE "ABRASIVE BALLOON WITH A SHEATH" IN THE CYTOLOGICAL DIAGNOSIS OF GASTRIC CANCER

by

#### YOSHIYUKI YOSHIDA

From the 2nd Surgical Division, Kyoto University Medical School (Director: Prof. Dr. Yasumasa Aovagu) Received for publication Nov. 15, 1960

#### INTRODUCTION

Since PAPANICOLAOU'S and TRAUT'S original report on vaginal cytology was published in 1943, the possibilities of cytologic diagnosis have been widely extended to other fields, such as lung, prostate and stomach.

The cytologic diagnosis in gastric carcinoma has come into the limelight with the recent advancement of cytologic investigations (PAPANICOLAOU, and GRAHAM) and the modern sampling techniques, such as the use of abrasion devices (PANICO, PAPNICOLAOU, CHAPMAN and COOPER) and the application of mucolytic agents (Rosen-THAL, KLAYMAN and GARRET). Although the lavage technique using mucolytic agents seems useful, PANICO's abrasive balloon method nowadays becomes more commonly used as a method of choice.

From the author's experiences, however, this method is considerd to have the following disadvantages, (1) it is too time-consuming to be widely employed as a screening method, (2) PANICO'S abrasive balloon may often fail to abrade the anal portion of the stomach, the most predilecting site of gastric carcinoma, because of the flexibility of the rubber tube and the rigidity and the lack of peristaltic movement of the cancerous gastric wall, which may hinder the balloon from its final approach to the antrum, (3) if the surface of the balloon is once smeared with mucous or deciduous tissues during its passage through the oroesophageal tract, it is no more capable enough to pick up the neoplasmic deciduous cells, even if it reaches the site of the lesion, and also most of the specimen abraded from the lesion tends to be taken away to the mucous membranes from the balloon during its withdrawal through the oroesophageal tract, and (4) the co-existence of the vast number of normal epithelial cells desquamated from the oroesophageal mucous membranes also often displace the few available pathological cells on the slides.

In order to eliminate almost all the above-mentioned drawbacks in PANICO'S method, a new instrument "abrasive balloon with a sheath" (modified PANICO'S abrasive balloon) was devised by the author.

## APPARATUS

(1) The abrasive balloon with a sheath (the author's device):

As shown in Fig. 2, 3, 4 and 5, the apparatus consists essentially of singlelumen polyvinyl tube of 100 cm in length, which ends in two pieces of net-covered inflatable balloon, and a sheath which sheathes the tube. To the distal end of the polyvinyl tube is attached a metal ball, to which a stainless wire cable running through the polyvinyl tube is attached. The diameter of the ball is so designed as to correspond with that of the sheath. A two-way stopcock and a syringe are attached to the proximal end of the polyvinyl tube, both of which are removable in order to clean and sterilize this apparatus. The external diameter of the distal end of sheath is 13mm, and the proximal 4.7mm. The sheath consists of a flexible stainlesssteel spiral which is coated with thin polyvinyl rubber. The balloons are kept in the distal thicker portion of the sheath while the tube is passing through the oroesophageal tract. The polyvinyl tube is to be just firm enough not to injure the stomach mucosa or not to be curled in the stomach but to be pushed down to the pylorus under control of examiner's hand. The sheath should have also the flexibility not to injure the surface structure of the oroesophageal tract.

The balloons are made of two fine rubber balloons opened at both ends. When these are inflated with 52cc of air, they measure  $3 \times 2.5$ cm and  $5 \times 4$ cm. The two pieces of balloon are fixed to the polyvinyl tube with silk ties 1cm apart each other and communicate to the inner lumen of the polyvinyl tube. The external surface are covered with an abrasive fine silk netting. The smaller distal balloon is devised for obtaining mainly the cells from antral and pyloric regions and the larger proximal one mainly from the corpus and cardiac portions. The Young's Modulus of the various part of this apparatus is given in Table 1. The Young's Modulus was calculated by the following formula:

Table 1 The Young's Modulus of the Various Part of the Abrasive Balloon with a Sheath



 $\delta = \frac{WL^3}{3IE}$ 

(2) The abrasive balloon without sheath (the author's device) :

This apparatus is essentially the same with that of the (1) except this has not a sheath.

(3) PANICO's abrasive balloon.

