Table 2 Impacts on cardiopulmonary parameters during gastric endoscopic submucosal dissection

	SPACE	Control	*P**
$EtCo_2$, median (range), mmHg			
Mean	25 (16.8–75.3)	26.5 (19–76.9)	N.s.
Maximum	26 (17–79)	27.5 (19–79)	N.s.
Elevation	1.5 (0–5)	1.5 (0–12)	N.s.
SpO_2, median (range), %			
Mean	100 (98–100)	99.8 (98.3–100)	N.s.
Minimum	100 (97–100)	99 (92–100)	N.s.
Depression	0 (0–3)	0 (0–1)	N.s.
Heart rate, median (range), beats/minute			
Mean	72.6 (62.5–123)	74.8 (58.5–104)	N.s.
Maximum	77.5 (64–142)	85.5 (59–109)	N.s.
Elevation	4 (0–31)	6.5 (0–35)	N.s.
Mean blood pressure, median (range), mmHg			
Mean	48.8 (37.8–81.4)	48.6 (39.2–78.6)	N.s.
Maximum	52 (42.5–84)	50.5 (42.5–84)	N.s.
Elevation	1.5 (0–10)	2 (0–19.5)	N.s.
Adverse events, *n*			
Superficial mucosal injury	Two animals	–	–

$EtCO_2$ end-tidal carbon dioxide; *N.s.* not significant; *SPACE* steady pressure automatically controlled endoscopy; *SpO_2* percutaneous oxygen saturation

* Wilcoxon signed-rank test

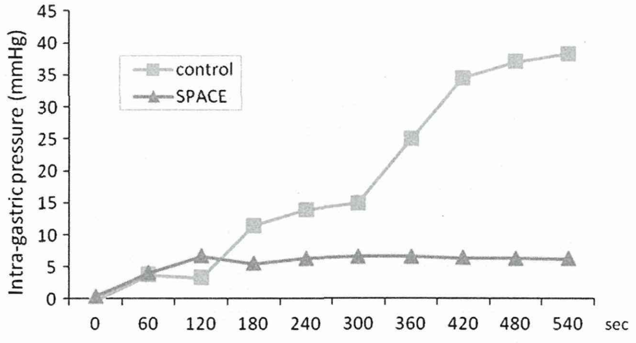

Fig. 7 Changes of intra-gastric pressure during SPACE and conventional endoscopy

button. It is possible to avoid total collapse of the GI lumen, when mild and intermittent suction is applied. SPACE thus enables simultaneous water suction/smoke evacuation and irrigation/energy device activation, while keeping the endoscopic exposure (video). This feature of SPACE is extremely attractive in cases of major bleeding or severe smoke production due to energy device activation, where suction is more frequently necessitated but the luminal collapse needs to be avoided as much as possible [6].

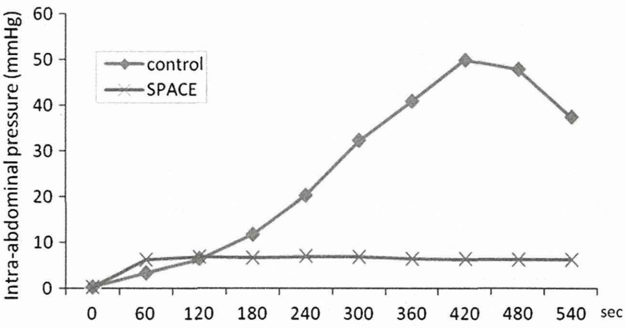

Fig. 8 Changes of intra-abdominal pressure during SPACE and conventional endoscopy

Fig. 9 Abdominal distension caused by excessive pneumoperitoneum, when the maximum pressure of intra-abdominal pressure was reached over 50 mmHg in control group

This study has shown that the gastric ESD under SPACE is feasible and safe. Though ESD time tended to be shorter under SPACE compared to conventional endoscopy, the difference did not reach to statistically significant level. Previously in the porcine esophagus, we could successfully demonstrate that ESD under SPACE reduced procedure time by 21.9 % compared to ESD under manual insufflation [6]. The esophagus is a tubal organ and is anatomically much straightforward than the stomach. This may partially explain the reason why we could show time reduction effect of SPACE, not in the stomach but in the esophagus. In a clinical setting, it is well known that technical difficulty of ESD is largely diverse depending upon the location of lesion in the stomach [7, 8]. Another explanation is that gastric procedure became even technically difficult due to current limitations of our SPACE system. The SPACE over-tube was much longer than commercially available products, and its tip was placed beyond the esophago-gastric junction, resulting in constriction of the movement of flexible endoscope, especially in the upper body of the stomach. The relatively bulky and rigid Leak Cutter itself might also limit the endoscopic maneuverability. To solve these problems, we are now positively working on downsizing of Leak Cutter and further improvement of SPACE over-tube.

