Clinical Publications Supporting the Efficacy of WATS³ᴰ®

1

Publication Title: **Wide-area transepithelial sampling with computer-assisted 3-dimensional analysis (WATS) markedly improves detection of esophageal dysplasia and Barrett's esophagus: analysis from a prospective multi-center community-based study**

Authors: Michael S Smith, Erkanda Ikonomi, Rajiv Bhuta, Natalya Iorio, Rahul D Kataria, Vivek Kaul, Seth A Gross and the US Collaborative WATS Study Group

Journal: Diseases of the Esophagus: December 2018

Summary:
- 12,899 patients enrolled at 21 community-based practices- the largest series of patients evaluated with WATS
- Approximately 80% were being screened and 20% were under surveillance
- WATS used as an adjunct to random and targeted FB increased the overall detection of esophageal dysplasia by 242% (95% CI: 191%-315%) and of BE by 153% (95% CI: 144-162%)
- The order of procedures- FB vs. WATS- did not impact the results

2

Publication Title: **Increased detection of Barrett's esophagus and esophageal dysplasia with adjunctive use of wide-area transepithelial sample with three-dimensional computer-assisted analysis (WATS)**

Authors: Seth A Gross, Michael S Smith, Vivek Kaul, and the US Collaborative WATS³ᴰ Study Group

Journal: United European Gastroenterol J 2018; 6(4): 529-35.

Summary:
- 4,203 patients enrolled at 25 community-based practices
- 95% were being screened
- WATS used as an adjunct to random and targeted FB increased the detection of BE by 83% (95% CI: 74% - 93%) and dysplasia by 88.5% (95% CI: 48% - 160%)

3

Publication Title: **Increased detection of Barrett's esophagus-associated neoplasia using wide-area transepithelial sampling: a multicenter, prospective, randomized trial**

Authors: Prashanth R Vennalaganti, Vivek Kaul, Kenneth K Wang, Gary W Falk, Nicholas J Shaheen, Anthony Infantolino, David A Johnson, Glenn Eisen, Lauren B Gerson, Michael S Smith, Prasad G Iyer, Charles J Lightdale, Felice Schnoll-Sussman, Neil Gupta, Seth A Gross, Julian Abrams, Gregory B Haber, Ram Chuttani, Douglas K Pleskow, Shivangi Kothari, John R Goldblum, Yaxia Zhang, Prateek Sharma

Journal: Gastrointest Endoscopy 2018; 87(2): 348–355.

Summary:
- 160 patients enrolled at 16 academic medical centers
- All patients under surveillance
- The addition of WATS to FB yielded an additional 23 cases of HGD/EAC missed by the Seattle protocol: 11 were classified by FB as non-dysplastic BE and 12 as LGD/indefinite for dysplasia
- The detection of HGD/EAC was 4-fold higher with WATS compared with the Seattle protocol
- Blinded independent review by 2 central Cleveland Clinic pathologists confirmed these findings
- The order of procedures- FB vs. WATS- did not impact the results

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Publication Title:	**Computer-assisted brush-biopsy analysis for the detection of dysplasia in a high-risk Barrett's esophagus surveillance population**
Authors:	Sharmila Anandasabapathy, Stephen Sontag, David Y Graham, Stephen Frist, Joan Bratton, Noam Harpaz, Jerome D Waye
Journal:	Dig Dis Science 2011; 56: 761-6.
Summary:	▸ 151 patients enrolled at 4 academic medical centers
	▸ All patients had a history of dysplasia and were under surveillance
	▸ WATS used as an adjunct to FB increased the detection of dysplasia by 42% (95% CI: 20.7–72.7)

5

Publication Title:	**Computer-assisted analysis of abrasive transepithelial brush biopsies increases the effectiveness of esophageal screening: a multicenter prospective clinical trial by the EndoCDx Collaborative Group**
Authors:	John. F Johanson, James Frakes, Drore Eisen, and the EndoCDx Collaborative Group
Journal:	Dig Dis Science 2011; 56: 767-72.
Summary:	▸ 1,266 patients enrolled at 8 community-based practices
	▸ Approximately 66% were being screened and 34% were under surveillance
	▸ WATS used as an adjunct to random and targeted FB increased the overall detection of BE by 39.8% (95% CI: 32% - 48%)

6

Publication Title:	**Inter-observer agreement among pathologists using Wide-Area Transepithelial Sampling with computer-assisted analysis in patients with Barrett's esophagus**
Authors:	Prashanth R Vennalaganti, Vijay Naag Kanakadandi, Seth A Gross, Sravanthi Parasa, Kenneth K Wang, Neil Gupta, Prateek Sharma
Journal:	Am J Gastroenterol 2015; 110: 1257-60.
Summary:	▸ 149 random WATS slides with varying degrees of BE and dysplasia analyzed by 4 pathologists as non-dysplastic, low-grade dysplasia (LGD), or high-grade dysplasia/ esophageal adenocarcinoma (HGD/EAC)
	▸ Kappa values for HGD/EAC: 0.947; LGD: 0.74; and no dysplasia: 0.884. Overall Kappa value: 0.864 (values of 0.81–0.99 are regarded as "almost perfect agreement")
	▸ Analysis of WATS specimens has very high inter-observer agreement compared with published data using standard histopathology

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