#### CASE SELECTION

One hundred and thirty-nine patients with clinical evidence of gastric disease have been examined by abrasive cytologic techniques during one year period. The patients with sign of active upper gastrointestinal bleeding, esophageal varices or esophageal obstruction were not studied.

These cases were divided into three groups. The first group of the 36 patients was examined with PANICO'S abrasive balloon technique in the latter part of 1959. The second group of 48 cases was examined with the abrasive balloon without sheath from the latter part of 1959 to the early part of 1960. The abrasive balloon with a sheath has been utilized in the third group of the 55 patients from the carly part in 1960 up to the present date.

From 5 to 8 slides were obtained from each patient.

Statistics and conclusions were based upon the results in the 119 patients whom the diagnosis of a pathologic condition has been established by surgical operation.

# PREPARATION OF THE PATIENT

The most important prerequisites for accurate cytologic diagnosis are the correct preparation of the patients and good specimens, that is, the stomach of the patients should be empty clean and free of the food residue, which must be emphasized especially in cytologic examination using abrasive technique, since "the abrasive effect of the balloon depends on contact between the mucosa and the silk bruches to get good cell group" and moreover "the presence of disintegrated material in the specimen tends to displace the few available cells that may be had on the smear", according to Panico.

When retention is present, the patient should be placed on liquid diet for several days and then retention are treated by vigorous gastric lavage with an Ewald's tube the night before and just prior to the examination again. An overnight abstinence and the aspiration with a Levin's tube of gastric contents prior to the examination are sufficient preparation for the unobstructed patients.

#### PROCEDURE

Dentures are removed, the mouth and pharynx are rinsed, and the patient should be encouraged to expectorate all saliva and to blow his nose, in order not to contaminate the specimen with nasal, oropharyngeal and respiratory epitheliums.

1. In the first method with PANICO's abrasive balloon.

After preliminary lavage of the stomach, the deflated balloon is passed down into the fundus with the aid of local anesthetics (4% xylocaine-solution). The balloon is carried further aborally by peristalsis until it reaches the pylorus and then inflated. And it is pulled back towards the fundus which is known by a wild gag reflex.



Fig. 2 Photograph of the half inflatable abrasive balloon with a sheath



Fig. 3 Photograph of the proximal portion of abrasive balloon with a sheath



Fig. 4 Photograph of the distal portion of abrasive balloon with a sheath



Fig. 5 Diagram of abrasive balloon with a sheath

This procedure is repeated for at least one hour intermittently aspirating the gastric secretion through the attached tube. Finally, it is deflated, withdrawn and subjected to the cytologic process.

2. In the second procedure with the abrasive balloon without sheath.

The patient is in sitting position. The metal tip is guided over the back of the tongue by the index finger of the examiner. Once the tip is beyond the pharynx, further introduction follows with ease, for the tube is of such consistency that it follows the outline of the esophagus and stomach smoothly down to the pylorus without the aid of peristalsis. When more flexible Levin's tube is used, it often causes vomiting action, which did not occur in cytologic examination using the author's device. Once the balloon reaches the pyloric region, it is inflated with 52cc of air and is moved back to the cardia. The procedure is repeated several times under the aid of fluoroscope. Finally, it is deflated to be withdrawn from the patient.



Fig. 6 The balloon may be readily maneuvered into position in contact with pyloric region

3. In the third technique with the abrasive balloon with a sheath.

When the balloon is dipped in Ringer's solution before it places in the sheath, it can be pushed out easily. The whole sheath is dipped in Ringer's solution and it passes the oroesophageal tract easily without application of local anesthetics.

In the examination using the methods of 2 and 3, the patients should be educated well while explaining the process and stressing the importance of this examination. In this way no difficulty was encountered in all cases, for the patients swallowed the apparatus easily and any anesthetic or gargle were not demanded. It is important for the examiner to take enough time to explain the procedure.

The instrument is first inserted in sitting position and once the tip of the sheath reaches the lower end of the esophagus, the proximal portion of the instrument is held with examiner's left hand and the patient's position is slowly changed into

recumbent or right lateral. The polyvinyl tube, to which two balloons are attached, is pushed out gently as shown in Fig. 6. Then the mucosa surface of the stomach is abraded in the same manner as described in the 2nd method. After the abrasion, the balloon is detlated and drawn into the sheath and then the whole tube is removed from the patient.