Table 3 Cardiopulmonary parameters during endoscopy under perforation to the stomach

	SPACE	Control	*P**
$EtCo_2$, median (range), mmHg			
Mean	24.2 (16.2–45.8)	20 (17.6–36.2)	N.s.
Maximum	25 (17–47)	22 (20–52)	N.s.
Elevation	2 (0–7)	4 (0–14)	N.s.
SpO_2, median (range), %			
Mean	100 (92.2–100)	99 (91.6–100)	N.s.
Minimum	100 (92–100)	97 (91–100)	N.s.
Depression	0 (0–1)	2 (0–4)	N.s.
Heart rate, median (range), beats/minute			
Mean	93.2 (52–142)	96 (53–147.4)	N.s.
Maximum	102 (52–144)	101 (55–154)	N.s.
Elevation	3 (0–33)	12 (3–15)	N.s.
Mean blood pressure, median (range), mmHg			
Mean	55.7 (46–70.4)	57.9 (43.5–72.2)	N.s.
Maximum	71 (55–73.5)	60 (45.5–83.5)	N.s.
Elevation	5 (0–23.5)	12 (3–18)	N.s.

$EtCO_2$ end-tidal carbon dioxide; *N.s.* not significant; *SPACE* steady pressure automatically controlled endoscopy; *SpO_2* percutaneous oxygen saturation

* Wilcoxon signed-rank test

This study also demonstrated the safety of SPACE when the perforation occurred on the gastric wall. In SPACE group, both intra-gastric and intra-abdominal pressures remained within the preset pressure range (up to 8 mmHg). On the contrary, in control group, intra-abdominal pressure elevated gradually as the intra-gastric pressure elevated. The pressures reached over 50 mmHg in 180 s. When we encounter visceral perforation in a clinical setting, we tend to insufflate the lumen continuously in order to keep visualization and working space. This may cause massive gas migration to the peritoneal cavity via the perforated site, and the resultant excessive pneumoperitoneum may give rise to lethal consequences such as ACS [1–5]. In SPACE, the insufflation is automatically terminated when the intra-luminal pressure reaches to the preset value. The intra-luminal pressure is continuously feedback to the endoscopist.

Our study suggested that an insidious over-insufflation can be avoidable under SPACE

There are several limitations in this study. First, this was an acute animal study with relatively small sample size. Further evaluation using larger number of animals will be necessary, to address the true effectiveness of gastric SPACE. Second, the gastric perforation was created from the serosal side, not from the mucosal side. This was due to extremely thick gastric wall of porcine, which was difficult to be perforated endoscopically in a standardized fashion. Lastly, we used continuos forceful insufflation in perforation study. The primary goal of the experiment was to clarify pressure profiles in perforated stomach; therefore, the experiment was performed under extreme setting. A manual "on-and-off" insufflation should be used to further demonstrate more practical pressure changes in case of gastric perforation.

Conclusions

SPACE is feasible in the stomach using modified over-tube system. It is safe and potentially effective for lengthy and complicated endoscopic procedures such as ESD. Although its true effectiveness must be verified in future clinical trials, SPACE might become a key technology in advanced endoscopic interventions.

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Disclosures Authors Takuya Yamada, Masashi Hirota, Shusaku Tsutsui, Motohiko Kato, Tsuyoshi Takahashi, Kazuhiro Yasuda, Kazuki Sumiyama, Masahiko Tsujii, Tetsuo Takehara, Masaki Mori, Yuichiro Doki and Kiyokazu Nakajima have no conflicts of interest or financial ties to disclose.

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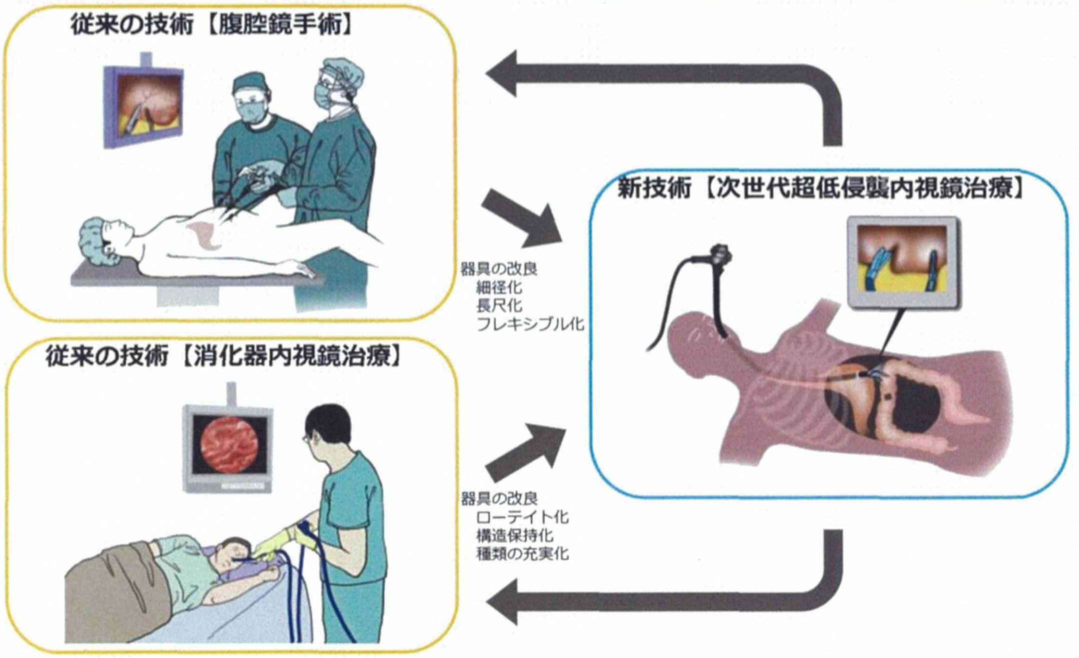
内科と外科の発展的統合



ENGINE: Endeavor for Next Generation of INterventional Endoscopy

内科と外科の違い(一部)

	腹腔鏡	消化器内視鏡
スコープ	硬い	軟らかい
送気	自動	マニュアル
視野	近接～遠景まで	主として近接
操作方向	正面～見下ろし	接線方向
洗浄・吸引	スコープと独立	スコープの先端から
天地あわせ	必須	原則行わない
組織の牽引	容易	困難
鉗子(デバイス)	硬くて短い(太い)	柔らかくて長い(細い)
把持鉗子の把持力	強い	弱い
鉗子先端のコントロール	完全	不完全
鉗子類のバリエーション	豊富	乏しい