In all methods, 1, 2 and 3, the balloon is reinflated and macroscopic findings are recorded. Both the balloon pinch smears and the balloon wash smears are prepared. The balloon pinch smears should contain not only the gross particle on the balloon, but the adherent substance which can be taken by wiping the balloon with rubber glove, and these substances are smeared on slide glasses. Then the balloon is washed with saline solution or Ringer's solution and the specimen is centrifuged for 30 minutes at 1,500 rev. per min. The sediment is smeared on slide glasses and these smears are fixed immediately with solution of one part ether-one part 99% alcohol, Carnoy's solution or acetone etc.. Three slides are stained by the Giemsa's staining, and other 2-5 slides are stained by several histochemical staining methods (the detail of which will be reported in the future publication).

After-care of the apparatus consists of thorough washing with soap and water, soaking in benzalkonium chloride solution 1:1,000 for thirty minutes and drying in a surgically clean towel.

#### RESULTS

There were 84 malignant lesions, which included 78 cases of gastric cancer and one of reticulum cell sarcoma of the stomach. In this group, 68 gastric resection were performed and 11 biopsy specimens were taken because of inoperability. In 5 instances there were no gastric cancer but cancers of the esophagus, gallbladder, liver and pancreas. There were 35 benign lesions including one polyp, 19 peptic ulcers, 2 cases of gastritis and one case of phytobezoar. In 12 instances there were no gastric lesion. In this group of 35 benign cases, 22 gastric resections and one simple excisions of polyp were performed.

All of the tests were performed before x-ray examination and surgery.

The following events were recorded, i.e., whether or not the balloon was inserted deep enough to brush the whole mucosal surface of the stomach, the degree of resistance on insertion and withdrawal of the instrument and whether or not the patient complained of nausea, vomiting, salivation and pain. When the balloon was withdrawn, it was also noted, if there were fresh blood, food debris, brown fragment, bile and smell.

As for the microscopic findings of the smear, presence or absence of malignant cells, doubtful or suspicious cells, normal cells including squamous cells and gastric mucosal surface cells, and of several kinds of inflammatory cells including polymorphonuclear leucocytes, lymphocytes, histiocytes and plasma cells, and of erythrocytes, and of microorganism especially cocci in tetrad formation and starch granules was recorded. The state of staining, the presence of the naked nuclei, swelling and shrinkage of several kinds of cells were also recorded.

Analysis of the Cytologic Interpretations of Three Different Abrasive Balloon Techniques Compared by Studying 119 patients

Cytologic Class	I	I	II	N	v	Total
Gastric cancer	1	4	7	6	4	22
Miscellaneous						
Gastric ulcer	5	2	2			9
a Gastritis						
Polyp of the stomach						
🛱 Duodenal ulcer						
Miscellaneous	3				,	3
Equivocal	2					2
Total	11	6	9	6	4	36

Table 2 The first technique

Table 3	The	second	technique
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Disease	Cytologic Class	Ι	I		, IV	V	Total
Gastric cane	er	1	2	8	4	11	26
Miscellaneou	s	1		1		:	2
Gastric ulcer			1	2			3
= Gastritis							1
E Polyp of the	stomach			1			1
🛱 Duodenal ulo	er	3		1			3
Miscellaneou	5	3	1	1			5
Equivocal	1	1		i <u>4</u>	1	2	8
Total	1	9	4	17	5	13	48

# Table 4 The third technique

I	Cytologic Class		I	Ш	Ш	IV	v	Total
gnant	Gastric cancer Reticulum cell sarcoma of the	İ		2	2	9	17	30
Malig	stomach Miscellaneous		1		1	1	1	1 3
	Gastric ulcer		1		1	1	ļ	3
Ξ	Gastritis	1		1	1	-		2
nig.	Polyp of the stomach	I.	i		<b>^</b>			2
ğ	Duodenal ulcer		1					1
	Miscellaneous		3	1			1	5
E	quivocal	1	1	3	3	2		10
Т	otal	1	7	7	7	14	20	55

Location. Size	Cytologic Class of Tumor	I	Ĩ	Ш	W	V	Total
Cardia	Large Middle Small			1	1		1
Corps	Large Middle Small		1	1	2	3	7
Antrum and Pylorus	Large Middle Small	1	2 1	1 4	1	1	3 · 8 1
Total		1	4	7	6	4	22