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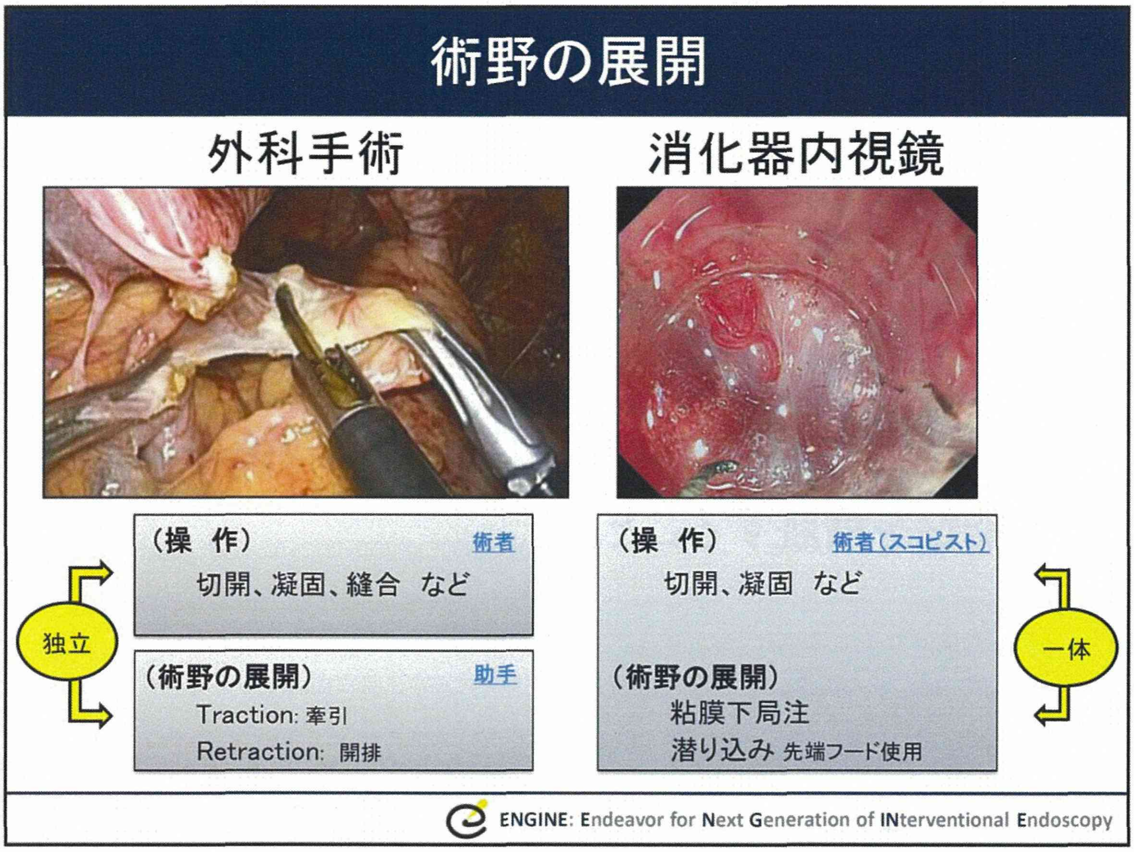
術野の展開
外科手術
消化器内視鏡
（操　作）
術者
切開、凝固、縫合　など
（術野の展開）
助手
Traction: 牽引
Retraction:　開排
独立
（操　作）
術者（スコピスト）
切開、凝固　など
（術野の展開）
粘膜下局注
潜り込み 先端フード使用
一体
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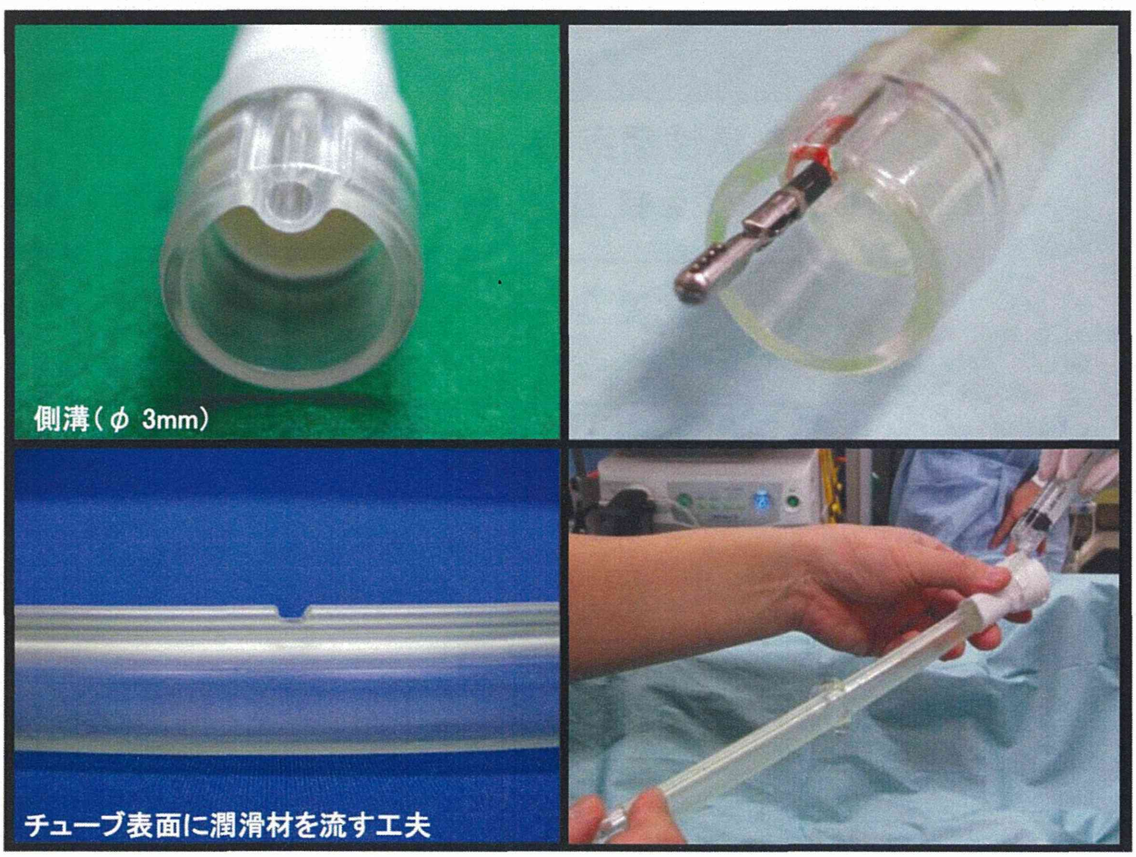
側溝（φ 3mm）
チューブ表面に潤滑材を流す工夫