Table 5 The first technique

Large : Over 7.1cm in diameter of tumor Middle : Diameter of tumor ranges from 4.1cm to 7.0cm

Small : Below 4.0cm in diameter of tumor

Table 6 The second technique

Location, Size	Cytologic Class of Tumor	I	I	M	IV	V	Total
Cardia	Large Middle Small					1	1
Corps	Large Middle Small		1	1 . 1 . 1	1 1	4 3	6 5 2
Antrum and Pylorus	Large Middle Small	1	1	2 3	1 1	2	2 4 5
Total		11	2	8	4	• 11	26

 Table 7
 The third technique

	Cytologic Class	I	Т	Π	W	v	Total
Location, Size	of Tumor		- <u> </u>				
Cardia	Large Middle Small	1	_		1	1 	1
Corps	Large Middle Small		2		2 2	4	6 4 4
Antrum and Pylorus	Large Middle Small			1 1	3	52	5 6 4
Total	ł 1		2	2	11	16	31

On the basis of these microscopic findings, the reports were classified into 5 degrees, and the class 1 and 2 are considered negative, class 3 suspicious, and class 4 and 5 positive, according to PAPANICOLAOU's classification.

The cellular interpretations are compared in Table 2-7. The tables show the correlation between the cytological interpretation and confirmed diagnosis on surgery and the improvement in detection of pyloric cancer, using the author's new device. 1) In the first procedure:

In the 22 patients proved to have malignant gastric lesions, smears contained no malignant cells in 5 cases, some suspicious cells in 7 cases and malignant cells in 10 cases.

2) In the second technique:

In the 26 patients proved to have malignant gastric lesions, smears contained no malignant cells in 3 cases, some suspicious cells in 8 cases and malignant cells in 15 cases.

3) In the third method:

In the 31 patients proved to have malignant gastric lesions, smears contained no malignant cells in 2 cases, some suspicious cells in 2 cases and malignant cells in 27 cases.

The correct cytologic diagnosis was obtained in 76 cases.

1) A false-positive cytologic diagnosis of carcinoma in these series was presented in the 2 patients of the total group. In the third series, 2 false-positive cases occurred in one patient with gastric ulcer and in another with gastric granuloma.

2) A false-negative cytologic diagnosis.

I A false-negative cytologic diagnosis of carcinoma in the first procedure in the 22 patients with confirmed diagnosis was presented in the 5 patients. In the present series, 5 false-negative cases occurred in the 4 patients with pyloric cancer and in one patient with scirrhus of the corpus.

I In the 26 patients in the second method proved to have malignant gastic lesion, three false-negative cases occurred in the following cases i.e.,

i) Adenocarocinoma of the middle of greater curvature, forming an ulcer of  $2 \times 5$  cm in size, which had no crater.

ii) Pyloric carcinoma of  $5 \times 5$ cm in size.

iii) Antrum carcinoma of  $2 \times 2$ cm in size where the tip of the instrument could not reach, because the stomach was of cascade-form.

If A false-negative cytologic diagnosis of carcinoma in the third technique in the 45 patients with confirmed diagnosis was made in the 2 patients. In one case the balloon instrument could not abrade the lesion because of the cascade-form stomach, and in the other case a plate-form antrum carcinoma of  $4 \times 4$ cm in size was found, of which microscopic finding in the resected specimen was submucous carcinoma infiltration and the surface of the lesion was covered with necrotized substance.

In the first procedure the smear revealed no malignant cells in 4 cases with antral cancer and pyloric cancer out of 12 cases, but in both second and third methods there was much improvement in accuracy of detection of malignant cells

originating from antrum and pylorus which were previously thought to be difficult to abrade, as shown in Table 5, 6, and 7.

In the third technique smears yield very little cellular remnants especially squamous cells which cause some displacement of the freshly exfoliated malignant cells. This fact shows the great contribution of the author's new device.

It is shown that the macroscopic findings of the balloon offered much information of the gross changes in the stomach, i.e., fresh blood was found in many cases, most of which had ulcer or carcinoma, and thus the fresh blood was demonstrated in high percentage in cases of gastric cancer, though no fresh blood was observed in some cases of gastric cancer. Contamination with food debris was found of no significance in diagnosis but it was found to indicate the necessity of reexa-The brown fragment was found to have some significance. Contamination mination. with bile was found to disturb the condition of staining and accelerate swelling and destruction of the cells. There was no significant correlation between smell and lesions

There were not enough cases to get criteria for diagnosis of gastritis from the presence or absence of the normal stomach mucosal surface cells and their amount but these cells were found abundantly in cases with carcinoma in which gastritis was found to coexist not uncommonly on histologic findings of resected materials apart The bizarre gastric cells were produced by process of gastritis. from the lesions.

The inflammatory cells were noted much in carcinoma, which were generally more polymorphonucleocytes than lymphocytes and plasma cells. The histiocytes were seen often in cases that the stomach wall was under some physical effects, e.g., the oppression from the neighbouring organs. The meaning of red blood cells in microscopic examination was just the same with macroscopic examination.

The presence of cocci in tetrad formation gave a key to the presence of pyloric stenosis. The presence of naked cells correlated with the presence of free hydrochloric acid.

No case of gastric massive haemorrhage and no harmful effects from use of the author's apparatus have yet been encountered. The author's procedure, described above, is a very simple and practical one to offer with a satisfactory detection of gastric cancer.

## DISCUSSION

In order to accomplish the more reliable and more efficient method of collecting malignant cells, attempts were made to analyse various factors which disturb malignant cell collection. According to many investigators including the author, factors which lead us to false diagnosis in the stomach cell cytology arc as follows. The patient is not adequately prepared. 1)

The balloon fails to contact with tumor in antral and pyloric regions. 2)

The tumor cells, even if abraded, are lost or spoiled before the smear is made. 3). This has two following possibilities.

When they are dropped in the oroesophageal tract. Ţ

I When they are relatively few and dislocated by other cells and substances collected en route which are larger in amount.

4) The tumor tissue is so firm as scirrhus, or the tumor cells are situated under the mucous membrane hardly exposing themselves on the surface.

5) Identification of malignant cell is difficult.

The importance of 1) has been emphasized by many investigators.

Modification of 2) have been attempted by many investigators without favorable results. The author's device seems to have solved this problem. Many cytologists have the opinion that diagnosis of antral or pyloric cancer should be only relied upon X-ray examination and other clinical findings but cytological procedures are of unimportance. Many authors have reported on high rate incidence of gastric cancer in antral and pyloric regions (WILLIS, and MIYACHI). Early diagnosis of gastric cancer in these regions is to be expected today. This problem should not be relied only upon X-ray examination and other procedures. The cytologic techniques which have shown about 100% accuracy in cardiac cancer by many cytologists should play an important role as early diagnostic procedure not only in cardiac cancer but in the case of antral or pyloric cancer. The author's device was designed for this purpose and showed fine results with the exception of a few cases of the cascade-form stomach. PANICO had described that "Better balloon specimens are obtained when the factor of retention is adequately corrected, and when gastric peristalsis has a chance to act on the silk brushes for at least an hour". But considering the high misdiagnostic rate of cancer in these regions and the difficulties to insert the balloon to reach the lesion, it is more likely that peristalsis in the rigid wall of neoplasm may not occur as smoothly as in the nomal area.

As to 3), the presence of numerous squamaus cells in the lavage specimens has been reported by SCHADE and others using lavage technique. These squamous cells are considered to be already in the stomach prior to the cytologic examination. Invasion of small amount of squamous cells in gastric specimen are inevitable. Yet, with the technique using the author's device, "abrasive balloon with a sheath", compared with the techniques using other abrasive balloon without sheath squamous cells in the smear were markedly reduced. By exclusion of numerous cells from the oroesophageal tract using the author's device density of stomach specimen, especially malignent cells, become higher.

As to 4), there was no available method to facilitate this cytologic examination.

The problem of identification of malignant cell, 5), will be discussed in the future publication.

As to the processing of obtained specimens, PANICO described that "The balloon pinch smears and the balloon wash smears were much superior to the routine and the mechanical irritation". In this respect, the author's device, "abrasive balloon with a sheath", sufficed to obtain enough amount of preparation to make the balloon pinch smears and the balloon wash smears. Moreover, as gastric aspiration with Levin's tube is to be done prior to the examination, the double-lumen tube is not of necessity. In the present studies, the balloon pinch smears and the balloon wash

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smears seem to have both merits and faults. The former are far more excellent than the latter, from the point of view that the cell groups were larger and the preservation was excellent, but poorer from the point of view of uniformity of the mixture of tumor cells in the specimen.