目的

開発中のワーキングチャンネル付きオーバーチューブを用いた回旋式ESDの実施可能性を検証すること。

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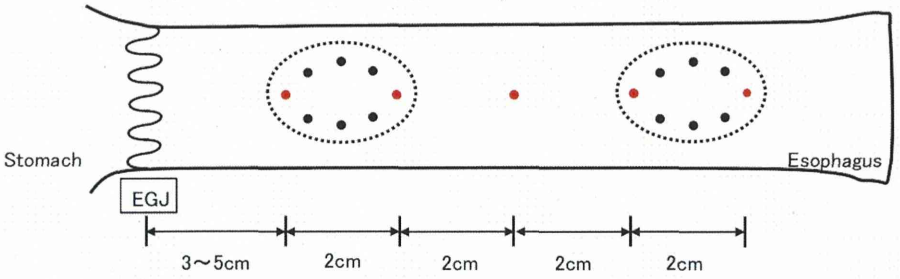
方法

- 雌ブタを用いた急性期実験(n=5)
- 2cm径の仮想病変を食道の2箇所に設定(計10病変)



- 使用デバイス
  フラッシュナイフBT 2.0mm(全周切開)
  SBナイフJr.(粘膜下層剥離)
- 内視鏡医(スコープ操作)、外科医2名(助手)

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評価項目

- 処置完遂率
- 一括切除率
- 切除食道の病理組織
- ESDの施行時間
- 偶発症の有無

チューブ挿入に関連するもの・・・口腔～食道粘膜損傷
ESDに関連するもの・・・術中穿孔

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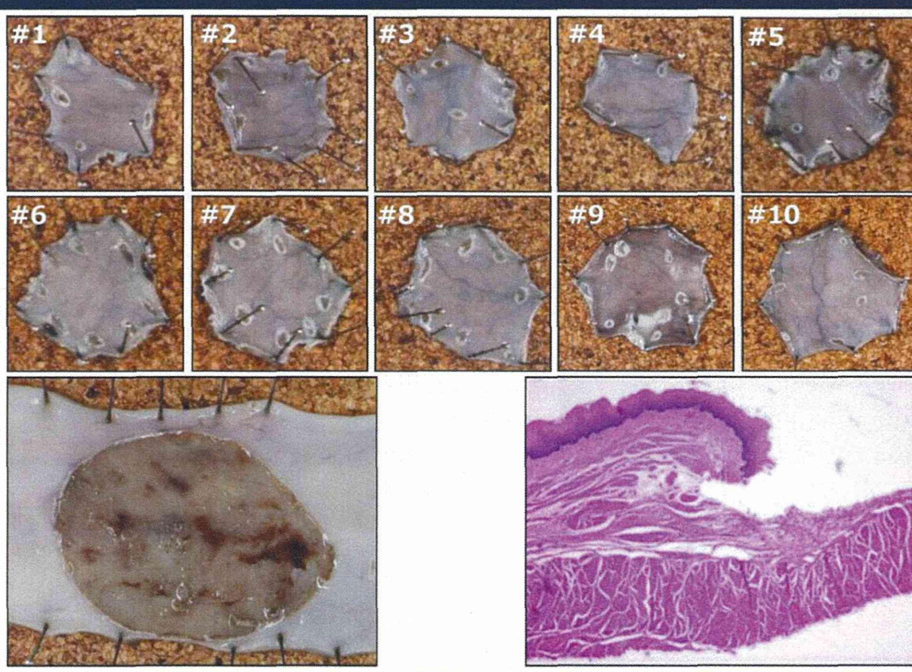
全例で病変を一括で切除し得た



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ESDは安全に実施可能であった

切除標本径*	, mm	28 (24-40)
処置時間*	全ESD, min	30 (25 - 69)
	下層剥離, min	22 (10 - 50)
偶発症	粘膜損傷	0%
	穿孔	0%

*: 中央値(範囲)

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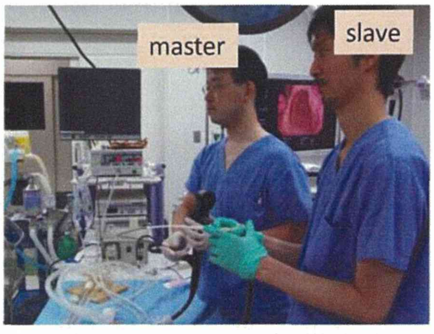
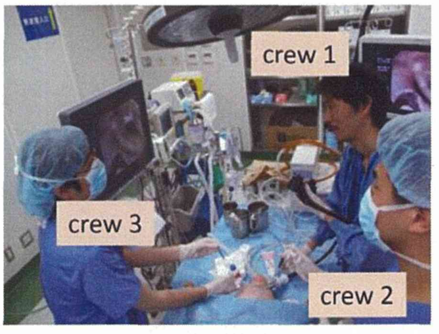
近未来の内視鏡治療



"solo" procedure



team effort

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結語

回旋式ESDにより、病変に対して適切なトラクションをかけつつ安全確実な粘膜下層剥離が可能となることが示唆された。

M. Kato et al. Endoscopy. 2014; 46: 499-502

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8th INTERNATIONAL NOTES WIDER
December 1 and 2, 2014, Barcelona, Spain

Future of NOTES: A new tool box from ENGINE for next generation endoscopy

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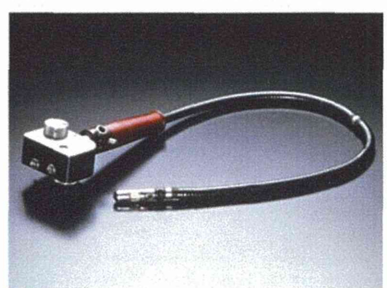
powered by® ENGINE

Current flexible GI endoscopy

- Originally developed for diagnostic purpose
- Various interventions driven by gastroenterologists
- NO CHANGE in basic design > 50 years !
- Chance of renovation triggered by NOTES

Are we asking it to perform tasks it was not designed to do ?



Towards NOTES

- Immediate destruction doesn't seem likely
- Too many features in a single endoscope
- Too many tasks for a single operating endoscopist
  - insufflation
  - irrigation/suction
  - traction/retraction
  - device manipulation

tasks done automatically and/or done by assistant in laparoscopic surgery

A tool box for advanced endoscopy

- Should contains accessories that enhance gradual transformation of current endoscopes
- Should be a set of devices that make "assistant tasks" independent from endoscopes
  - insufflation
  - irrigation/suction
  - traction/retraction

Summary

- Future operating endoscopist should be free from assisting tasks e.g. insufflation and suction
- The tool box should contain accessories that make assistant tasks independent from endoscopsit
- Current endoscopes will be gradually transformed with gradual acceptance of new accessories

Kiyokazu Nakajima, MD
2014, Barcelona, Spain

8th INTERNATIONAL NOTES WIDER
December 1 and 2, 2014, Barcelona, Spain

Scientific Symposium

Endoscopic Insufflation Revisited

from air to CO_2, from manual to automatic

Kiyokazu Nakajima, MD, FACS

Division of Next Generation Endoscopic Intervention (Project ENGINE)
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powered by® ENGINE

History of CO_2 endoscopy

First introduced in colonoscopy

- To prevent gas combustion during electrosurgical polypectomies in 195X
- Re-discovered in 198X to reduce abdominal pain and bloating after outpatient colonoscopy
- Gradually accepted in early 200X as dedicated equipment became commercially available

Minimizing postcolonoscopy abdominal pain by using CO_2 insufflation: a prospective, randomized, double blind, controlled trial evaluating a new commercially available CO_2 delivery system.