The most important requisite of the method is the safty of the patient and the ease of application. The author's device was adequately designed in these respects. The present apparatus is simple and practical but suffices to offer a satisfactory detection of gastric cancer. No anesthetics are necessary in this procedure and it takes no more than about 10 minutes for the whole procedure. No dangerous injuries, such as massive haemorrhage have ever occurred, though the adherence of a small amount of fresh blood has been experienced in most cases of gastric cancer and gastric ulcer. The findings of the resected stomach have shown none of injuries.

The histopathological diagnosis is based on a malignancy in a histological preparation, not so much on the morphological features of the cells but on the invasive, destructive and uncoordinated growth of cell complexes and their relation to the neighbouring tissues. On the other hand, cytologic diagnosis of cancer is based on the confirmation of malignancy from the study on the single cells or the cell groups without being able to observe their behaviour towards or their relationship to the neighbouring structures.

Therefore, the cytologic diagnosis is one of the most difficult procedures to make even for the experts in this field. But considering the fact that it has been contributing greatly to the establishment of the early diagnosis of cancer, the appearance of the more reliable and practical scale for the identification of malignancy of the suspicious cells of tumors is to be highly expected.

#### SUMMARY

1) Author's "abrasive balloon with a sheath" (modified PANICO's abrasive balloon) was presented as an improved instrument of obtaining fresh, well preserved and relatively selective gastric specimens.

2) The gastric cytology of 139 patients was studied by means of three kinds of abrasive balloon techniques and the results in 119 cases to which diagnosis had been confirmed postoperatively were reported. These cases were divided into three groups: the first group with PANICO'S abrasive balloon technique, the second group with the author's device "abrasive balloon without sheath" and the third group with the author's device "abrasive balloon with a sheath".

- 3) Following conclusions were made from the present study:
  - i The invasion of many cells and substances exfoliated from the structures of the oroesophageal tract into the specimen is prevented.
  - ii The loss of the specimen en route in the oroesophageal tract is prevented.
  - iii Abrasive balloons are able to reach tumor surface without unspoiling with detached cells and substances from the oroesophageal tract.
  - iv Balloon is easily accessible to antral and pyloric regions without the aid of peristalsis.

v The author's apparatus is simple and safe, and certifics less time-consuming in cytologic examination.

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和文抄録

# 胃癌細胞診の診断適中率向上を 目的とする二,三の試み 第一編 われわれの考案になる外套管付

Abrasive Balloon

京都大学医学部外科学教室第2講座(指導:青柳安誠教授)

吉 旧 良 行

著者は外套管付 abrasive balloon を考案した.本器具は Paxico の abrasive balloon を改良したもので,新鮮で良く保存された胃癌細胞を比較的選択的に採取することが出来る.

2) 胃疾患を訴える 139 名の患者について、3 種類の balloon法(すなわち,第1 群は Pasico の abrasive balloon を使用したもの,第2 群は著者の作成せる外套管なしの2 球式 abrasive balloon を使用したもの,第3 群は著者の考案せる外 套管付 abrasive balloon を使用したもの)によつて胃癌細胞診が施行された.これらの症例の中で手術後,病理組織診断で診断の確定したもの 119 例の結果に基づいてこれら3 種類の方法が比較研究された.

3) その結果, 外套管付 abrasive balloon は次の 諸点において PANICO の abrasive balloon よりす ぐれていることを認めた.

i) 口腔から食道下端に至る粘膜面からの剝雄物質 が鏡検試料中に混入するのを防ぐことが出来る.

ii) 採取した胃内剝離細胞が食道下端から口腔に至る途中で失はれるのを防ぐことが出来る.

iii) balloon は口腔から 食道下端に至る 粘膜面か らの剝離物質によつて、その表面が汚染されることな く癌腫表面に達することが出来る。

iv) 幽門前庭部並びに幽門部の 擦過が 瀑状胃の極 く一部の症例を除いては容易,且つ確実に 行われう る.

v)本器具使用による胃癌細胞採取操作は,簡単, 安全でしかも従来の balloon 法に比較して遙かに短時 間である。