Sumanac K et al: *Gastrointest Endosc* 2002; 56: 190-4

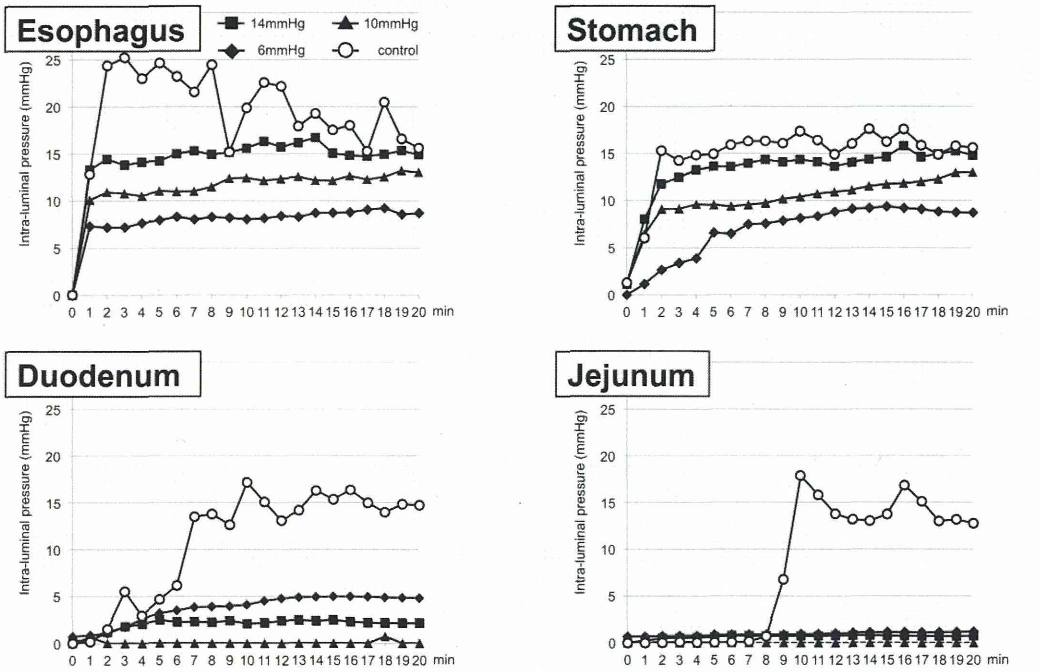
RCT in Canada, n=97, outpatient setting

- Olympus ECR CO_2 insufflator
- VAS pain scoring @ 0, 1, 6, 24 hr after colonoscopy
- AXR to evaluate residual gas @ 1 hr after colonoscopy

➡

- CO_2 reduced pain 1 / 6 hr after colonoscopy
- CO_2 reduced gas 1 hr after colonoscopy

Gas does not migrate into downstream



SPACE, its clinical introduction

We have four techniques:

1. **The original SPACE technique** using overtube, Leak Cutter and new GI insufflator
2. **Overtube-less technique** using biopsy channel for insufflation (for diagnostic purpose)
3. **Overtube-less technique** using double channel endoscopy
4. **Impact Shooter technique** using transparent distal attachment with tube for insufflation

Summary

- Carbon dioxide is now replacing room air as insufflating agent in flexible GI endoscopy
- Pressure-regulated insufflation is feasible, safe and effective in both upper & lower GI endoscopy
- Pressure-regulated insufflation may be key technology for future endoscopy including robot and NOTES

本報告書は、厚生労働省の医療機器開発推進研究委託事業による委託業務として、国立大学法人大阪大学が実施した平成２６年度「企業人材の育成と連動した革新的国産内視鏡治療機器の研究開発」の成果を取りまとめたものです。